Rebound Tonometer

User Manual

Chongqing Sunkingdom Medical Instrument Co., Ltd

Acknowledgement

Thank you for choosing to use the rebound tonometer produced by Chongqing Sunkingdom Medical Instrument Co., Ltd. (hereinafter referred to as "Sunkingdom"). "Sunkingdom" rebound tonometer can be trusted by you, we are deeply honored. In order to give you a general understanding of the "Sunkingdom" rebound tonometer, we have configured this instruction manual for you, which includes the installation, usage, instructions for use, maintenance, transportation, storage, etc. of the instrument. It is an essential guide for you to use this instrument.

In order to enable you to better understand the relevant knowledge of the instrument, please read the instruction manual carefully before use. I believe it will be of great help to you in effectively using this instrument.

Before use, it is recommended that you carefully carry out the following tasks:

1.First, carefully check whether the instrument is consistent with the packing list, and whether the instruction manual and accessories are complete.

2.Please read the random documents carefully and keep them properly.

The pictures attached to this manual are **renderings**, and the specific configuration is subject to the packing list. If you have any unknown information, please consult Sunkingdom Company.

Consultation telephone number: 023-68102805

Supervision telephone number: 13808351344

Attention

To protect the equipment from the environment (moisture, dust, liquids, direct exposure to sunlight, etc.), it should be placed in a dry place. Please be careful to prevent liquid or other debris from entering the equipment, otherwise it may cause a short circuit in the internal components of the equipment, which may cause electric shock or fire.

Please use only certified original probes supplied by the manufacturer. The probes are intended for single use only (use one per measurement). If the eye is irritated or infected, the healthy side of the eye should be measured first. Please only use original and well packaged probes. Repeated use of probes may result in incorrect measurements, broken probes, bacterial or viral cross-infections, or ocular

infections. Reuse of the probe will relieve the manufacturer of all responsibilities and obligations related to the safety and effectiveness of the rebound tonometer.

To avoid contamination, keep unused probes in the box, do not touch exposed probes, and do not reuse probes if they come into contact with unsterilized surfaces such as tables or floors. Do not use a probe that has been touched or dropped and dispose of it correctly (place it in a container for disposable needles).

Except for replacing the battery and probe holder, the equipment shell cannot be opened without the permission of the company, otherwise the company will not be responsible for the adverse consequences caused.

The instrument does not require routine maintenance or calibration, but the battery is replaced at least once every 12 months and the probe holder is replaced.

The instrument should only be used by operators trained by our engineers.

Catalogue

Chapter I Overview

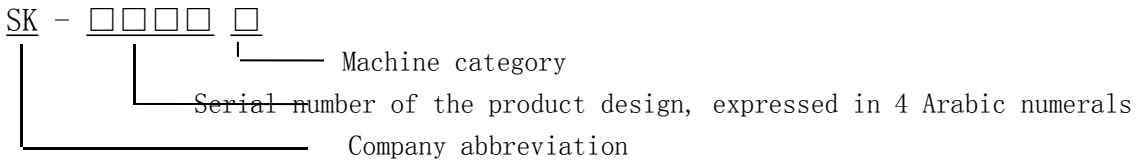
1.1 Product Introduction

1.1.1 Introduction

This equipment adopts electromagnetic induction technology and is used to collect human intraocular pressure data.

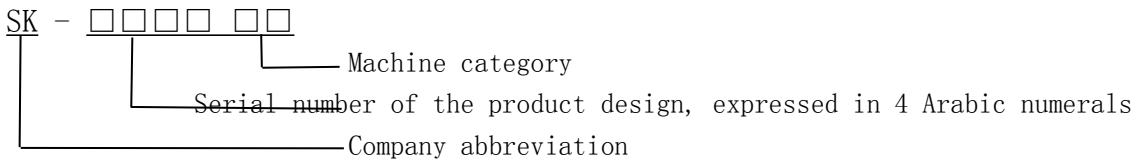
1.1.2 Model Description

1.1.2.1 Product model marking



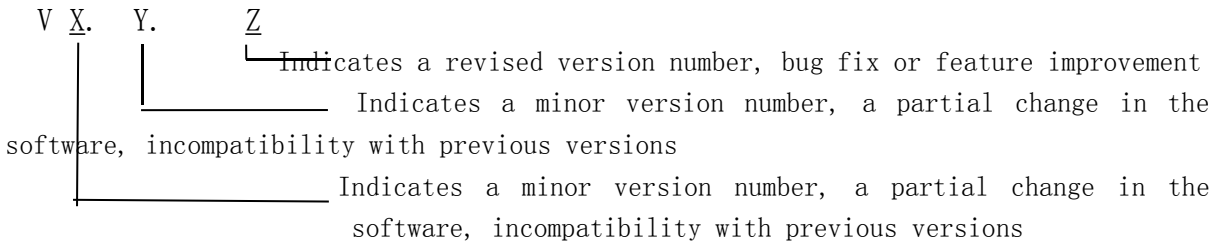
Marking example: SK-5500A indicates the rebound tonometer model SK-5500A manufactured by Chongqing Sunkingdom Medical Instrument Co.

1.1.2.2 Software model



Marking example: SK-5500UA, indicating that the software model SK-5500UA is the image system software for the SK rebound tonometer produced by Chongqing Sunkingdom Medical Instrument Co.

1.1.2.3 Software version naming rules



Marking example: V1.0.1 indicates that the full version of the software produced by Chongqing Sunkingdom Medical Instrument Co. The release version includes only the major version number and the minor version number, which is V1.0.

Note: X changes in the range of 0-9, when the following changes, incremented by 1.Adjustments that have an impact on the stability and performance of the entire system, such as: changes in the architecture of the software, changes in the division of modules, algorithm optimisation, and so on.

Y change range is 0-9, when the following changes, increment by 1.Adjustments that have no effect on the stability and performance of the whole system, mainly fine-tuning of the function, modification of performance parameters, and so on. For example, increase the display content, increase the key function, etc..

Z change range 0 to 999, when the following changes, increment by 1.Adjustments that do not affect the stability and performance of the entire system, mainly for the revision of the bugs (does not involve the underlying logic), the display interface layout, picture replacement, changes in the description of the prompt file, and so on.

1.2 Registration information

Product name: Rebound tonometer

Product model: SK-5500A

Registrant/Manufacturer: Chongqing Sunkingdom Medical Instrument Co., Ltd

Product production address: 35-2, Yingtian Optoelectronics Valley, Caijiagang Town, Beibei District, Chongqing

Registrant/Manufacturer Address: No.1 Xinmao Road, Beibei District, Chongqing (Free Trade Zone) Postcode: 400700

Registrant/manufacturer contact information: 023-68102805

Production license number of this product:

Product registration certificate number:

Product technical requirement number:

After-sales service company name: Chongqing Sunkingdom Medical Instrument Co., Ltd

After-sales service address: 35-2, Yingtian Optoelectronics Valley, Caijiagang Town, Beibei District, Chongqing

After-sales service telephone: 17316790887 Postcode: 400700

Production date of this product: see nameplate

Use life of this product: 8 years

Instruction manual preparation date: May 10, 2024

Instruction manual version: 1st edition

1.3 Scope of application

Rebound tonometer is suitable for measuring human intraocular pressure.

1.4 Product contraindications

[Contraindications]

Severe corneal lesions (such as obvious corneal thinning, inflammation, etc.) are forbidden;

Use with caution if there are corneal lesions (such as edema, scar, etc.);

Corneal infectious lesions are contraindicated.

[Notes]

This instrument is intended for use by trained ophthalmology clinicians only.

1.5 System Configuration

1.5. 1 Hardware

- The rebound tonometer consists of a host and a probe.

1.5. 2 Software Features

- a patient information entry module;
- an intraocular pressure acquisition module;
- File management module;
- Output print module.

1.6 Technical parameters

- Unit conversion formula

  1 kilopascal (kPa) = 7.500616 millimeters of mercury (mmHg).

- Measurement range

  Tonometer measurement range: 3mmHg ~ 60mmHg.

- Measurement accuracy

  ± 1.0 mmHg (3-25 mmHg)
  ± 1.7 mmHg (25-60 mmHg)

- Measurement repeatability

  The measurement repeatability accuracy of tonometer is < 8%.

- Cleaning, disinfection or sterilization measures

Parts that contact patients or operators and nearby parts are easy to clean. There is no dead spot for disinfection or sterilization at the site to be disinfected or sterilized.

The method of cleaning, disinfection or sterilization given in the instruction manual of this product will not cause damage to the product or deterioration of the material, and will not affect the safety protection performance.

The probe of this product contacting the patient is for single use, and the forehead support component shall be cleared, disinfected or sterilized according to the instructions for use of this product.

- Software Requirements

Identification and labeling

Software products are marked with name, version, and model number.

The release version of the software should be reflected in the login interface, and the complete version of the software and the release version of the software should be reflected in the "About" interface.

Software Instructions

The release version of the software should be specified in the specification, and all functions of the software should be reflected.

Software functionality

The software shall have the following modules:

a) Patient information entry module: the patient ID can be selected for entry and storage;

b) Intraocular pressure acquisition module: capable of acquiring intraocular pressure values and saving them;

c) File management module: can view and delete historical records;

d) An output printing module capable of establishing medical documents and printing them;

- User Access Control

The software should have a user access control mechanism, and users should log in with username and password for identity authentication and permission restriction.

- Appearance and Construction

a) The components of the product should be tightened without loosening, and the control of switches, buttons and other control components should be flexible and reliable.

b) There should be no obvious dents, scratches, cracks, distortions and smudges on the surface of the product.

- Safety Requirements

The general safety requirements comply with all applicable requirements in GB 9706.1-2020 standard, except the clauses that have been replaced by the technical requirements of this product and 21.6.

- Electromagnetic compatibility

Rebound tonometers are grouped into Group 1 Class A according to GB 4824.

The electromagnetic compatibility of rebound tonometer shall comply with the requirements of YY 9706.102-2021.

Rebound tonometer Under the test conditions specified in 6.2 of YY 9706.102-2021, the rebound tonometer shall be able to provide basic performance (see "Electromagnetic Compatibility Safety Features" for details of basic performance) and maintain safety, and the performance degradation related to basic performance and safety in 6.2.1.10 of YY 9706.102-2021 is not allowed.

- Optical radiation safety

(1) Rebound tonometers are grouped as Class 1 instruments according to ISO 15004-2: 2007 Chapter 4. The optical radiation hazards of rebound tonometers comply with the requirements of 5.1, 5.2 and 5.4 of ISO 15004-2: 2007.

- Environmental testing

Carry out the test according to the provisions of Climate Environment Group II and Mechanical Environment Group II in GB/T 14710, in which the rated working low temperature test temperature is changed to 10 ℃, and the high temperature storage test temperature is changed to 70 ℃, and the test shall be carried out according to the provisions of Table 2 of Technical Requirements. After testing, the product meets all the requirements of performance and technical requirements of this product.

1.7 Working environment

- Environmental conditions: Temperature: 5 ℃ ~ 40 ℃; Relative humidity: ≤ 85%; Atmospheric pressure: 700 hPa ~ 1060 hPa.
- Power Condition: d.c.3.7 V.
- Others: No strong electromagnetic field interference.

1.8 Transportation and storage

When transporting this instrument, attention should be paid to moisture-proof, inversion-proof and violent vibration.

It should be stored in a clean room with temperature of 0 ℃ ~ 55 ℃, relative humidity not greater than 85%, atmospheric pressure: 700 hPa ~ 1060 hPa, no

corrosive gas and good ventilation.

If the instrument needs to be transported over a long distance, it should be reloaded into the original packaging before transportation.

Transportation conditions: Transportation shall be carried out according to the requirements of the order contract. During transportation, rain and snow splashing and mechanical collision shall be avoided, and it shall not be inverted or exposed to the sun.

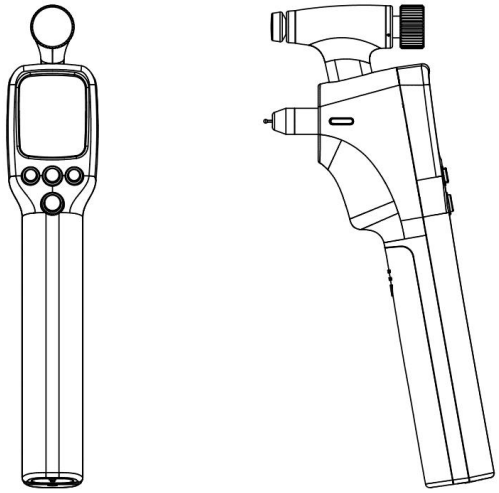
1.9 Product Characteristics

- Electric shock prevention type: Class I equipment;
- Degree of protection against electric shock: Type B application part;
- Classification of degree of protection against incoming liquid: ordinary equipment;
- Classification according to the degree of safety when used in the case of flammable anesthetic gas mixed with air or flammable anesthetic gas mixed with oxygen or nitrous oxide: equipment that cannot be used in the case of flammable anesthetic gas mixed with air or flammable anesthetic gas mixed with oxygen or nitrous oxide;
- Operating mode: continuous operation with intermittent loading;
- Rated voltage and frequency of equipment: d.c.3.7 V;
- Input power of equipment: N/A;
- There is no application part of protection against defibrillation discharge effect;
- There is a signal output or input part;
- Non-permanently installed equipment;

Chapter II Installation Instructions of Instrument

2.1 Appearance diagram of instrument

2.1.1 Appearance diagram of instrument



Front View Side View

Figure 2 Appearance of SK-5500A rebound tonometer

2.2.2 Main structure diagram

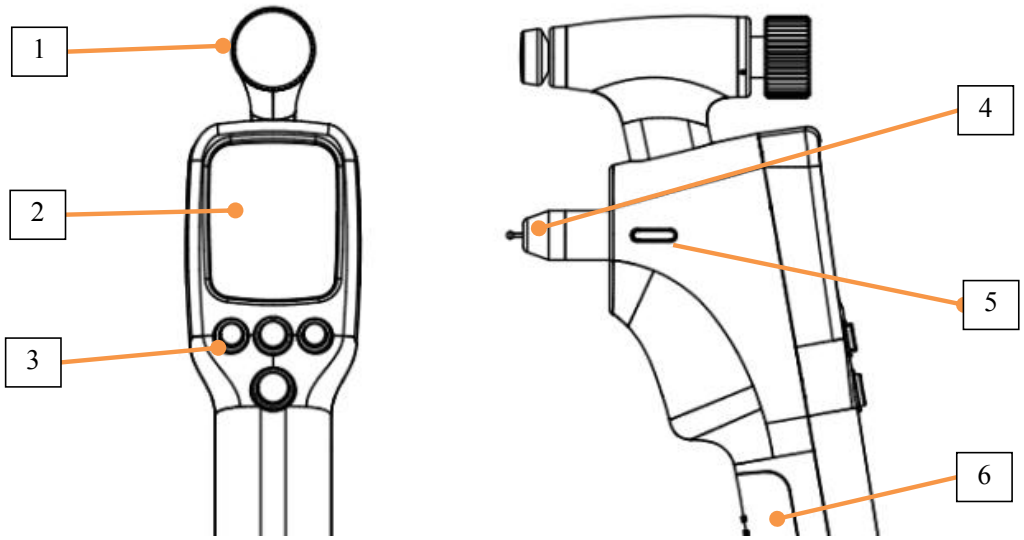


Fig.3 Main structure diagram of SK-5500A rebound tonometer

1 Forehead bracket and adjustment wheel

2 Function button:

3 Display screen

4 Measuring probe and probe holder

5 Probe signal indicator lamp

6 Battery cavity

2.3 Instrument packaging and accessories description

2.3.1 Instrument packaging

This instrument is packed in a special carton with a special foam protection instrument for molding, as shown in Figure 4. When handling the instrument, pay attention to handling it carefully. The packing box cannot be handled upside down. The instrument should be stored in a dry and clean environment.

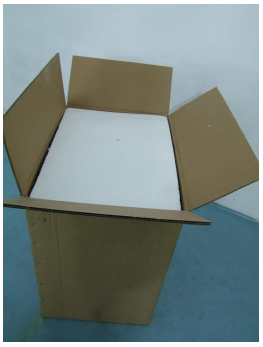


Fig. 4 Schematic diagram of packaging of rebound tonometer

2.3.2 Inventory of accessories

All parts must be carefully removed from the shipping box. Please check the instruments and related accessories according to the randomly sent instrument list, and install them only after checking correctly.

Table 1 Accessories List of SK-5500A Rebound Tonometer

Name	Quantity
Rebound tonometer host	1
probe	1
probe holder	1
Instructions	1
Certificate of conformity	1
Qualification Documents	1

Chapter III Operation Steps

3.1 Main interface

① **Patient ID: Displ**ays the ID set by the user. It can be turned off in the settings interface.

② **Alignment indication:**

	Interface display	Description	Interface display	Description
count terpoint		It appears green when aligned to the center of the cornea.		It appears yellow when misaligned to the center of the cornea.

③ **Mean intraocular pressure:** Mean intraocular pressure measured; Depending on the deviation of the measured value, different displays are used.

Show	Deviation case
	Shows green average when 6 measurements are stable
	Orange mean value is displayed when the deviation of 6 measurements is slightly large

④ **Measurement point:**

Measured marks are green and unmeasured marks are gray; Errors occurred in a single measurement and were not counted in the total number of times.

⑤ **Eye difference:**

Press the left and right buttons to set the measurement eye tag, and the eye tag mark will be added to the measurement result.

⑥ **Bluetooth status icon:**

The Bluetooth connection status is displayed, and the icon distinguishes between

connected (green) or unconnected (white). The icon is not displayed when it is not turned on.

⑦ **Multi-function keys:**

When there is no measurement data or when printing is not connected, the setting icon  is displayed here. Click it to enter the setting interface;

When there is measurement data (6 measurements have not been completed), it is displayed as the settings icon  here, and the data will be cleared after clicking;

When there is measurement data and the printer is connected, the print icon  is displayed here. Click to print the report, and the data will be automatically cleared after printing.

3.2 Operating instruction

3.2.1 Measurement process

1）Power-on: Press and hold the multi-function key to display the power-on screen.

2）Login: Enter the correct password.

3）Probe installation: Install the probe according to the prompts (Note: Do not touch the surface of the probe directly with your hands when installing the probe)

4）Select the measurement eye type, and do not select the eye type by default when booting

5）The patient relaxes upright or lies flat, eyes are fixed straight ahead, the tonometer forehead bracket is placed close to the patient's forehead, and the probe is aligned in front of the measuring corneal apex; The distance between the probe tip and the patient's cornea should be about ± 5 mm.

6）Fine-tune the tonometer so that the alignment indication turns green and remains unmoved.

7）Click the measurement button, measure the result once, repeat it 6 times, and measure the result 6 times;

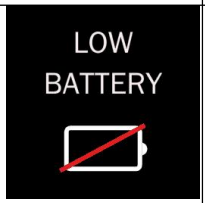
8）According to the printer connection, click the multi-function key to print the measurement result

9）Switch eyes and follow the above steps 5, 6, and 7 to continue measuring;

10）When the next patient needs to be measured, press and hold the measurement key for 3 seconds to pop up the measurement probe. After replacing the new probe, measure the next patient.

3.2.2 Tips during measurement

	Interface display	Description	Interface display	Description

Measurement process and result prompt		Measurement error: displayed when no data is measured or the data exceeds the measurement limit; Automatically closed after 2 seconds of display.		The distance is too far: when measuring, it prompts when the probe stroke is too long; Automatically closed after 2 seconds of display.
		The distance is too close: when measuring, it prompts when the probe stroke is too short; Automatically closed after 2 seconds of display.		Large deviation of 6 measured values; After clicking the multi-function key or measurement key, discard the data and re-measure;
		The green average value is displayed when the 6 measurements are stable;		The orange average value is displayed when the deviation of 6 measurements is slightly large;
Other		Low battery: When the battery is lower than 25%, it prompts a low battery interface once; Automatically closed after 2 seconds of display.		Insufficient battery: When the battery is less than 10%, it prompts the low battery interface and shuts down automatically.

3.2.3 Key description

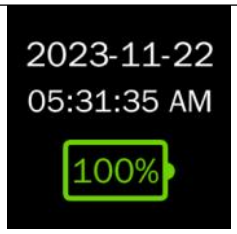
Name	Action	Status	Acquisition interface	Settings interface
Multi-function key	Click	/	When there is no measurement data, enter the setting interface; There is measurement data (6 measurements have not been completed), and the data is cleared after clicking; When there is measurement data (6 measurements have been completed) and printing is not connected, click to enter the settings interface; When the printer is connected, the report is printed, and the data is automatically cleared after printing.	Confirm the options and jump to the page (next level of settings or return to the first level)
	Long press for 3 seconds	Starting up	Shut down and eject the probe at the same time	Shut down and eject the probe at the same time
Left button	Click	/	Set eye type to left eye	Toggle Function
Right click	Click	/	Set eye type to right eye	Toggle Function

Measurement key	Click	/	Manual measurement 1 time;	Second-level and third-level interfaces: enter the first-level interface; Set the first-level interface: enter the acquisition interface.
	Long press for 3 seconds	/	Ejector probe	/
 Left button;  Right click  ; Multi-function keys  ; Measurement keys;				

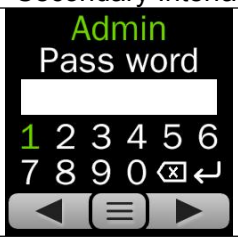
3.3 Interface description

3.3.1 Power-on interface

Press and hold the "Multi-function" button to turn on, display the power-on screen, detect the battery power when turning on, and display the date and battery interface.

			
Power-on screen	The boot power is greater than 25%; Shows 2 seconds.	The boot power is less than 25% and greater than 10%; Shows 2 seconds.	The boot power is less than or equal to 10%; Automatic shutdown after 2 seconds of display.

3.3.2 Login

Primary Interface	Secondary Interface	
		According to the system settings, the user login function is on (default is off). At this time, the user enters the login interface. After selecting the account and entering the password, the user enters the collection interface (the default user name of the system is Admin; the password is empty)

3.3.3 Probe installation

 	Before entering the acquisition interface, check whether the probe has been installed; Displaying probe mounting when not mounted is detected; The user inserts the new probe into the installation hole, and the instrument automatically sucks in the probe. After the installation is in place, the probe installation interface automatically closes and enters the acquisition interface; Click the multi-function key to skip the probe detection interface and enter the setting interface.

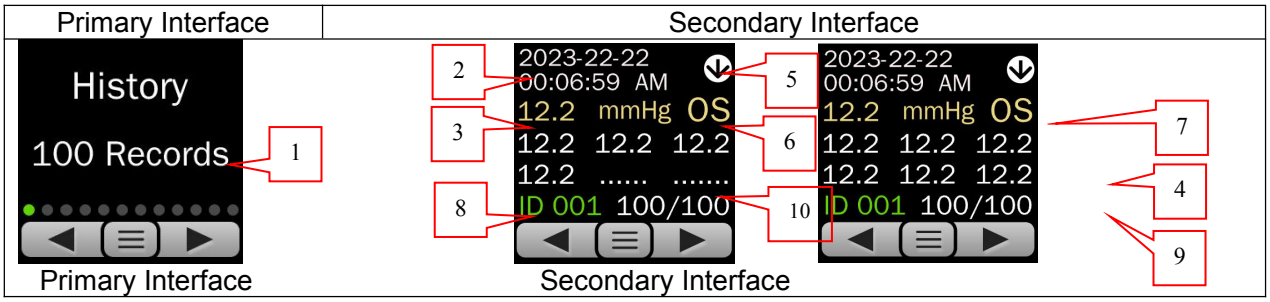
3.3.4 Acquisition interface

Same as 3.1 main interface

3.3.4 Setup interface

3.3.4.1 History

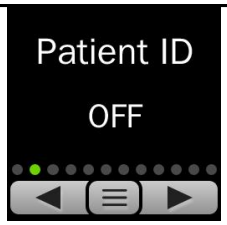
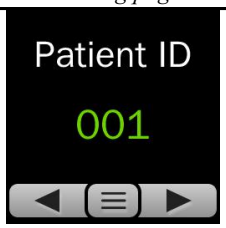
The last 100 measurement records can be saved and viewed in the history record. After saving 100 records, the previous records will be automatically overwritten in a cycle. Right-click to press the right cycle to view the measurement data in sequence according to the positive time sequence. Click the left button, press the left loop, and click to view the measurement data in reverse chronological order.



① Total number of data records
② Measurement DateTime
③ Mean intraocular pressure:
④ Single intraocular pressure
⑤ Posture markers at the time of measurement: patient sitting position, reclining position, patient lying position.
⑥ Eye alignment, will not be displayed when eye alignment is not selected.
⑦ Intraocular pressure unit
⑧ ID Number
⑨ Current data location/total number of pieces of data
⑩ Single unmeasured

3.3.4.2 Patient ID

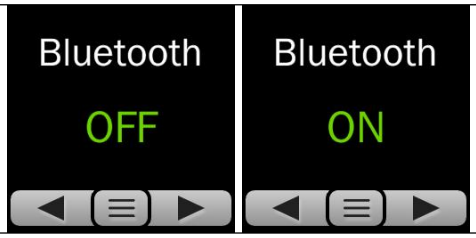
Primary Interface	Secondary Interface	Description

		Numbering and closing cycles in the level 2 interface are switched; When set to OFF: the collection interface does not display the number; numbered at 001-100 cycles; Once selected, the number is displayed in the acquisition interface and the saved measurement data.

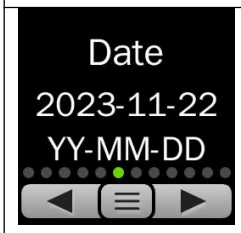
3.3.4.3 Language settings

Primary Interface	Secondary Interface	Description
		The default is Chinese. Users can change languages, including Chinese, English, French, Spanish, German, Portuguese and other languages

3.3.4.4 Bluetooth Settings

Primary Interface	Secondary Interface	Description
		Defaults to Off. The user can choose to turn it on, and after turning it on, it will automatically search for connectable printers.

3.3.4.5 Date Settings

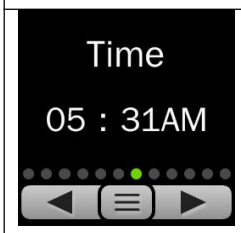
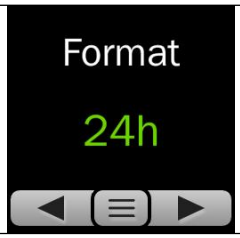
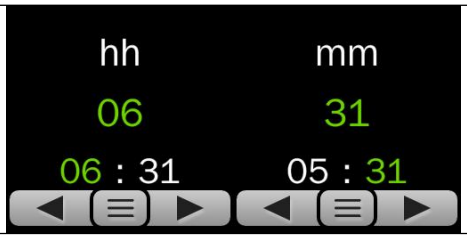
Primary Interface	Secondary Interface	Three-level interface
		

Description:

In the level 1 interface, click the multi-kinetic energy key to enter the level 2 interface; In the level 2 interface, use the left and right keys to select the date format; After selecting the date format with the multi-function key, enter the level 3 interface date setting; Date setting, left and right keys to adjust the date. When DD is set, press the multi-function key to return to the level 1 interface.

Default date format: YYYY-MM-DD (Chinese), MM-DD-YYYY (English)

3.3.4.6 Time Settings

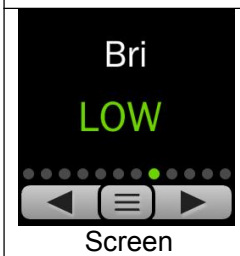
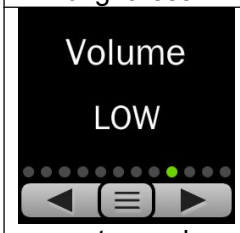
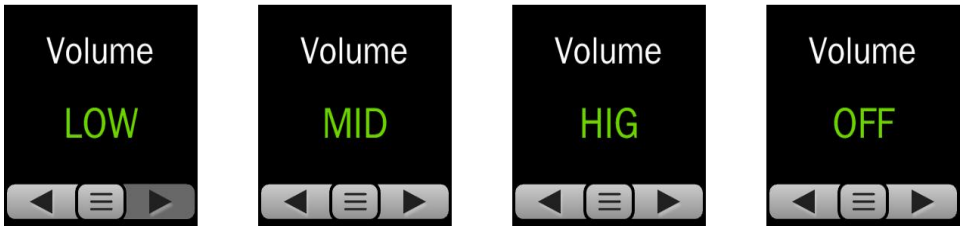
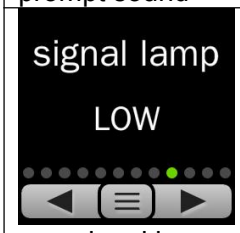
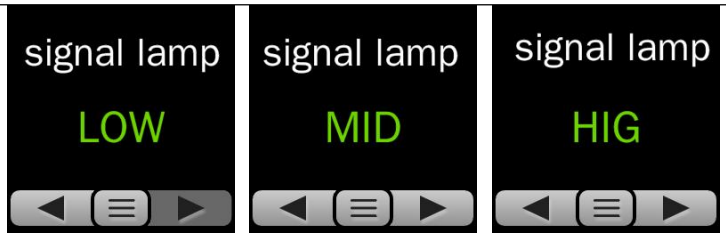
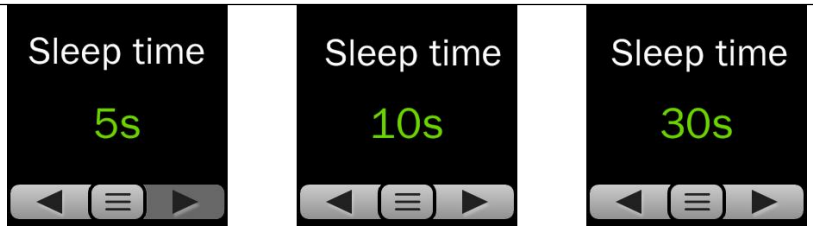
Primary Interface	Secondary Interface	Three-level interface
		

Description:

In the level 1 interface, click the multi-kinetic energy key to enter the level 2 interface. In the level 2 interface, use the left and right keys to select the time format; After selecting the time format with the multi-function key, enter the level 3 time setting; Time setting, adjust the time left and right. When setting min, press the multi-kinetic energy key to return to the level 1 interface.

Time format default: 24-hour clock

3.3.4.7 Brightness, prompt tone, signal lamp, sleep time

Primary Interface	Secondary Interface
 Screen brightness	
 prompt sound	
 signal lamp	
 Dormancy time	

Description:

Brightness: Default; Prompt tone: Default;

--Power on--Short prompt tone; --Probe not installed--Short prompt tone; --Probe installation completed--Short prompt tone; --Single measurement completed--Short prompt tone

--All measurements are completed--Long tone prompt; --button----short prompt tone

Signal light brightness: default; Light up when entering the measurement state; Displays green when measurement is ready; When a status prompt (such as too close, too far, retest, error)

appears in the measurement, it flashes red.
Sleep time: 5S by default; During this period, the equipment will automatically sleep without any operation, and the probe will not be ejected during sleep. Press any key after sleeping, or wake up when lifting the instrument, and directly enter the acquisition interface; After 2 minutes, without any operation, the device automatically shuts down, and the probe is not ejected at this time.

3.3.4.7 User login

Primary Interface	Secondary Interface	Three-level interface	Four-level interface
			

User login: Off by default; In the level 3 interface, select Return and press the multi-kinetic energy key to return to the level 1 interface. Select User to enter the password entry interface.

2 fixed user names, names cannot be modified; The password can be modified, and the password is up to 8 digits. Admin login users can modify the passwords of other users, and non-Admin users can only modify their own passwords.

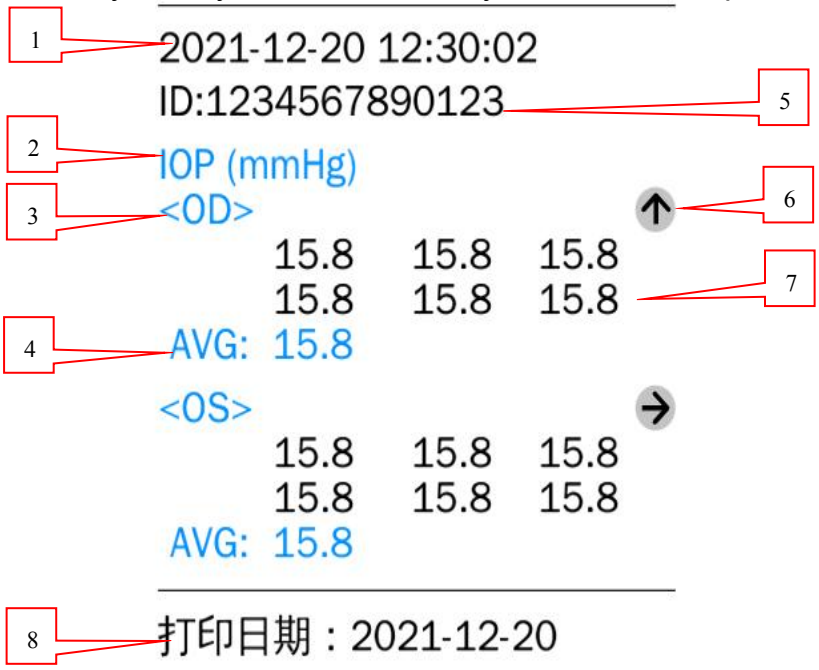
3.3.4.8 About the interface

Primary Interface	Secondary Interface		Description
			About the interface: Display software name, model and version.

3.4 Report

① Inspection Time
② Intraocular pressure unit
③ Eye distinction: When there is no eye distinction, it will not be displayed
④ Mean intraocular pressure:
⑤ Patient ID: Blank after ID: when there is no ID.
⑥ measurement azimuth
⑦ Measurement data: There is no data of 6 groups, fill it with---
⑧ Print Date

Other: When there is only one eye data, no other eye information is printed.



3.5 Shutdown

After the inspection is completed, press and hold the multi-function key for 3 seconds, shut down and eject the probe, place the probe in the container for disposable needles and dispose of it as medical waste.

Chapter IV Introduction to rebound tonometer software

4.1 Introduction to rebound tonometer system software

4.1.1 Software Name

Sunkingdom rebound tonometer system software model: SK-5500UA

4.1.2 Version Number

Software release version number: V1.0

4.1.3 Software Provider

Name of operating software provider: Chongqing Sunkingdom Medical Instrument Co., Ltd

Address of operating software provider: No.1 Xinmao Road, Beibei District, Chongqing (Free Trade Zone)

4.1.4 Software support

Chongqing Sunkingdom Medical Instrument Co., Ltd. provides technical support and software operation training to software users.

Chapter V Equipment Maintenance Matters

5.1 General consideration

- This equipment should be handled carefully, away from the source of earthquake, and placed in a cool, dry and ventilated place.
- Do not mix it with toxic, corrosive, flammable and explosive items during storage.
- Please check whether the appearance of the equipment is damaged before use.
- Do not load or unload any parts of the equipment after starting the machine.
- If the machine is not used for a long time, please remove the battery. The main unit is stored in a dry and ventilated environment.
- If the instrument is returned to the factory for maintenance, please disinfect the forehead support parts with 75% medical alcohol.

5.2 Cleaning and maintenance of equipment

- After the equipment inspection is completed, the surface dust should be removed with a cleaning cloth every day and covered with a dust cover.
- Every week, wipe the stains on the outer surface of the equipment with a wet rag dipped in a little center cleaner, and then dry them with a dry rag. And disinfect the forehead support parts and main body with 75% medical alcohol.
- Display screen maintenance: The display screen is easily damaged. Wipe with a damp cloth only. No solvents or alcohol can be used.

5.3 Preventive inspection and maintenance

- When this equipment is not in use, the battery should be removed.
- The probe holder needs to be replaced every six months. If the display displays a Change error message on a line more than twice after replacing the probe, replace the probe holder before using the device again.

5.4 Component Replacement

Instructions for replacing the probe holder:

- Power off the rebound tonometer.
- Unscrew the probe seat ring by hand and place it in a safe place.
- Pull the probe holder out with your fingers.
- Insert a new probe hub into the rebound tonometer.

◆ Screw down the probe seat ring until it securely holds the probe seat.

5.5 Common troubleshooting

Table 2 Common troubleshooting

phenomena	Causes	SOLUTIONS
Unable to power on, shut down quickly after power on	Low battery charge	Replace the battery
The indicator light does not light up	Indicator lamp wire connector is loose, indicator lamp is bad	Tighten the loose connection, replace the indicator light

DESIGN OR SPECIFICATIONS SUBJECT TO CHANGE WITHOUT NOTICE!

5.6 Waste treatment

Discarded probes generated due to inspection should be placed in the medical waste disposal box.

During the normal use and maintenance of this equipment, the replaced components or other wastes should be properly disposed of according to the requirements of local laws and regulations, and cannot be discarded at will. At the end of its life, the equipment shall be recycled according to the requirements of local laws and regulations. So as not to cause environmental pollution.

5.7 Electromagnetic compatibility requirements

This equipment should not be placed in strong electromagnetic field environment.

5.8 Manufacturer's Responsibility

The manufacturer is only responsible for the impact on the safety and reliability of this equipment under the following circumstances:

--Assembly, addition, commissioning, modification or maintenance are carried out by personnel approved by the company;

--The electrical facilities in the relevant rooms meet the relevant requirements;

--The equipment is used according to the requirements of the instruction manual.

Chapter VI Explanation of Symbols

6.1 Explanation of equipment symbols

Table 3 Explanation of equipment symbols

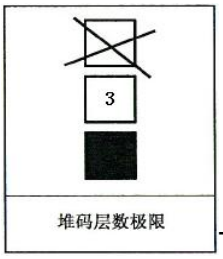
⎓direct current	Communicate
Type B Application Part	Attention! Consult random files
Protective grounding	d.c. alternating current

6.2 Explanation of symbols on packing boxes

The shipping package contains fragile items, which should be handled with care.

The package shipping piece shall be shipped vertically upward.

The packaging and transportation pieces are afraid of rain.



The package shipments are stacked up to 3 layers.

Chapter VII Electromagnetic Compatibility

7.1 Equipment grouping classification

The rebound tonometer belongs to Group 1 Class A equipment according to the grouping classification in the national standard GB 4824.

7.2 Basic Performance

Under the test conditions specified in 6.2 of YY 9706.102-2021, the rebound tonometer shall comply with the following requirements:
The parameters can be displayed normally as expected, the normal functions of each key should not fail, the software runs normally and the inspection results are recorded;

7.3 Electromagnetic emissions

<table>
<tr><td colspan="3">Guidelines and Manufacturer's Statement-Electromagnetic Emissions</td></tr>
<tr><td colspan="3">The rebound tonometer (model: SK-5500A) is intended to be used in the following specified electromagnetic environments, and the purchaser or user shall guarantee that it is used in such electromagnetic environments:</td></tr>
<tr><td>launch test</td><td>Compliance</td><td>Electromagnetic environment-guidelines</td></tr>
<tr><td>Radio frequency transmission
GB 4824</td><td>Group 1</td><td>The rebound tonometer (model: SK-5500A) uses RF energy only for its internal function. As a result, its radio frequency emission is low and there is little chance of interference with nearby electronic devices.</td></tr>
<tr><td>Radio frequency transmission
GB 4824</td><td>Class A</td><td rowspan="3">Rebound tonometer (model: SK-5500A) is suitable for use in non-household and hospital-specific low-voltage power supply grids that are not directly connected to the public low-voltage power supply grids of households and houses.</td></tr>
<tr><td>Harmonic emission
GB 17625.1</td><td>Not applicable</td></tr>
<tr><td>Voltage fluctuation/flicker emission
GB 17625.2</td><td>Not applicable</td></tr>
</table>

7.4 Electromagnetic immunity

Guidelines and Manufacturer's Statement-Electromagnetic Immunity

The rebound tonometer (model: SK-5500A) is intended to be used in the following specified electromagnetic environments, and the purchaser or user shall guarantee that it is used in such electromagnetic environments:

Immunity test	IEC 60601 Test Level	coincidence level	Electromagnetic environment-guidelines
static discharge GB/T 17626.2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV contact discharge ± 8 kV air discharge	The floor should be wood, concrete or ceramic tile, and if the floor is covered with synthetic materials, the relative humidity should be at least 30%.
electric fast Transient pulse swarm GB/T 17626.4	± 2 kV to power line	± 2 kV to power line	Grid power supplies should be of the quality typical for use in commercial or hospital settings.
surge GB/T 17626.5	± 1 kV line-to-line ± 2 kV line to ground	± 1 kV line-to-line ± 2 kV line to ground	Grid power supplies should be of the quality typical for use in commercial or hospital settings.
Voltage sag, short-term interruption and voltage variation on power supply input line GB/T 17626.11	< 5% UT for 0.5 cycles (> 95% sag on UT) 40% UT for 5 cycles (On UT, 60% sag) 70% UT for 25 cycles (On UT, 30% sag) < 5% UT for 5 s (> 95% sag on UT) Note: UT is the AC network voltage 220 V before the test voltage is applied.	< 5% UT for 0.5 cycles (> 95% sag on UT) 40% UT for 5 cycles (On UT, 60% sag) 70% UT for 25 cycles (On UT, 30% sag) < 5% UT for 5 s (> 95% sag on UT) Note: UT is the AC network voltage 220 V before the test voltage is applied.	Grid power supplies should be of the quality typical for use in commercial or hospital settings. If the user of the rebound tonometer (model: SK-5500A) requires continuous operation during power interruption, it is recommended that the rebound tonometer (model: SK-5500A) be powered by an uninterruptible power supply.
Power frequency magnetic field (50 Hz)	3 A/m	3 A/m	The power frequency magnetic field shall have the power frequency magnetic field level characteristics of a

GB/T 17626.8			typical location in a typical commercial or hospital environment.

7.5 Electromagnetic Immunity-to Non-Life Support Equipment and Systems

Guidelines and Manufacturer's Statement-Electromagnetic Immunity			
The rebound tonometer (model: SK-5500A) is intended to be used in the following specified electromagnetic environments, and the purchaser or user shall guarantee that it is used in such electromagnetic environments:			
Immunity test	IEC 60601 Test Level	coincidence level	Electromagnetic environment-guidelines
Radio frequency conduction GB/T 17626.6 Radio frequency radiation GB/T 17626.3	3 V (effective value) 150 kHz ~ 80 MHz 3 V/m 80 MHz ~ 2.5 GHz	3 V (effective value) 3 V/m	Portable and mobile radio frequency communication devices should not be used closer to any part of the rebound tonometer (model: SK-5500A), including cables, than the recommended isolation distance. This distance should be calculated by the formula corresponding to the transmitter frequency. Recommended isolation distance $d = 1\sqrt{P}.2$ $d = 1.2\sqrt{P}$ 80 MHz ~ 800 MHz $d = 2.3\sqrt{P}$ 800 MHz ~ 2.5 GHz Where: P-according to the transmitter's maximum as provided by the transmitter manufacturer Output power rating in watts (W); d-Recommended isolation distance in meters (m). The field strength of the fixed RF transmitter is determined by surveying the electromagnetic field, and should be lower than the coincidence level in each frequency range. Interference may occur near devices marked with the following symbols. 

Note 1: At 80MHz and 800MHz frequencies, the formula of the higher frequency band is used.
Note 2: These guidelines may not be suitable for all situations. Electromagnetic propagation is affected by absorption and reflection from buildings, objects and human bodies.

A Field strength of fixed transmitters, such as base stations for wireless (cellular/cordless) telephones and terrestrial mobile radios, amateur radios, amplitude and frequency modulation radio broadcasts, and television broadcasts, cannot be accurately predicted theoretically. In order to evaluate the electromagnetic environment of fixed RF transmitters, the survey of electromagnetic fields should be considered. If the field strength of the location where the rebound tonometer (model: SK-5500A) is measured is higher than the above RF coincidence level, the rebound tonometer shall be observed to verify that it can operate normally. If abnormal performance is observed, supplementary actions may be necessary, such as reorientation or position of the rebound tonometer (model: SK-5500A).

b In the entire frequency range of 150kHz-80MHz, the field strength should be lower than 3V/m.

7.6 Recommended isolation distance between portable and mobile radio frequency communication equipment and rebound tonometer (model: SK-5500A)

--For non-life support equipment and systems

Recommended isolation distance between portable and mobile radio frequency communication equipment and rebound tonometer (model: SK-5500A)

The rebound tonometer (model: SK-5500A) is intended for use in electromagnetic environments where radio frequency radiation disturbance is controlled. Depending 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 rebound tonometer (model: SK-5500A) as recommended below.

Maximum rated output power of the transmitter W	Isolation distance/m corresponding to different frequencies of the transmitter		
	150 kHz ~ 80 MHz $d = 1.2\sqrt{P}$	80 MHz ~ 800 MHz $d = 1.2\sqrt{P}$	800 MHz ~ 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For the maximum rated output power of the transmitter not listed in the above table, the recommended isolation distance d, in meters (m), can be determined by the formula in the corresponding transmitter frequency column, where P is the maximum rated output power of the transmitter, in watts (W), provided by the transmitter manufacturer.

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

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

7.7 Installation environment

The rebound tonometer (model: SK-5500A) is powered by an internal power source. Other equipment used near this equipment at the same time shall meet the relevant requirements of electromagnetic compatibility.

The possible impact of portable and mobile radio frequency communication equipment on rebound tonometer (model: SK-5500A) is detailed in "6 Recommended isolation distance between portable and mobile radio frequency communication equipment and rebound tonometer (model: SK-5500A)".

The rebound tonometer (model: SK-5500A) is limited to the use of batteries, components and accessories randomly supplied by the manufacturer (see the list of accessories in Table 6 for details). When these batteries, components and accessories are used, they comply with the requirements of YY 9706.102-2021.

CAUTION: The use of accessories and cables other than those sold by the manufacturer of the system as spare parts of internal components may result in increased emissions or decreased immunity of the system.

CAUTION: Use of non-specified accessories or cables with the system may result in increased emission or decreased immunity from the system.

Warning: The system 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 in which it is used.

WARNING: The system may be interfered with and/or undergo degradation related to basic performance and safety when used in the vicinity of marked equipment.，

WARNING: This device is not intended for use in residential environments where it does not provide adequate protection for radio reception.

7.8 List of annexes

Table 4 List of annexes

Serial number	Name of attachment	Model	Parameter
1	battery	AA battery	1.5 V

2	probe holder		
3	screwdriver		
4	probe		

Warranty Statement

Commitment: The manufacturer can provide the necessary information for the equipment parts designated by the manufacturer to be serviceable.

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

2.This equipment is guaranteed free of charge for one year from the date of purchase, subject to compliance with this instruction manual.

3.During the warranty period, repairs will be charged under the following circumstances:

● Damage caused by failure to use, maintain and store according to the instruction manual;

● Personnel without the authorization of Chongqing Sunkingdom Medical Instrument Co., Ltd. dismantle/modify the equipment without permission, causing damage to the equipment;

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

4. The design or specifications are subject to change without prior notice!

If you have any objection to the instructions, or don't understand anything, please call: 023-68102793.