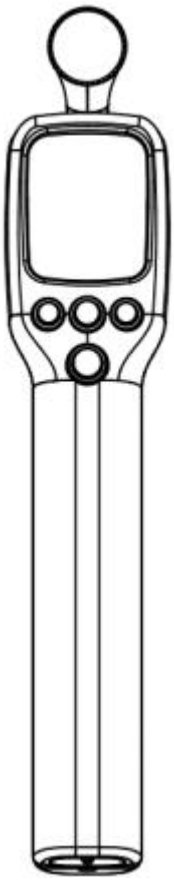
Rebound Tonometer

Instruction Manual



- English

February,20,2025

ChongQing SunKingdom Medical equipment Co., Ltd.

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Preface

Respected user:

Thank you for choosing the rebound tonometer manufactured by ChongQing Sunkingdom Medical equipment Co., Ltd. (here in after referred to as "Shangbang"). We are deeply honored that "Shangbang rebound tonometer" can be trusted by you. In order to give you an overall understanding of "Shangbang rebound tonometer", we have provided you with this instruction manual, which covers the installation, operation method, instructions for use, maintenance, transportation, and storage of the equipment, and is an essential guide for you to use the equipment.

Registrant Information

◆**Product name:** Rebound tonometer

◆**Product model:** SK-5500A/SK-5500B

◆**Registrant / Manufacturer:** ChongQing Sunkingdom Medical equipment Co., Ltd.

◆**Registrant address:** No.1 XinMao Road (Free Trade Zone), BeiBei District,Chongqing,China

◆**Production address:** 35-2, Ying Tian Guang Dian Gong Gu, Cai Jia Gang Industrial Zone, BeiBei District, Chongqing, China

◆**Registrant/manufacturer Phone:** +86-23-68102805

After-sales service Information

◆After-sales service company name: ChongQing Sunkingdom Medical equipment Co., Ltd.

◆After-sales service address: 35-2, Ying Tian Guang Dian Gong Gu, Cai Jia Gang Industrial Zone, BeiBei District, Chongqing, China

◆After-sales service phone:+86-23-68643990

Manufacturer's responsibility:

The company in the following situations to think should be responsible for the safety, reliability and performance of device, that is:

◆assembly operations, expand, reset, improvement and repair are authorized by the company personnel.

◆The relevant electrical equipment conforms to the national standards.

◆Device shall be carried out in accordance with the conditions and requirements listed in instruction manual.

Others

◆Production date of this product: See nameplate

◆Product life: 8 years

It is recommended that you do the following carefully before use:

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

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

The pictures in this manual are renderings, and the specific configuration is subject to the packing list. If you have any questions, please consult ChongQing SunKingdom Medical equipment Co., Ltd.

Tel: +86 23-68102805

Chapter 1 Overview

1.1 Product introduction

The equipment uses electromagnetic induction technology to collect the data of human intraocular pressure. It is important for the diagnosis of ocular diseases and for the surgery.

1.2 Usage notice

[Precautions]

This equipment is intended only for trained ophthalmic clinicians.



Attention

1.2.1 For your safety and benefit, please read this product manual and all accompanying materials carefully before you use the equipment. We shall not be liable for any personal injury, property or other loss which may result from your not using and operating the equipment in accordance with the product instructions.

1.2.2 To protect the equipment from the environment (humidity, dust, liquid, direct exposure to sunlight, etc.), it should be placed in a dry place. Please be careful of liquid or other sundries entering the equipment, or it may cause short circuit of internal components of the equipment, thus causing electric shock or fire.

1.2.3 Use only authentic, certified probes supplied by the manufacturer. Probes are for single use only (one for each measurement). If the eye is inflamed or infected, the eye on the healthy side should be measured first. Use only the original, well-packaged probes. Repeated use of the probe may result in incorrect measurements, probe breakage, bacterial or viral cross-infection, 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.

1.2.4 To avoid contamination, place unused probes in a box, do not touch exposed probes, and do not use probes if they touch an unpasteurized surface, such as a table or floor. Do not use a touched or dropped probe and dispose of it correctly (place it in a container for disposable needles).

1.2.5 In addition to replacing the battery and the probe holder, the equipment shell cannot be opened without the permission of our company, or we will not be responsible for the adverse consequences caused by it.

1.2.6 The equipment does not require routine maintenance or calibration, but the battery is replaced at least once every 6 months, and the probe holder is replaced.

1.2.7 The operator shall wear disposable medical surgical gloves when using the equipment.Disinfect the parts in contact with patients according to the instructions before use, which will not pose unacceptable risks.

1.2.8 The equipment can only be used by operators who have received the training of engineers from our company.

1.2.9 The equipment shall be avoided in a strong electromagnetic interference environment, otherwise it may lead to inaccurate measurement results and delay in diagnosis.

1.2.10 Do not modify this equipment without the authorization of the manufacturer.

1.2.11 This product has no basic performance. In order to ensure the basic safety of the equipment, check whether the equipment can be started normally before starting every day;

1.2.12 The rebound tonometer has no materials that may pose unacceptable risks in contact with patients and operators.

1.3 Product configuration

1.3.1 Structure and Composition

The rebound tonometer consists of a host, a probe and software.

1.3.2 Product model list

Form 1 List of product models

Model	Hardware	Embedded software				Workstation software		
		Name	Function	Model	Version	Name	Model	Version
SK-5500A	Host,probe ,software	Shangbang rebound tonometer system software	Measurement intraocular pressure	SK-5500UA	V1.0	/	/	/
SK-5500B	Host,probe ,software		Measurement intraocular pressure and preserve data	SK-5500UB	V1.0	Shangbang rebound tonometer workstation software	SK-5500PA	V1.0

1.3.3 Software operating environment

The equipment should be avoided in a strong electromagnetic interference environment.

1.3.4 Network Security Requirements

This equipment only connects to the printer through bluetooth, and has the user access control mechanism, and the user uses the user name and password to login for identity authentication and permission limitation.

User Type	Permission to use
System administrator	Permission for all functions of the software
Ordinary user	All functions except user management.

1.4 Intended use, patient population, user and measurement principles

1.4.1 Intended use

The product is use in medical institutions for intraocular pressure measurement;

Application place: medical institution.

1.4.2 Intended patient population and user

User:

Education: At least a professional physician or nurse, with no ceiling.

Knowledge:

—Minimum: after training, you can understand the symbol explanation in the instruction manual, and there is no upper limit.

Language understanding: Models SK-500A and SK-500B are languages specified in the sales plan.55

Experience: minimum: use after training. There is no upper limit.

Allowable damage:

—Slight reading visual impairment or visual acuity correction to 0.6;

—the ability to control and grasp with one hand;回弹式眼压计

—40% of the impairment results in only 60% of normal hearing at 500 Hz at 2 kHz.

Patient population:

Age: No special requirements;

Weight: No special requirements;

Health: See 1.5
Nationality: multiple;
Patient status: Good coordination required.
—The patient is not a user: not relevant unless the patient is anxious.

1.4.3 Measurement principles

The rebound tonometer uses electromagnetic induction technology. After the measurement probe is inserted into the tonometer, it is magnetized to generate polarity. When the alignment start measurement is completed, the instantaneous current in the solenoid in the equipment generates an instantaneous magnetic field that causes the magnetized probe to move toward the cornea at a constant speed. The probe is decelerated and rebounded after impacting the anterior surface of the cornea; the electric control switch monitors the solenoid voltage caused by the rebounded magnetized probe; the electronic signal processor and the micro-sensor calculate the deceleration after the probe impacts the cornea; and finally, the integrated information is converted into the intraocular pressure reading. When the intraocular pressure is higher, the deceleration after the probe impact is larger and the impact duration is shorter. In contrast, when the intraocular pressure was low, the deceleration after probe impact was small and the impact duration was long.

1.5 Product contraindications and side effect

Severe keratopathy (such as obvious corneal thinning and inflammation) is prohibited;
Keratopathy (such as edema and scar) should be used with caution;
Corneal infectious diseases are forbidden.

1.6 Transport and Storage conditions

Transportation conditions:
This instrument should pay attention to moisture-proof, anti-inversion, and avoid violent vibration.
Transportation conditions: according to the requirements of the order contract transportation, in the process of transportation should avoid rain and snow and mechanical collision, can not inverted, can not be exposed in the sun.
If the installed instrument needs to be moved and moved in a short distance, the connecting line between the instrument should be removed and moved separately. If the instrument needs long-distance handling, it should be reloaded into the original package before handling.
Storage environment:
Fully packaged rebound tonometer shall be stored in a clean room with ambient temperature: 0℃ ~55℃, relative humidity: 85%, atmospheric pressure: 620 hPa ~ 1060 hPa, ventilated, dry, and free of corrosive gas.

1.7 Light radiation safety

Not applicable

1.8 Warning Information

See 1.2 Usage notice

Chapter 2 Specifications and Performance

2.1 Equipment Classification

● Shock proof type:Internal power supply, ME equipment(Plastic part of probe front end, plastic part of forehead support);

● Against electric shock: the degree of B type application part (frontal zone, jaw);

● On the degree of protection into liquid categories: ordinary equipment;

● According to the sterilization method classification: not applicable;

● According to suitable for oxygen-enriched environment classification: not applicable.

● Running mode: the continuous operation (the longest incentives (open) time: continuous dut.

● The rated voltage and frequency of the equipment: d.c.3. 7 V (battery model: 18650; capacity: 3000 mAh);

● Altitude: 4000 meters or less.

● Pollution level: Level 2.

●Whether there is a signal input / output part: Yes.

2.2 Performance

2.2.1 Technical parameters

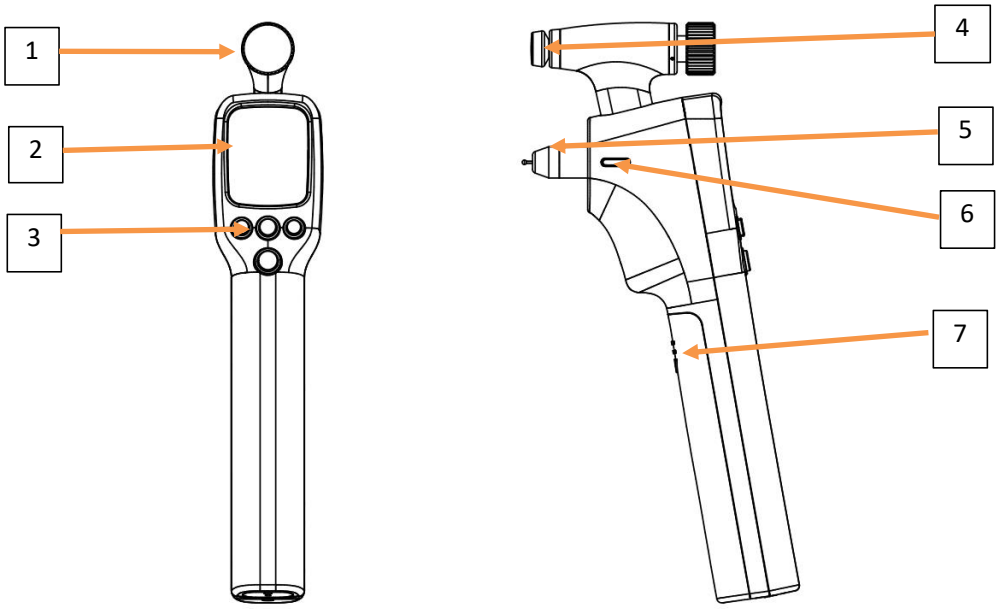
Item	**Requirements**
Range of the tonometer measurements	7-50mmHg
measuring accuracy	±1.2 mmHg（≥7mmHg,and ≤20mmHg） ±2.2mmHg （＞20mmHg,and ≤50mmHg）
Display accuracy	0.1mmHg
Measurement repeatability (coefficient of variation)	＜8%

2.2.2 Physical dimensions and Mass

Model	**SK-5500A**	**SK-5500B**
Overall dimensions (length, width and height)	200mm*100mm*50mm	
Weight	154g	

2.3 Product structure diagram

2.3.1 Front view



1 Forehead support adjusting wheel

2 Monitor

3 Function key

4 Frontal plastic part

5 Probe and probe base

6 Probe signal lamp

7 Battery compartment

2.4 Reference standards

- ISTA 3A：2018
- IEC 62366-1:2015+AMD1:2020 Medical devices-Part 1: Application of usability engineering to medical devices
- IEC 60601-1-6:2010+AMD1:2013+AMD2:2020 Medical electrical equipment-Part 1-6: General requirements for basic safety and essential performance-Collateral standard: Usability
- 14971:2019 Medical devices-Application of risk management to medical devices
- IEC TS 60601-4-2:2024 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
- GS03 IEC 60601-1-2:2014+AMD1:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- GS01 IEC 60601-1:2005+AMD1:2012+AMD2:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- ISO 15004-1：2020

- ISO 8612:2009 - Ophthalmic instruments - Tonometers

Chapter 3 Overview Equipment installation instructions

3.1 Equipment operating conditions

3.1.1 Environment temperature:10℃～35℃;Relative humidity: 30%～75%
3.1.2 Atmospheric pressure:620hPa～1060hPa

3.1.3 Power: d.c.3.7 V

3.2 Equipment packaging and components description

3.2.1 Equipment packaging

After unpacking the equipment, confirm whether the main components and accessories are complete and whether there is transportation damage according to the "Appendix List".

3.2.2 Checking package contents

Appendix List

NO.	Attachment	Parameter
1	Host	1
2	Probe	One box
3	Probe seat	1
4	Spire lamella	1
5	3.7V lithium battery	1
6	Screwdriver	1
7	Instructions	1

3.3 Installation Environment

- Environmental conditions
- Temperature: 10℃ ~ 35℃.
- Relative humidity: 30% ~ 75%.
- Atmospheric pressure: 620 HPA ~ 1060 HPA.
- Power supply condition: d.c. 3.7 v.
- Others: no strong electromagnetic interference.

3.4 Installation

The host of rebound tonometer has been installed at the factory.

Battery installation:

- Carefully take out the instruments and accessories from the packing box.

- Preparation items: Phillips screwdriver and an AA battery.

- Unscrew the battery compartment screw with a phillips screwdriver and remove the battery cover.
- Install the battery into the battery card slot (pay attention to the positive and negative poles).
- Replace the battery cover and tighten the screws.

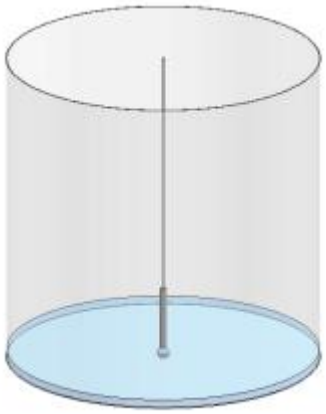
Chapter 4 Instructions for operating

4.1 Cleaning (preparation before use)

1) When changing patients for examination, clean and disinfect the forehead support parts with 75% medical alcohol.

2) probe disinfection:

- Take the probe out of the package and observe it with naked eyes in a well-lit room. There is no visible dirt on the probe, otherwise replace the probe;
- Rinse the plastic part at the front end of the probe under purified water for 2 min;
- Dry with sterile lint-free cloth;
- Immerse the spherical part of the probe head in 0.55% phthalaldehyde solution at 20℃ for 12min；;
- Immerse the disinfectant in the plastic part at the front end of the rinse probe with purified water for 5min；;
- Rinse the plastic part at the front end of the probe under purified water for 2 min;
- Rinse with sterile water for 30s;
- Dry with a sterile lint-free cloth for later use.



Schematic diagram of probe immersion depth

4.2 Boot-strap

Press the multi-function key for a long time to display the startup screen, and enter the correct password after entering the login interface (the default user name of the system is Admin; password is blank), and according to the prompts to install the probe (note: do not directly touch the surface of the probe with your hand when installing the probe), you can enter the main interface of the software.

4.3 Selecting the patient

Enter the Patient ID interface and select the Patient ID (optional).

4.4 Patient position correction

Instruct the patient to relax, stand upright or lie flat with eyes fixed straight ahead.

4.5 Testing process

- Select the eye to be measured, place the tonometer forehead support close to the patient's forehead, and align the probe to the front of the corneal vertex of the eye to be measured. The distance between that tip of the probe and the cornea of the patient is kept about 5mm by rotate the adjusting wheel support the forehead.
- Fine-adjust the tonometer so that the alignment indicator light turns green and remains fixed.
- Click the "Measure" button, and the measured results were measured six times in sequence to obtain the measured intraocular pressure indication.

4.6 Printing

Set the Bluetooth mode to "printer", turn on Bluetooth and connect the printer. Click the multifunction key to print the measurement results.
Note: The printer using Bluetooth 5.1 protocol is recommended.

4.7 Synchronization

Set the Bluetooth mode to "Export", turn on Bluetooth and connect the workstation software, or use USB to connect the tonometer and the workstation, and the workstation software can click Synchronize to synchronize the data in the tonometer.

4. 8 Shut down

After the inspection, press and hold the multi-function key for 3 seconds, turn off the machine and pop up the probe. Place the probe in a container for disposable probes and treat it as medical waste.

4.9 Charging

Method 1: One end of the USB cable is connected to the charging plug and electrified, and the other end is connected to the USB port (the screw at the bottom of the tonometer needs to be removed with a screwdriver), and the power indicator light of the tonometer lights up to start charging.

Method 2: Open the back cover of the tonometer battery compartment, take out the battery, put the battery into the battery charger with an output voltage of 4.2V, and the indicator light of the battery charger f lashes to start charging; The indicator light is always on, and the charging is complete. After charging, take out the battery and install it in the tonometer correctly.

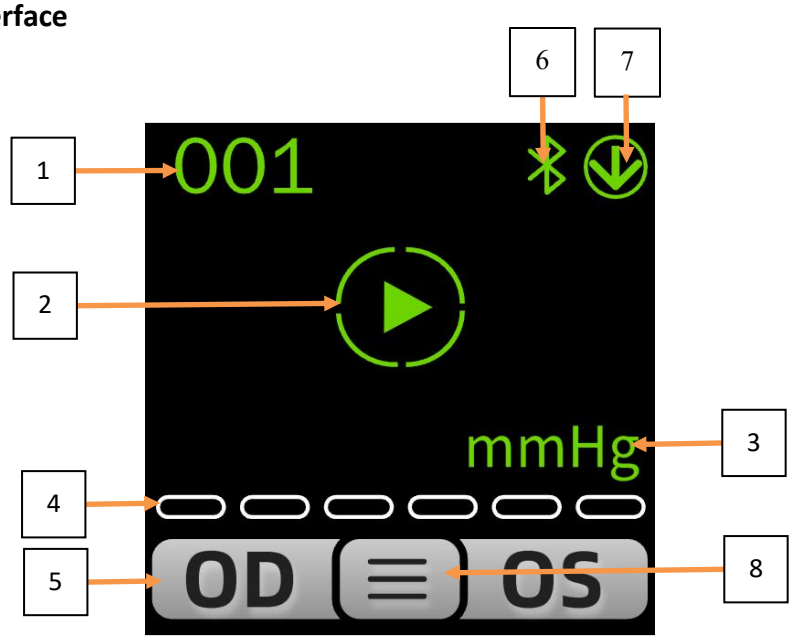
Chapter 5 Software Operation

Take SK-5500UB as an example. Compared with SK-5500UB, SK-5500UA has no storage function. There is no history in the setting interface of SK-5500UA.

5.1 Login interface

Level 1	Level 2	Description
		According to the system settings, the user login function is on (off by default), and then the login interface is entered. After the user selects an account and enters a password, the collection interface is entered (the default user name is Admin and the password is empty).

5.2 Main interface



1 Patient ID: displays the ID set by the user, which can be turned off in the setting interface.

2 Alignment indication.

3 IOP unit: mmhg and kpa can be selected in the setting interface.

4 Measurement times: The measured ones are displayed in green, and the unmeasured ones are displayed in gray.

5 Eye classification: Press the left and right buttons to set the measuring eye classification.

6 Bluetooth status icon: Bluetooth status is displayed, which shows green when connected, white when Bluetooth is turned on and turned off.

7 Measuring posture: Measuring posture includes horizontal posture, prone posture and inclined posture.

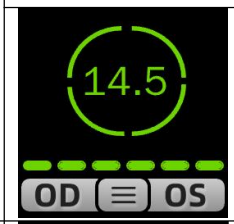
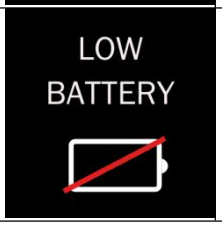
The instrument will automatically recognize the measurement posture, and the color of the measurement posture indication is synchronized with the indicator light.

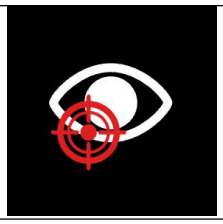
8 Multifunction key:

- When there is no measurement data or a printer is not connected, the setting icon will be displayed here. Click it to enter the setting interface.
- When there is measurement data (6 measurements have not been completed), it will be displayed as a setting icon here, and click it to clear the data;
- When there is measurement data and a printer is connected, it will be displayed as a print icon here. Click it to print the report, and the data will be automatically cleared after printing.

9 Average intraocular pressure: the average intraocular pressure was measured for 6 times.

5.3 Tips in the process of measurement

	Interface display	Description	Interface display	Description
Tips in the process of measurement		Measurement error: data is not measured or data exceeds the measurement limit; automatically after 2 seconds.		Too far distance: when the probe travel is too long; automatically after 2 seconds.
		Too close distance: when the probe travel is too short; automatically after 2 seconds.		6 measurement deviations greater than 5mmHg; Click multi-function key or measurement key to discard data and measure again.
		Show the green average value when the 6 measurements are stable.		Show the orange average value when the mean at 2 – 5mmH.
Others		Low power: when the power is lower than 25%, prompt the low power interface; automatically close after 2 seconds.		Low power: when the power is less than 10%, prompt the low power interface, and automatically shut down.

		The probe is not perpendicular to the cornea, or the probe hits the eyelid or eyelashes.		

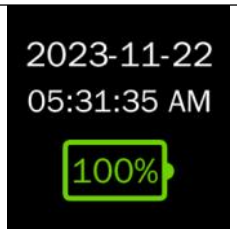
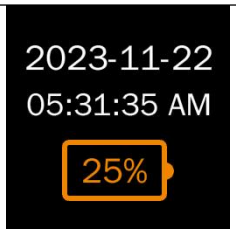
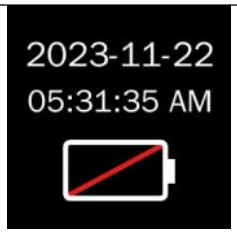
5.4 Key description

Name	Operate	State	Acquisition interface	Setting interface
Multi-function key	Point press	/	When there is no measurement data, enter the setting interface; There are measurement data (6 measurements have not been completed), click to clear the data; When there is measurement data (6 measurements have been completed) and printing is not connected, click and enter the setting interface; When the printer is connected, print the report and automatically clear the data after printing.	Confirm the options and jump to the page (next level set or return to the level 1)
	Press for 3 seconds	Shut down	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 to left eye	Switching function
Right button	Click	/	Set eye to right eye	Switching function
Measurement key	Click	/	Manual measurement once	Setting interfaces: ①Level 2 and 3 interfaces: enter Level 1 interface; ②Level 1 interface: enter the collection interface.
	Press for 3 seconds	/	Eject probe	/
 Left key;  Right-click;  Multi-function key;  Measurement key;				

5.5 Interface Description

5.5.1 Boot interface

Press the "Multi-function" key for 3 seconds to start the equipment, display the startup screen, detect the battery power when starting the machine, and display the date and battery interface.

			
Boot interface	Boot power is greater than 25%; Display for 2 seconds.	The starting power is less than 25% and more than 10%; Display for 2 seconds.	The starting power is less than or equal to 10%; Automatic shutdown after 2 seconds display.

5.5.2 Probe installation

	Before entering the acquisition interface, check whether the probe has been installed; When it is detect that that probe is not installed, the installation of the probe is display; The user inserts a new probe into the installation hole, and the instrument automatically sucks in the probe. After it is installed in place, the probe installation interface automatically closes and enters the acquisition interface. Click the multifunction key to skip the probe detection interface and enter the setting interface.
	After the probe is put as required, the equipment automatically loads the probe. If the equipment fails to load the probe for three consecutive times, it prompts “Replace probe”, and the prompt disappears and the probe popup after 2s.

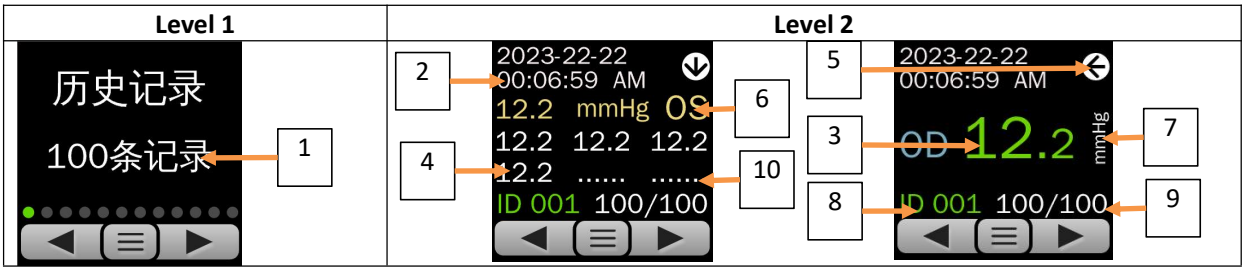
5.5.3 Acquisition interface

Same as 5.1 main interface.

5.5.4 Setting interface

5.5.4.1 History (SK-5500B applies)

The last 100 measurement records can be saved and viewed in the history record, and the previous records can be automatically and cyclically overwritten after the full 100 measurement records are saved. Right-click to cycle through the right, and view the measurement data in sequence according to the time sequence. Click the left key, press the left cycle, click according to the time reverse order to view the measurement data.



1 Total number of data records

2 Measurement date time

3 Mean intraocular pressure

4 Single intraocular pressure

5 Posture markers for measurement: level, tilt, prone position.

6 Eye contact, not displayed when eye contact is not selected.

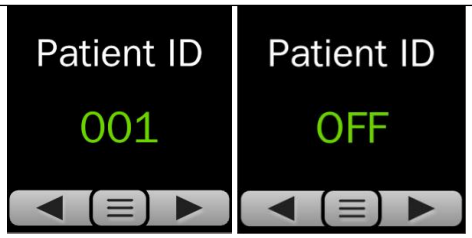
7 Intraocular pressure unit: mmHg and kPa can be selected.

8 ID number

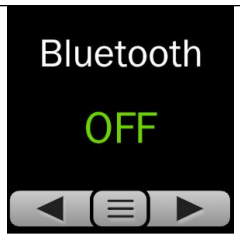
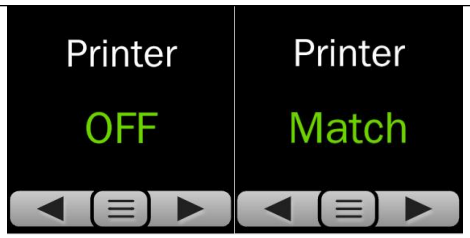
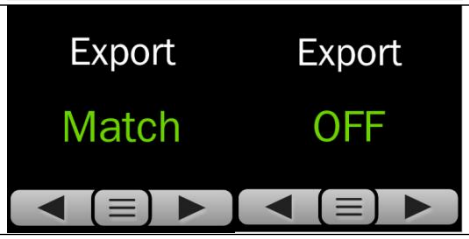
9 Current data position/total number of data

10 Not measured

5.5.4.2 Patient ID

Level 1	Level 2	Description
		After it is set to OFF: No number will be displayed in the acquisition interface; Number in 001-100 cycle; After selection, the number will be displayed in the acquisition interface and the saved measurement data.

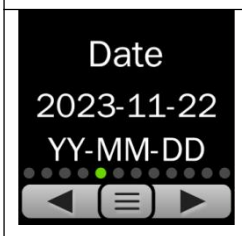
5.5.4.3 Bluetooth settings

Level 1	Level 2	Description
		The default is off. Users can choose pairing, and after selecting pairing, they will automatically search for printers that can be connected. (Bluetooth mode is set to printer)
		The default is off. The user can select pairing, and after selecting pairing, the connectable workstations will be automatically searched. (Bluetooth mode is set to Export)

5.5.4.4 Language settings

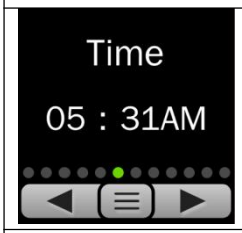
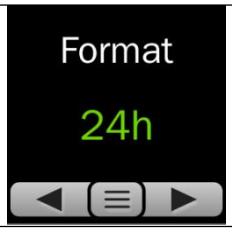
Level 1	Level 2	Description
		Default is chinese. Users can change the language, including Chinese, Janpanese,English, French, Spanish, German, Portuguese, etc.

5.5.4.5 Date setting

Level 1	Level 2	Level 3
		
Note: 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 the date format is selected by the multi-function key,		

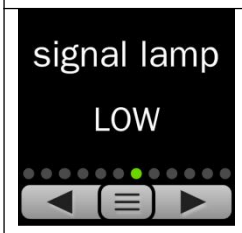
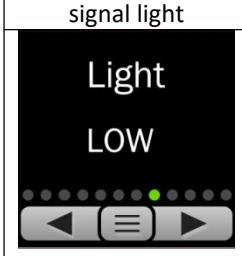
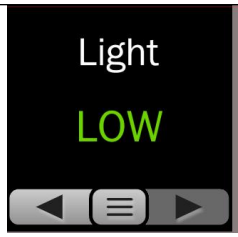
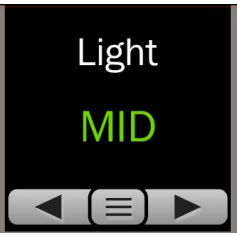
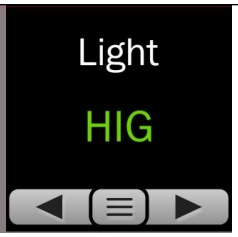
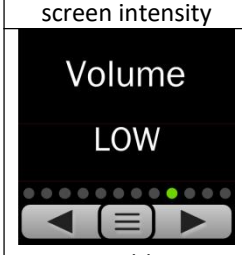
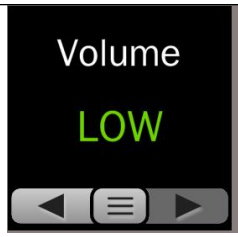
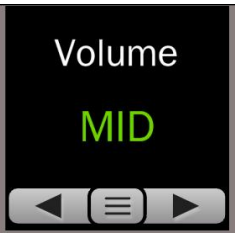
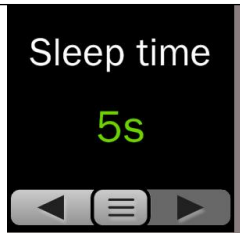
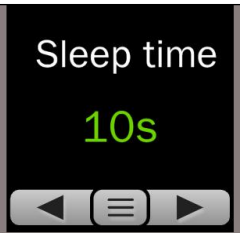
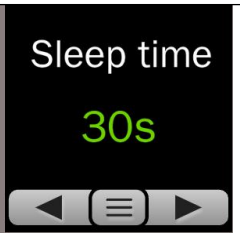
enter the level 3 interface date setting; Date setting, left and right keys to adjust the date, when after the setting date, press the multi-function key to return to level 1 interface.
Date Format Default: MM-DD-YYYY.

5.5.4.6 Time setting

Level 1	Level 2	Level 3	
			

Note:
In the level 1 interface, click the multi-function key to enter the level 2 interface, and in the level 2 interface, use the left and right keys to select the time format; After the multi-function key selects the time format, enter level 3 time setting; Time setting, adjust the time around, when after setting min, press the multi-function key to return to level 1 interface.
Time format default: 24h.

5.5.4.7 Signal lamp, brightness, volunme, sleep time

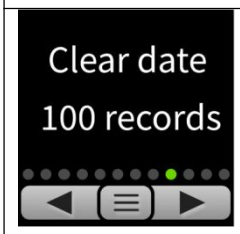
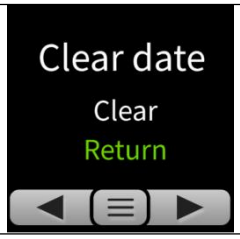
Level 1	Level 2			
 signal light				
 screen intensity				
 prompt tone				
 Sleep time				

Note:
- Brightness: MID by default;
- Volume: MID by 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; -Press the key-short prompt tone.

- Signal lamp: MID by default; Light up when entering the measurement state; Display green when the measurement is ready; When there are status prompts (such as too close, too far, retest, error) in the measurement, it flashes red.
- Sleep time: 5 s by default; During this period, no operating equipment will sleep automatically, and the probe will not pop up when sleeping. Press any key after sleep, or wake up when lifting the instrument, and directly enter the acquisition interface; When there is no operation after 2 minutes, the device will automatically turn off, and the probe will not pop up at this time.

5.5.4.8 Clear date (SK-5500B applicable)

Level 1	Level 2
	
Clear Data: in Level 2 interface, select Return to Level 1 interface; Select clear to clear all test data from the database.	

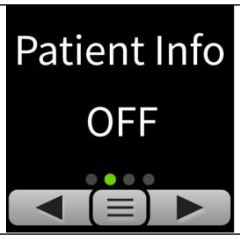
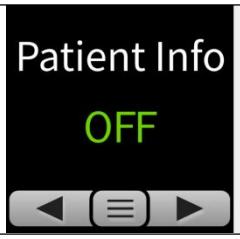
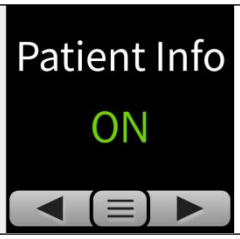
5.5.4.9 Other

Level 1


5.5.4.9.1 Unit

Level 2	Level 3
	 
In the level 2 interface, click the multi-function key to enter the level 3 interface. In the level 3 interface, use the left and right keys to select the intraocular pressure unit; After the multi-function key selects the unit, press the multi-function key to return to the level 2 interface. Default unit format: mmHg. 1kPa=7.500616mmHg.	

5.5.4.9.2 Patient information

Level 2	Level 3
	 

In the level 2 interface, click the multi-function key to enter the level 3 interface, and in the level 3 interface, use the left and right keys to select patient information; After the multi-function key is selected to be on or off, press the multi-function key to return to the level 2 interface. Patient information default: Off. The name and gender lines will be added to the printed report after opening.

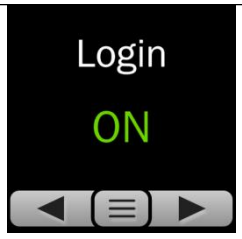
5.5.4.9.3 Machine ID

Level 2	Level 3
	
In the level 2 interface, click the multi-function key to enter the level 3 interface. In the level 3 interface, use the left and right keys to select the machine ID; After the multi-function key is selected to be on or off, press the multi-function key to return to the level 2 interface. Machine ID default: Off. Machine ID will be printed in the print report after opening.	

5.5.4.9.4 Bluetooth mode

Level 2	Level 3
	
In the level 2 interface, click the multi-function key to enter the level 3 interface. In the level 3 interface, use the left and right keys to select Bluetooth mode; After the multi-function key is selected, press the multi-function key to return to the level 2 interface. Bluetooth mode default: printer. When selecting a printer, Bluetooth is turned on and automatically connected to the printer; When Export is selected, Bluetooth will automatically connect to the workstation after it is turned on.	

5.5.4.10 Login settings

Level 1	Level 2	Level 3	Level 4
			
User login: off by default; In the Level 3 interface, select Return and press the multi-function key to return to the Level 1 interface. Select user to enter the password entry interface. There are 2 fixed user names, and the names cannot be modified; The password can be modified, and the password is up to 8 digits. Admin login users can modify other users' passwords, while non-admin users can only modify the current account password.			

5.5.4.11 About

Level 1	Level 2	Description

			About interface: display the software name, model, version and machine ID.

5.6 Report

1 Inspection time

2 Patient ID, name and gender: If there is no ID, blank will be displayed after ID.

3 IOP unit

4 Eye display: OD right eye OS left eye, and it will not be displayed when no eye is selected.

5 Average IOP

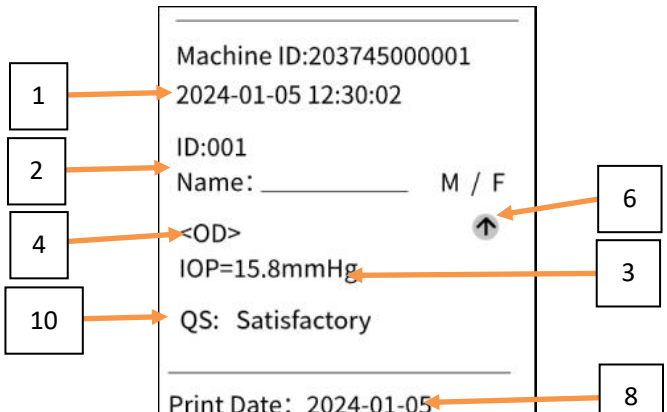
6 Measure azimuth.

7 Measurement data: There are no six groups of data, so fill them with-.

8 Print date

9 Machine ID

10 Quality score: the quality score will not be displayed if the test is not completed for 6 times.



Chapter 6 Software Description

6.1 Software name and model

Software name:Shangbang rebound tonometer system software
Model:SK-5500UA,SK-5500UB

6.2 Software release version

Software model	Software release
SK-5500UA	V1.0
SK-5500UB	V1.0

6.3 Software provider

Operating Software Provider Name: ChongQing Sunkingdom Medical Instrument Co., Ltd.
Operating Software Provider Address:35-2, Ying Tian Guang Dian Gong Gu, Cai Jia Gang Industrial Zone, BeiBei District, Chongqing, China.

6.4 Software support

ChongQing Sunkingdom Medical Instrument Co., Ltd provides technical support and software operation training for software users.

6.5 Software backup

Inbedded software, no backup software. Patient data advises users to perform regular data backup. For backup, connect to the workstation software and synchronize the data in the tonometer to the workstation.

6.6 Software maintenance

After the software configuration is completed, no maintenance is basically required. The new software can be upgraded; serious misoperation or hardware system failure may damage the software system of the equipment.

6.7 Software installation

The system is embedded, the software has been installed in the factory, and can be used after boot-strap.

6.8 Software uninstallation

The system is embedded and does not need to uninstall the software.

Chapter 7 Maintenance, Troubleshooting and Calibration

7.1 General precautions

- The equipment shall be handled carefully away from the earthquake source and placed in a cool, dry and ventilated place.
- Do not mix with toxic, corrosive, flammable and explosive goods when storing.
- Please check the appearance of the equipment for damage before use.
- Do not load or unload any part of the equipment after the machine is started.
- If the machine is not used for a long time, please remove the battery. The host should be stored in a dry and ventilated environment.
- If the equipment is returned for maintenance, please disinfect the forehead support part with 75% medical alcohol.

7.2 Cleaning and maintenance of the equipment

- After the equipment inspection is completed, remove the surface dust with a cleaning cloth every day and put it back in the packing box.
- Wipe the stains on the external surface of the equipment with a wet rag and a little neutral detergent every week, and then dry them with a dry rag. The forehead support parts and the main body were cleaned and disinfected with 75% medical alcohol.
- Maintenance of display screen: the display screen is easily damaged. Wipe only with a damp cloth. Do not use solvents or alcohol.

7.3 Preventive checks

- When this equipment is not in use, remove the battery,the host is stored in a dry and ventilated environment;
- The probe holder needs to be replaced every six months. If the error message with the word (replace probe) appears on a line more than twice after replacing the probe, please replace the probe holder before using the equipment again;
- When the instrument is not in use, cut off the power supply and put it in the metal aluminum box. If this equipment is not used for a long time, it must be powered on for more than 4 hours every 3 weeks to ensure that the equipment meets the basic safety. If damage is found, please contact our company for maintenance.

7.4 Component replacement

Instructions for replacing the probe holder:

- Turn off the power supply of the rebound tonometer.
- Unscrew the probe seat ring by hand and put it in a safe place.
- Pull out the probe holder with your fingers.
- Insert the new probe holder into the rebound tonometer.
- Screw down the probe seat ring until it firmly fixes the probe seat.

7.5 Accessory List

NO.	Accessory	Parameter
1	Host	1
2	Probe	One box
3	Probe seat	1
4	Spire lamella	1
5	3.7V lithium battery	1
6	Screwdriver	1
7	Instructions	1

7.6 Common trouble shooting

Breakdown	**Possible cause**	**Treating ways**
Unable to boot, boot after the boot quickly shut down	Low battery power	Replace the battery
The indicator light is not on	The indicator light line connector is loose, and the indicator light is broken	Turn on the loose line tightly and replace the indicator light

7.7 Waste disposa

Discarded probes resulting from inspection shall be placed in a medical waste disposal bin.
During the normal use and maintenance of this equipment, the replaced components or other wastes shall be properly handled in accordance with the requirements of local laws and regulations, and cannot be arbitrarily discarded. Equipment to the end of life, should according to the requirements of local laws and regulations for recycling. So as not to pollute the environment.

Chapter 8 Symbols

8.1 Definition of Symbols

⎓	Direct-current
	Type B application part
	Protective earthing
	Power light
	Open the battery cover in the direction of the arrow
+	Positive pole
−	Negative electrode
	Forehead support part adjusting knob
	Follow Instructions for Use Refer to instruction manual/Booklet. NOTE on ME EQUIPMENT “Follow Instructions for use”
	General warning sign Indicates a hazard of potential personal injury to patient or operator
	Manufacturer Indicates the medical device manufacturer
	Date of Manufacture
MD	Medical device
SN	Series Number
UDI	Unique Device Identifier
	Use by date
EC REP	Authorized representative in the European Communit Indicates the Authorized representative in the European Community.
CE xxxx	European certificate of conformity
SK	ChongQing Sunkingdom Medical Instrument Co., Ltd.
	WEEE; waste electrical and electronic equipment; crossed-out wheeled bin
	Keep dry
	This way up
	Fragile, handle with care.
	Stacking limit by number ,”3” is limit number.
	Storage Temperature range.

	Recycling
	Clamp as indicated
	Humidity range.
	Atmospheric pressure limitation
	Keep away from sunlight

Chapter 9 Warranty Statement

Commitment: The manufacturer can provide the necessary information for the manufacturer to specify the repairable parts of the equipment.

1. Our company will provide equipment maintenance and free consultation for life.
Before contacting our company by telephone, we suggest that you confirm the following work:
●The name and model of the equipment you are using
●The factory number of the equipment you are using
●Accurately describe what is happening to the equipment
●What happened? What were you doing when it happened?
●What measures have you taken to solve this problem?
2. This product is guaranteed free of charge for one year from the date of purchase, subject to the operation of this instruction.
3. In accordance with the instructions and the operating precautions in the normal operation state, once the machine breaks down, please contact our company immediately.
4. The following items are not included in the warranty:
●Damage caused by failure to follow the instructions for use, maintenance and storage.
●Personnel unauthorized by ChongQing Sunkingdom Medical Instrument Co., Ltd., who demolished or refitted the equipment without authorization, caused damage to the equipment.
●Damage to equipment caused by accident, misuse or irresistible natural factors.

Note:

1. Medical accident caused by irregular operation or not following operation procedure, Sunkingdom will not take any medical liability.
2. The right of final interpretation of this instruction is vested in Chongqing Sunkingdom Medical Instrument Co., Ltd.

Chapter 10 Electromagnetic Compatibility

10.1 Equipment classification

The rebound tonometer was classified into 1 group of Class A devices according to the national standard CISPR 11:2024.

10.2 Basic performance

The rebound tonometer, under the test conditions specified in IEC 60601-1-2:2014+AMD1:2020:, shall meet the following requirements:
It can display normally according to the expected set parameters, and the normal function of each key shall not become invalid. The software shall operate normally and record the inspection results.

10.3 Electromagnetic emission

<table>
<tr><th colspan="3">Guidelines and Manufacturer's Statement - Electromagnetic Emission</th></tr>
<tr><td colspan="3">The rebound tonometer (models: SK-5500A, SK-5500B) is intended to be used in the following specified electromagnetic environment, and the purchaser or user shall ensure that it is used in such electromagnetic environment:</td></tr>
<tr><td>launching test</td><td>Compliance</td><td>Electromagnetic Environment - Guide</td></tr>
<tr><td>Rf emission
CISPR 11:2024</td><td>1 group</td><td>Rebound tonometers (models SK-5500A, SK-5500B) use RF energy only for their internal functions. As a result, its radio frequency emissions are low and the potential for interference with nearby electronic equipment is low.</td></tr>
<tr><td>Rf emission
CISPR 11:2024</td><td>Class A</td><td rowspan="3">The rebound tonometer (model: SK-5500A, SK-5500B) is suitable for use in non-domestic and hospital special low-voltage power supply grid that is not directly connected to the public low-voltage power supply network of domestic residence.</td></tr>
<tr><td>Harmonic emission
IEC 61000-3-2:2018+AMD1:2020 +AMD2:2024</td><td>not applicable</td></tr>
<tr><td>Voltage fluctuation/scintillation emission
IEC 61000-3-2:2020</td><td>not applicable</td></tr>
</table>

10.4 Electromagnetic Immunity

<table>
<tr><th colspan="4">Guidelines and Manufacturer's Statement - Electromagnetic Immunity</th></tr>
<tr><td colspan="4">The rebound tonometer (models: SK-5500A, SK-5500B) is intended to be used in the following specified electromagnetic environment, and the purchaser or user shall ensure that it is used in such electromagnetic environment:</td></tr>
<tr><td>Immunity test</td><td>IEC 60601 test level</td><td>Coincidence level</td><td>Electromagnetic environment-guide</td></tr>
</table>

Electrostatic discharge IEC 61000-4-2:2008	±6 kV contact discharge ±8 kV air discharge	±6 kV contact discharge ±8 kV air discharge	Floors shall be of wood, concrete or tile and, if covered with synthetic material, shall have a relative humidity of at least 30%.
Electrostatic discharge IEC 61000-4-2:2008	±2 kV pair power line	±2 kV pair power line	The mains supply should be of the quality used in a typical commercial or hospital environment.
Surge IEC 61000-4-5:2014	±1 kV line to line ±2 kV line to ground	±1 kV line to line ±2 kV line to ground	The mains supply should be of the quality used in a typical commercial or hospital environment.
Power input line voltage sag, short interruption and voltage change IEC 61000-4-11:2004	< 5% ut for 0.5 cycles (on UT, > 95% sag) 40% UT for 5 cycles (60% sag on UT) 70% UT for 25 cycles (30% sag on UT) < 5% ut for 5 s (on UT, > 95% sag) Note: UT refers to the AC network voltage of 220 V before the test voltage is applied.	< 5% ut for 0.5 cycles (on UT, > 95% sag) 40% UT for 5 cycles (60% sag on UT) 70% UT for 25 cycles (30% sag on UT) < 5% ut for 5 s (on UT, > 95% sag) Note: UT refers to the AC network voltage of 220 V before the test voltage is applied.	The mains supply should be of the quality used in a typical commercial or hospital environment. If the user of the rebound tonometer (model SK-5500A, SK-5500B) needs continuous operation during power outages, it is recommended that the rebound tonometer (model SK-5500A, SK-5500B) be powered from an uninterruptible power supply.
Power frequency magnetic field(50 Hz) IEC 61000-4-8:2001	3 A/m	3 A/m	The power frequency magnetic field shall have power frequency magnetic field level characteristics typical of typical locations in typical commercial or hospital environments.

10.5 Electromagnetic IMMUNITY – for ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

Guidelines and Manufacturer's Statement - Electromagnetic Immunity			
Rebound tonometers (models SK-5500A, SK-5500B) are intended to be used in the electromagnetic environment specified below and shall be guaranteed to be used by the purchaser or the user:			
Immunity test	IEC 60601 test level	Coincidence level	Electromagnetic environment-guide
Radio frequency conduction IEC 61000-4-6:2013 Radio-frequency radiation IEC 61000-4-			Portable and mobile radio frequency communications equipment, including cables, shall not be used on any part of the rebound tonometer (models SK-5500A and SK-5500B) closer to the recommended isolation distance. This distance shall be calculated by a formula corresponding to the transmitter frequency.

3:2010	not applicable	not applicable	Recommended isolation distance d=1.2$\sqrt{P}$ d=1.2$\sqrt{P}$ 80 MHz～800 MHz d=2.3$\sqrt{P}$ 800 MHz～2.5 GHz Where: P— according to transmitter manufacturer's maximum transmitter size Output rated power in watts (W); D— recommended isolation distance in meters (m). The field strength of a stationary rf transmitter is determined by surveying the electromagnetic field and should be lower than the coincidence level at each frequency range. Interference may occur near equipment marked with the follc ıbols.
Note 1: At 80MHz and 800MHz, the higher-band formula is used. Note 2: these guidelines may not be appropriate for all situations wher nagnetic propagation is affected by absorption and reflection from buildings, objects, and humans.			
A field strengths of stationary transmitters, such as base stations for wireless (cellular/cordless) telephones and terrestrial mobile radios, amateur radios, am and fm radio broadcasts, and television broadcasts, are theoretically unpredictable. In order to evaluate the electromagnetic environment of a stationary rf transmitter, a survey of the electromagnetic field should be considered. If the rebound tonometer (models SK-5500A, SK-5500B) is found to have a field strength above the RF compliance level, the rebound tonometer should be observed to verify proper operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or repositioning the rebound tonometer (models SK-5500A, SK-5500B). B The field strength should be less than 3V/m over the entire frequency range of 150 kHz to 80 MHz.			

10.6 Installation Environment

The rebound tonometers (models SK-5500A, SK-5500B) are powered from an internal power supply. Other equipment used simultaneously in the vicinity of this equipment shall conform to the relevant requirements for electromagnetic compatibility.

The possible impacts of portable and mobile RF communication equipment on the rebound tonometer (models SK-5500A and SK-5500B) are detailed in "6 Recommended Isolation Distance of Portable and Mobile RF Communication Equipment from the rebound tonometer (models SK-5500A and SK-5500B)".

The rebound tonometer (models: SK-5500A and SK-5500B) is limited to the batteries, components and accessories supplied by the manufacturer (see Table 5 for the list of accessories). Comply with YY 9706.102-2021 when using these batteries, components and accessories.

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

Caution: use of out-of-specification accessories or cables with the system may result in increased system emissions or reduced immunity.

Warning: the system should not be used in close proximity to or stacked on top of other equipment. if the system must be used in close proximity or stacked on top of other equipment, the system should be observed and verified to operate normally in the configuration in which it is used.

Warning: the system may be interfered with and/or degraded in performance related to basic performance and safety when being used near -marked equipment.

Warning: this device is not intended for use in a residential environment where radio reception is not adequately protected.

10.7 Cable list

NO.	Aaccessory	parameter
1	Rebound tonometer host	1
2	Probe	one box
3	Probe holder	1
4	3.7V lithium battery	1

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