Applanation Tonometer

SK

SK-T
SK-R
SK-Q

Operation Instruction Manual

www.shtopview.com

SHTOPVIEW

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Preface

Dear User：

Thanks for choosing the SK series Applanation Tonometer produced by Us (hereinafter called Shanghai Topview).We are deeply honored that the “Shanghai Topview” Applanation Tonometer can gain your trust. In order to give you a general understanding of the "Shanghai Topview"Applanation Tonometer, we have configured this instruction manual for you, including the installation, use, use instructions, maintenance, transportation, storage, etc. of the instrument. It is an essential guide to the instrument.

◆Product Name:Applanation Tonometer

◆Medical Device Registration Certificate Number:

◆Product technical requirement number:

◆Production date: see product label

◆Usage period: 5 years

◆Date of preparation of the manual: 2018.01.05

◆Manual revision date:

◆Manual version: V1.0

Scope of application: This manual is applicable to SK-T, SK-R, SK-Q Applanation tonometer produced by Us.

Contents

1. Summary

1.1 Product Instruction

This product was developed according to the principle of the Immant-Fick of the Goldman applanation tonometer: Pt (intraocular pressure) = W (external force of the flattened cornea) / A (flattened area), and intraocular pressure measurement was performed under a slit lamp microscope.

◆The measurement result is accurate, the measurement deviation would not exceed ±0.066KPa (0.5mmHg) or 1.5% of the measured value, whichever is greater.

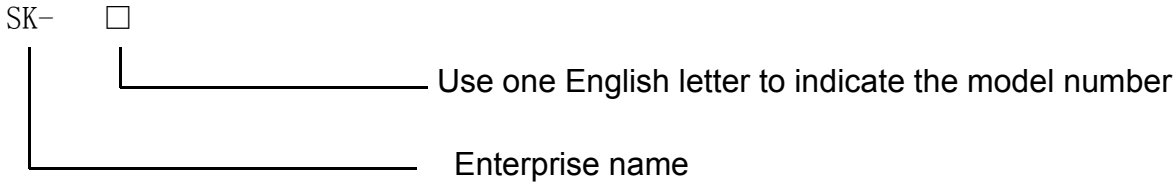
◆Read the measurement result directly on the display screen,no need to look up the table or use other conversions, display the unit KPa or mmHg

◆The pressure value will not be affected by the hardness of the eye wall, the volume change of eyeball will be only 0.56mm³.

◆Checking with the weight rod to ensure the long-term stability of the product and the reliability of the measurement results.

1.2 Model Description

1.2.1 Product number



Marking example: SK-T, which represents the T-type applanation tonometer produced by us.

1.2.2 Product model list

Table 1 Product model list

Product number	Structure and composition	Software component		
		Name	Model specification	Release version
SK-T	Optical Pressure Head,Main body，Calibration rod,T type plug-in connection assembly	/	/	/
SK-R	Optical Pressure Head,Main body，Calibration rod,R type-hanging connection assembly	/	/	/
SK-Q	Optical Pressure Head,Main body，Calibration rod,Q type-Side suspension connection assembly	/	/	/

Dimensions：

SK-T TypeLength×Width×Height（105mm×88 mm×295 mm）Total Weight:0.65kg

SK-R TypeLength×Width×Height（170mm×88 mm×250 mm）Total Weight:0.8kg

SK-Q TypeLength×Width×Height（190mm×88 mm×175 mm）Total Weight:0.85kg

1.3 Usage Notice ⚠

1.3.1 For your security and benefit, please read the operation instruction as well as the datum of the instruments carefully before using it.Our company will not be liable for any personal injury, property or other damage caused by operating the device not in accordance with the product instructions.

1.3.2 This device must be used by trained and authorized medical personnel.

1.3.3 This instrument is only suitable for use in a patient environment with an Optical Pressure Head.

1.3.4 To protect the equipment from the environment(Moist, dust, liquid, direct exposure to sunlight, etc.),keep the product clean and dry, and do not use it in a flammable, hot, dusty environment. Please be careful not to get liquid or other debris into the device.Beware of liquids or other foreign matter entering the device, as this may cause a short circuit in the internal components of the device and cause electric shock or fire.

1.3.5 The equipment enclosure cannot be opened without the company's permission, otherwise the company will not be responsible for the consequences.

1.3.6 All parts in this equipment cannot be disassembled,all parameters (hard, software) cannot be changed.

1.3.7 Do not touch the Optical Pressure Headand the patient's eye surface with your hands or hard objects.

1.3.8 Environmental protection clauses: When the equipment or components in the system are damaged or reach the end of their useful life, discarding them may cause environmental pollution and recycling or disposal according to local laws and regulations.

1.3.9 Do not use this equipment in the presence of flammable anesthesia mixed with air or a flammable anesthetic gas mixed with oxygen or nitrous oxide.

1.3.10 In the correct use of the equipment, if there is an accident, stop using it immediately, cut off the power of the equipment and contact the authorized service provider or the company.

1.4 Applicable Scope

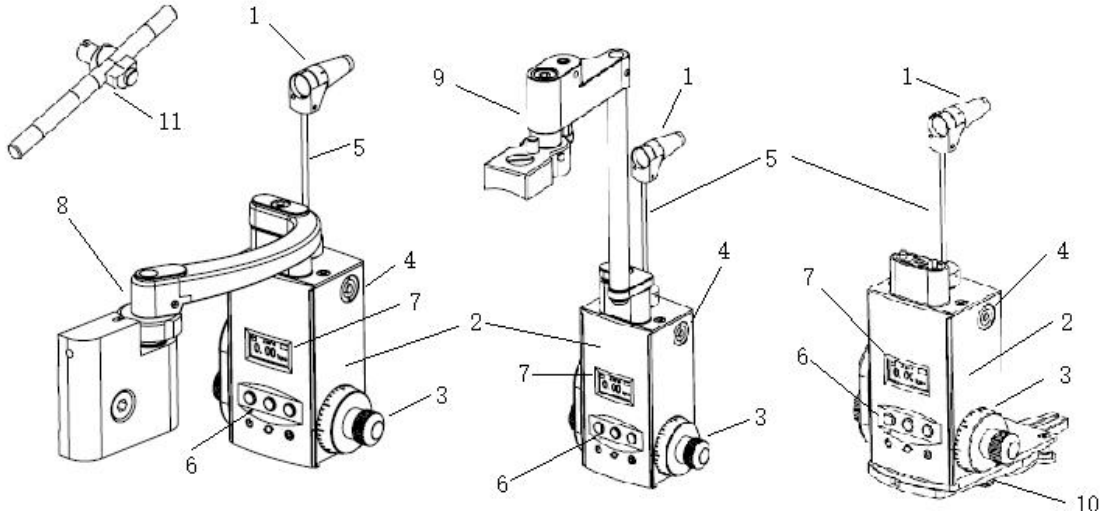
This product is suitable for the measurement of intraocular pressure by trained and authorized medical personnel.

1.5 Product contraindications

[Contraindications] There are corneal lesions (such as edema, inflammation, scars, etc.), corneal thickening or unevenness, etc. are prohibited.

2. Product Structure

2.1 Tonometer Component Composition and Name



SK-Q Tonometer SK-R Tonometer SK-T Tonometer

1—Optical Pressure Head

2—Main Body

3—Rotating knob with measuring drum

4—Calibration rod socket

5—Measuring arm

6—Function button*

7—LED Display*

8—Q type-Side suspension connection assembly

9—R type-hanging connection assembly

10— T type plug-in connection assembly

11—Calibration rod

*Function button instruction：

Power switch:

a. Long press for 3sec to power on/off

b. In the state of power-on, press once to enter the sleeping mode and press again to wake.

Unit switch:

a.Long press for 3 sec to swtich the decimal display.

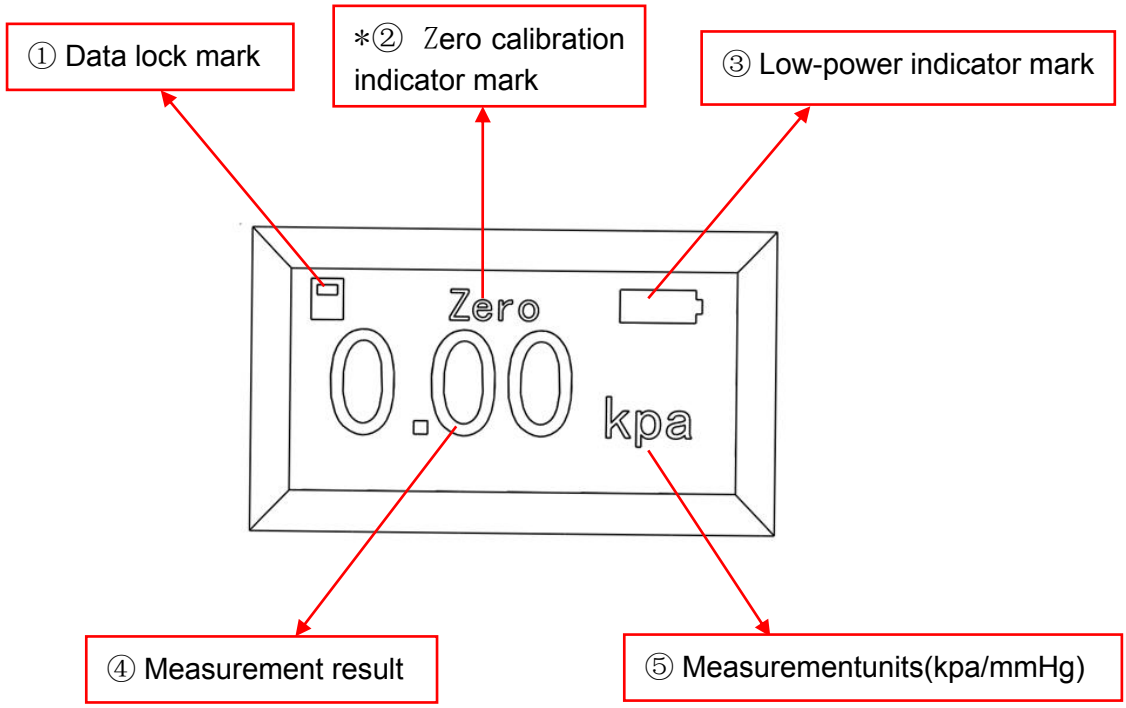
b. Press once to switch the units(mmHg/kpa).

Lock button:

a.Long press for 3 sec to clear the data(zero calibration).

b. Press once to lock the data.

Display interface:



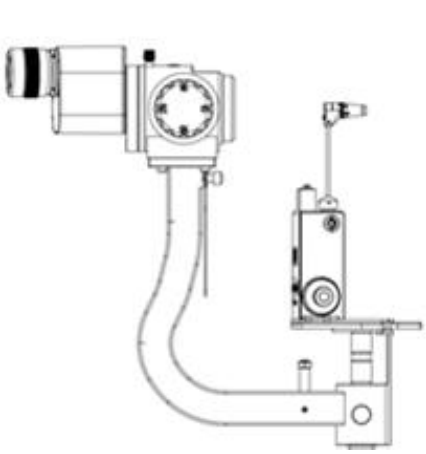
Notes:

*Zero calibration indicator mark "**Zero**":

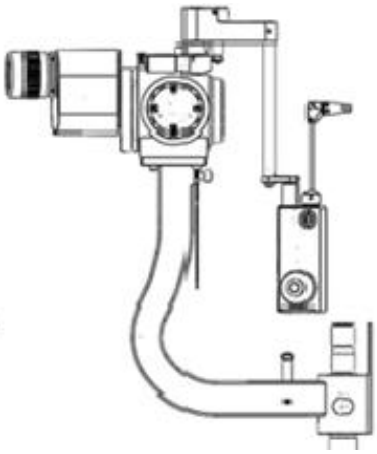
This mark is displayed every time when the device is turned on, for reminding the user to check if the measuring rod is in zero position.

Please rotate the knob to the zero position and long press the lock button for 3s to clear the data until the mark "**Zero**" disappears, then the normal measurement can be started, or the result will be inaccurate.

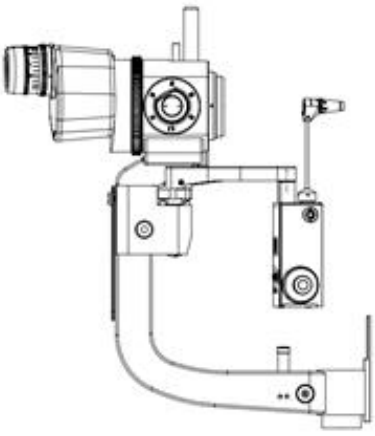
2.2 The Methods to Install SK-T, SK-R and SK-Q Tonometers on the Slit Lamp



SK-T Type



SK-R Type



SK-Q Type

⚠ SK-T, SK-R tonometer is suitable for desktop slit lamps manufactured according to YY 0065 slit lamp standard. SK-Q tonometer is suitable for slit lamp with mounting hole on the side of optical bending arm (such as Haag-Streit BQ900).

2.3 Tonometer Parts List

Item No.	Name	Unit	QTY	SK—T	SK—R	SK—Q
1	Optical Pressure Head	PC	1	●	●	●
2	Main body	Unit	1	●	●	●
3	Calibration rod	Set	1	●	●	●
4	Ttype plug-in connection assembly	Set	1	●	○	○
5	Rtype-hanging connection assembly	Set	1	○	●	○
6	Qtype-Side suspension connection assembly	Set	1	○	○	●
7	Button battery (CR2450, installed in the device)	PC	1	●	●	●

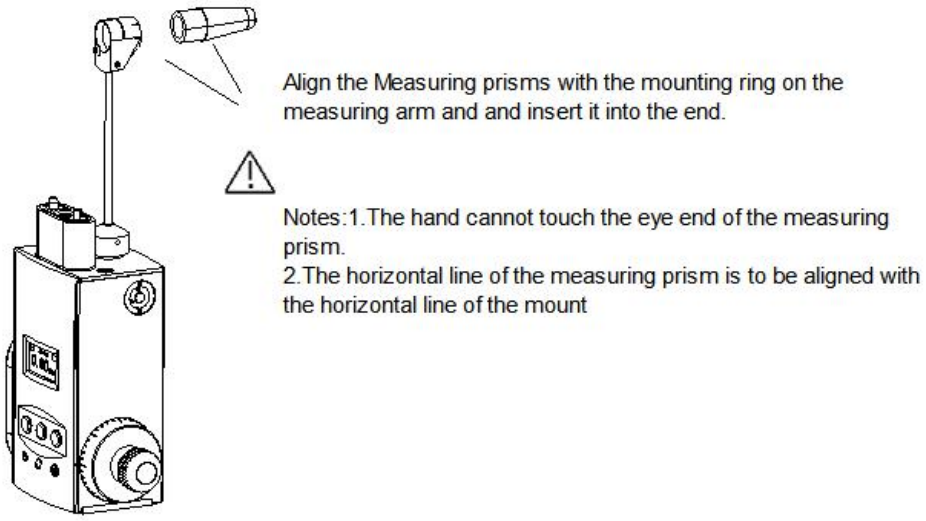
● With the configuration ○ Without the configuration

2.4 Loss and Accessories Replacement Instructions

2.4.1 Optical Pressure Head

⚠ The optical pressure head of this device is a disposable product, cannot be used repeatedly. After use, it should be recycled according to local laws and regulations.

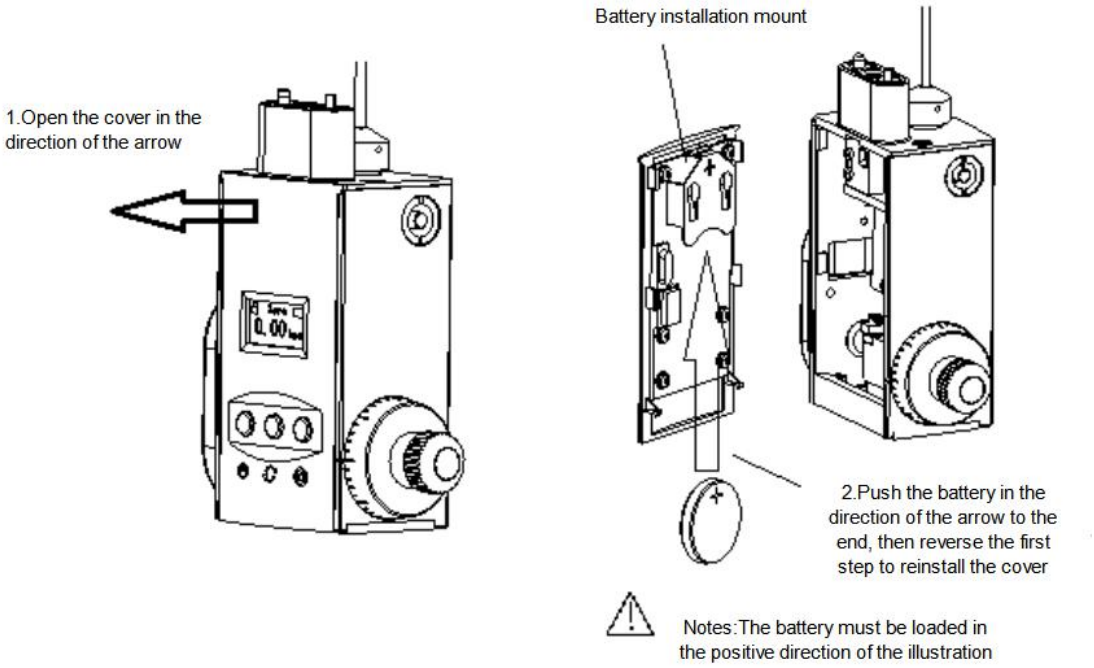
The replacement method is as follows:



2.4.2 Replace Battery

⚠ Notes:The battery for this device is a button battery, the voltage is 3V, the specification is CR2450, when the LED display remind  ,should replace the battery in time.The replace battery should be recycled according to local laws and regulations.

The replacement method is as follows:



3.1 Product Features

3.1.1 Type of equipment: Class II equipment,Part B application part.

3.1.2 Working conditions

Internal power supply : 3V button battery (CR2450).

3.1.3 Operating mode: continuous operation.

3.1.4 Anti-injection program for equipment and application parts: common type equipment.

3.2 Performance Requirements

Item No.	Item description	Index
1	Measurement accuracy	±0.066kpa(0.5mmHg) or amounts to a maximum of ±1.5%of the measuring value (taking the larger of them).
2	Digital display accuracy	0.1mmHg
3	Measurement range	0-79.9mmHg（0-10.63kpa）(Reading number of LED display blinking means out of range)
4	Diameter of corneal applanation surface	3.06±0.02mm

5	Front diameter ofOptical Pressure Head pressure	6.8±0.2mm
6	Reverse hysteresis	≤0.49mN
7	Forward range ofOptical Pressure Head	≤3mm
8	Continuous working time	≥20hours

3.3 Show the Relationship Between Data and Force and Pressure by Flatting Plane

LED Display mm Hg	**Force** mm N	**Pressure** Kpa
10	9.81	1.33
20	19.62	2.66
30	29.43	3.99
40	39.24	5.32
50	49.05	6.65
60	58.86	7.98
70	68.67	9.31
80	78.48	10.64

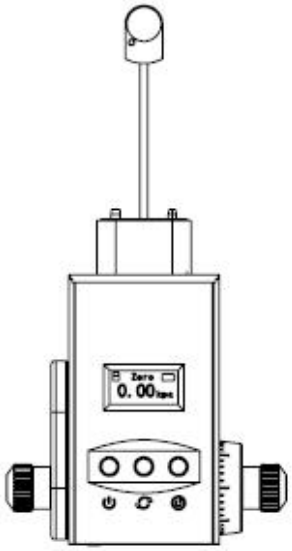
4. Installation

4.1 Open Box to Check

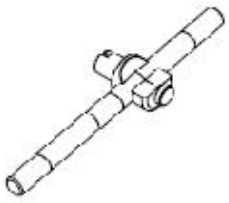
Open the box and take out the tonometer and its accessories from the box. Three types of tonometers and their accessories are as follows.

4.2 SK-T Tonometer Assembly Method

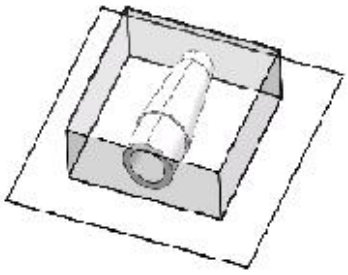
SK-T tonometer accessories are as follows:



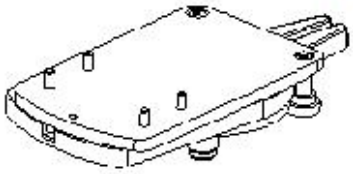
Main Body×1 unit



Calibration rod×1 set

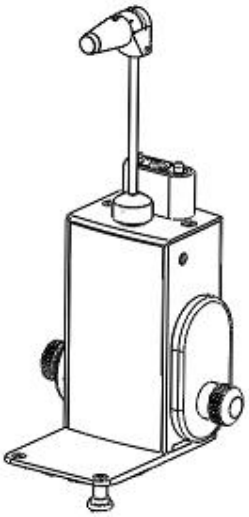


Optical Pressure Head×1 Piece



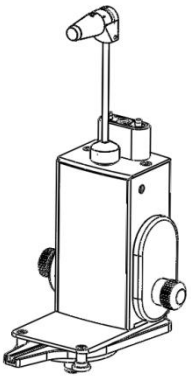
T type plug-in connection assembly×1 Piece

4.2.1 Connect the tonometer main body to the connection plate assembly with a countersunk screw (as shown below);

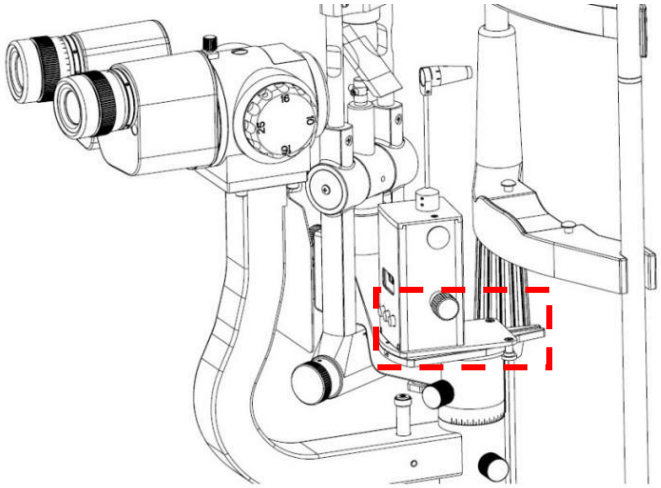


4.2.2 Then connect the tonometer to the tonometer holder of the slit lamp (as shown below);

Tonometer holder

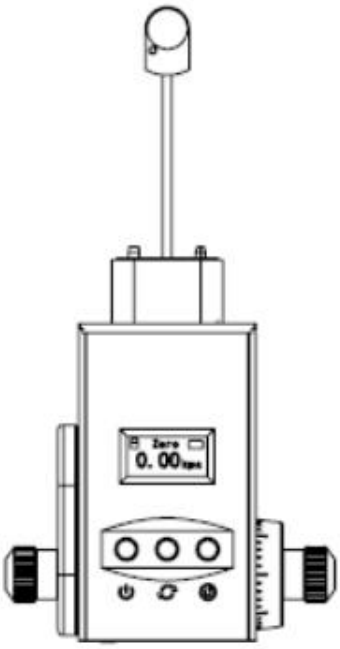


4.2.3 Insert the tonometer into the Focus BarHole of the slit lamp and adjust the position (as shown below).

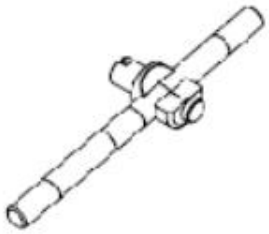


4.3 SK-R Tonometer Assembly Method

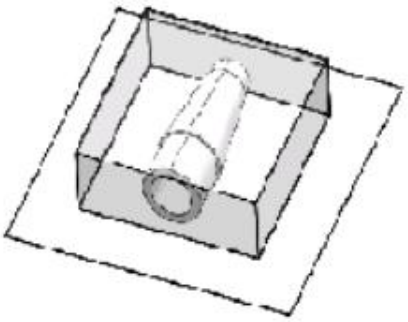
SK-R tonometer accessories are as follows:



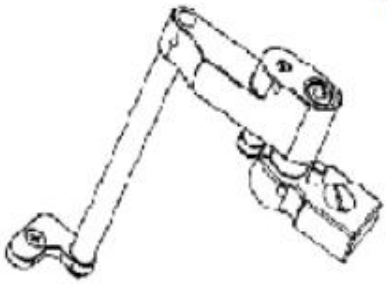
Main Body×1 unit



Calibration rod×1 set

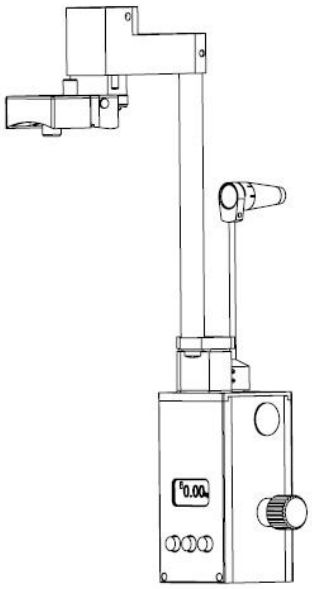


Optical Pressure Head×1 Piece

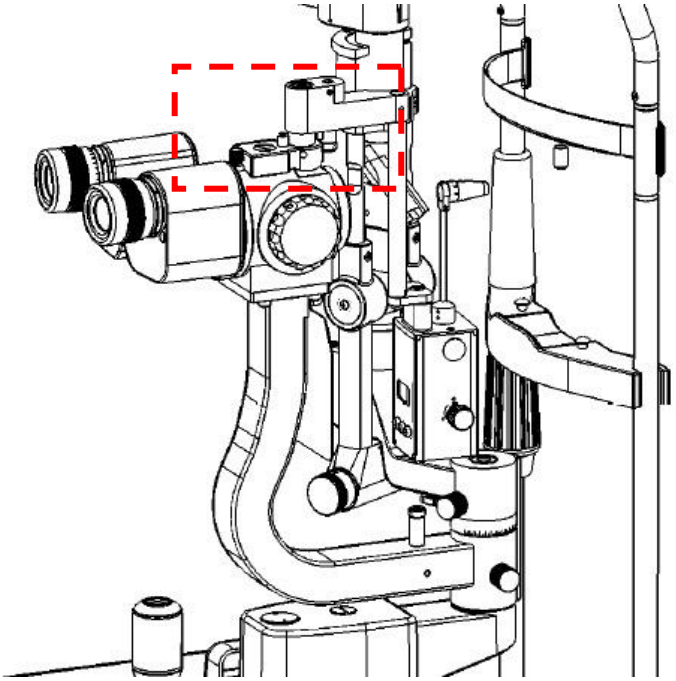


R type-hanging connection assembly×1 Piece

4.3.1 Connect the R type-hanging connection assembly to the tonometer main body (as shown below);

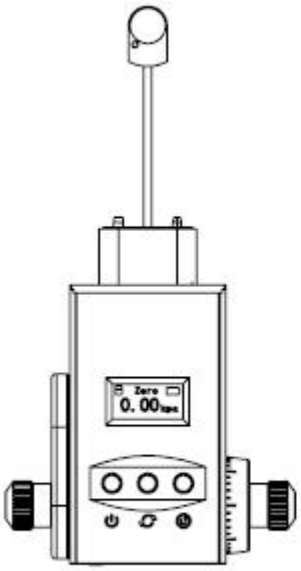


4.3.2 Remove the screw at the corresponding position of the slit lamp, hang up the tonometer bracket, and lock it with the bracket special screw (as shown below).

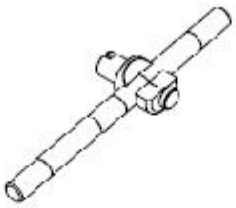


4.4 SK-Q Tonometer Assembly Method

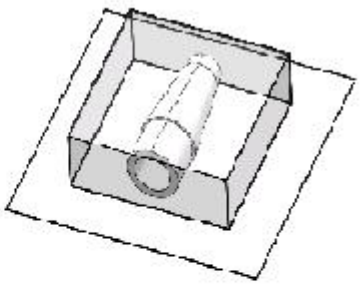
SK-Q tonometer accessories are as follows:



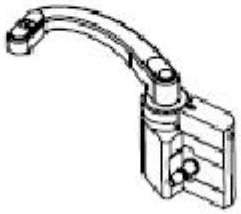
Main Body×1 unit



Calibration rod×1 set

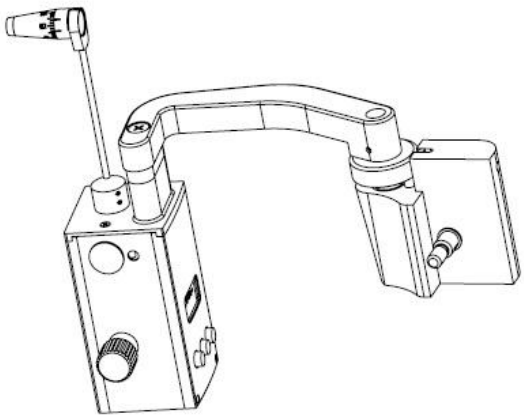


Optical Pressure Head×1 Piece

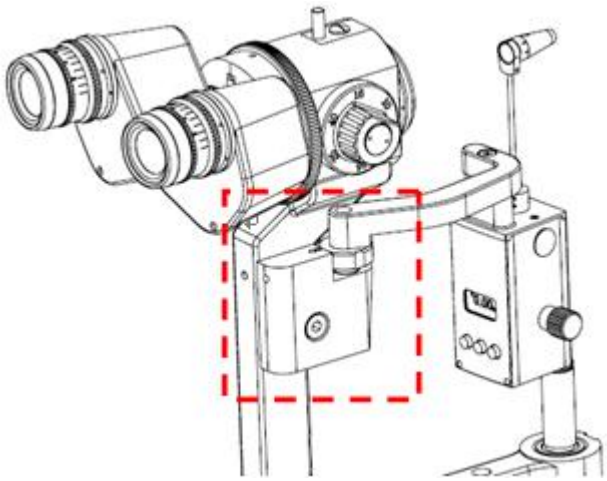


Q type-Side suspension connection assembly×1 Piece

4.4.1 Connect Q type-Side suspension connection assembly to the tonometer main body (as shown below);



4.4.2 Then install the tonometer bracket to the corresponding position of the slit lamp (as shown below).



5. Operation Instruction

5.1 Preparation Before Measurement

5.1.1 Take out the disposable Optical Pressure Head from the aseptic package and install it on the tonometer measuring arm mount;

Notes：  Do not touch the front end of the Optical Pressure Head and check if damage before use.

5.1.2 Turn on the tonometer power switch and adjust the knob to the 0 position,then the display on the screen is “0kpa (0mmHg)” and the number does not flash. Otherwise, it needs to calibrate 0. The measuring rod should be in the vertical state and can swing freely back and forth;

5.1.3 Turn the tonometer knob to the screen display “1.33 kpa (10.0 mmHg)”

5.1.4 Adjust the slit spot to the maximum and adjust the filter to cobalt blue filter;

5.1.5 The slit lamp illumination part is at an angle of 40 to 60 degrees with the eyepiece microscope;

5.1.6 Slit lamp choose 10 times magnification;

5.1.7 Ocular anesthesia with 1% tetracaine and simultaneous anesthesia of both eyes to reduce blinking

5.1.8 Place luciferin paper or luciferin solution in the conjunctival sac of the test eye to do eye staining;

5.1.9 Place the patient's jaw on the chin rest and the forehead against the forehead strap;

5.1.10 Allow the patient to open his eyes and look straight ahead, if necessary, use your hand to widen the patient's eyelids, but do not oppress the eyeball.

5.2 Measuring

5.2.1 In the absence of the target eye, the slit lamp lights on thetosmometer Optical Pressure Head. When refracting to the slit lamp eyepiece, we can see one of the upper

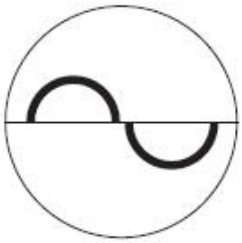
and lower reflective rings.When measuring, this aura is always the same, and it is called a fixed reflection ring.

5.2.2 Moving the slit lamp from a distance to the target eye, you can see that there is a small reflective ring on the left and right sides,that is, the slit lamp lights on the surface of the cornea and is reflected by the eyepiece after being reflected, which is called the moving reflective ring.

5.2.3 Then slowly move the slit lamp forward. From the slit lamp eyepiece, we see the corneal surface refracting slit lamp eyepiece reflector ring slowly moving closer to the middle, and the small reflective ring on the upper side moves toward the fixed reflective ring above the horizontal line. The small reflective ring below moves toward the fixed reflective ring below the horizontal line.

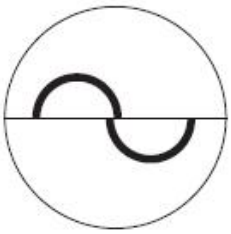
5.2.4 The small reflective ring above is close to the fixed reflective ring above the horizontal line, and the lower small reflective ring is also close to the fixed reflective ring below the horizontal line, indicating that the surface of the cornea and the surface of the Tonometer Optical Pressure Head are coming into contact.

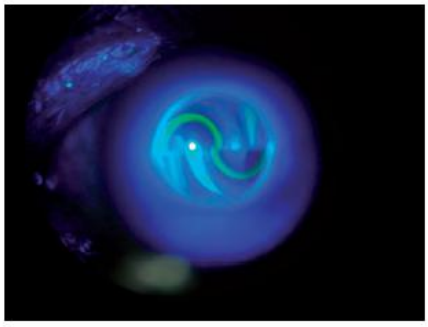
5.2.5 At this point, gently push the Joystick of the slit lamp(Note: ⚠ Gently push the top of the Joystick and do not push it horizontally, to prevent the movement distance from being too large),then you can see the two green half rings. As shown below:



Semicircular image of the center of the View Field

5.2.6 Keep the slit lamp still, slowly rotate the tonometer knob until the inner edge of the two semicircles are contacting each other, and then read the display value on the screen.





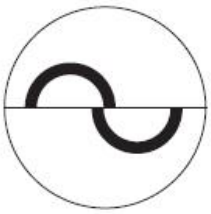
Correct Final Position

5.2.7 The above operation is repeated three times, and each reading is basically consistent, indicating that the measurement is correct, and taking the three average values is the measured intraocular pressure value.

5.2.8 After the measurement is completed, the tonometer is quickly removed from the patient's cornea by pulling the slit lamp Joystick backwards.

5.3 Trouble Shooting

5.3.1 Fluorescein band too wide or small



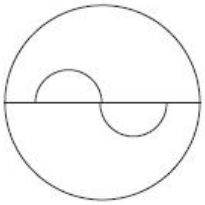
Cause：

Fluorescein band too wide. TheOptical Pressure Head was not dried after cleaning or the eye-lids came into contact with theOptical Pressure Head during measurement. Display value higher than real status.

Solution:

The slit lamp must be pulled back and theOptical Pressure Head dried with absorbent cotton or a lint-free cloth.

Cause：



Fluorescein band too small. The tear fluid has dried up during a prolonged measuring process.Display value lower than real status.

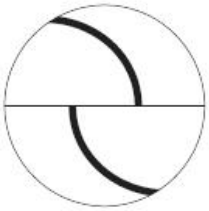
Solution：

The slit lamp must be pulled back. Allow the patient to close his/her eyes

A few times and then repeat the measurement.

5.3.2 The Optical Pressure Head does not contact the cornea

Cause：

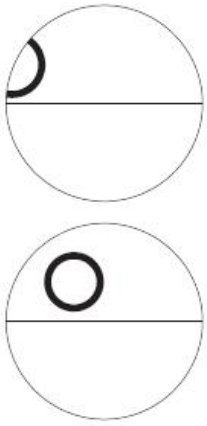


If the patient pulls the head a little bit backwards, the beating will become irregular and the contact between theOptical Pressure Head and the eye will become intermittent. If the patient pulls the head back again, the fluorescent semicircles will all disappear.

Solution：

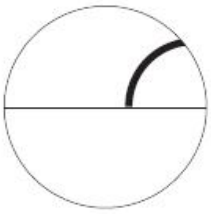
If possible, use the strap to hold the patient's head in place.

5.3.3 Two semicircles are not at the center of the view field



Solution：

Use the joystick to move the slit lamp up and left.

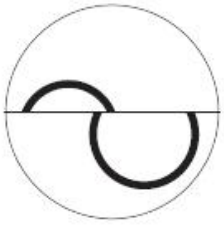


Cause：

The ring is too far right.

Solution：

Use the joystick to move the slit lamp to the right.



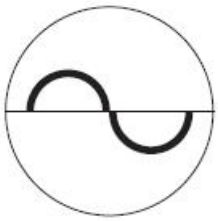
Cause：

The reading at this position is much larger than theactualintraocular pressure.

Solution：

Using the slit lamp height adjustment mechanism, lower the slit lamp until the two fluorescent semicirclesto the same size. The pressure measured will be decreased.

5.3.4 The inner border of the fluorescent rings are not aligned or connected

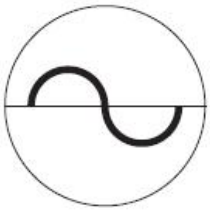


Cause：

The outer edge of the semicircle image is aligned but the inner edges are not aligned.

Solution：

Increase the pressure by rotating the measuring drum.

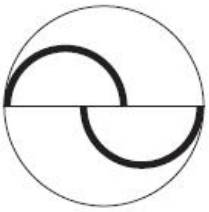


Cause：

The inner edge of one semicircle is not aligned with the outer edge of the other.

Solution：

Increase the pressure slightly more by rotating the knob on the tonometer.

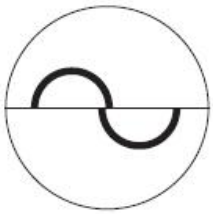


Cause：

Pressure is too high.

Solution：

The pressure is reduced until the semicircular images are brought together, and finally the inner edges are aligned with each other(show as in the last chart).



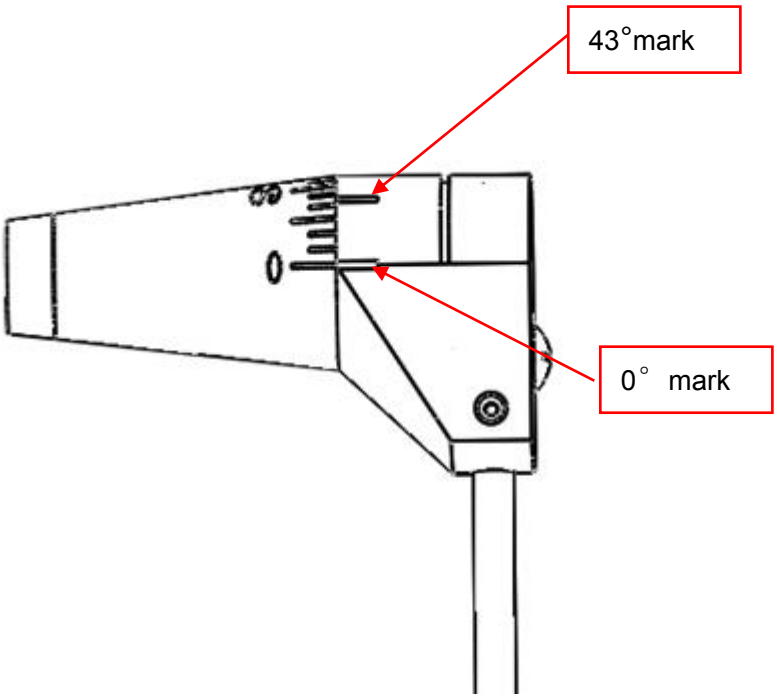
The correct final position:

The inner edges of the fluorescent semicircular image are aligned and just coincide with each other.

5.4 Astigmatism

If the cornea is spherical, it can be measured along any radial scale, but usually measured along a horizontal 0° radial scale. When thecorneal astigmatism of the eye to be measured is greater than 3D, the situation is different because the flattened portion is not round but elliptical.

It has been calculated that, in cases of greater corneal astigmatism, a surface of 7.354mm²(Φ3.06mm) must be flattened; in this case,the measuring head forms an angle of 43° with respect to the maximum radius radial scale.Align the weak main diameters on the side of the measuring head tothe horizontal line of the measuring head.



6. Maintenance and Care

6.1 Daily Maintenance

⚠ We recommend that users perform this routine maintenance frequently to ensure safe and accurate measurements.In the event that the equipment exceeds the calibration tolerance, it is necessary to return the equipment to our company or local distributor for repair and recalibration.

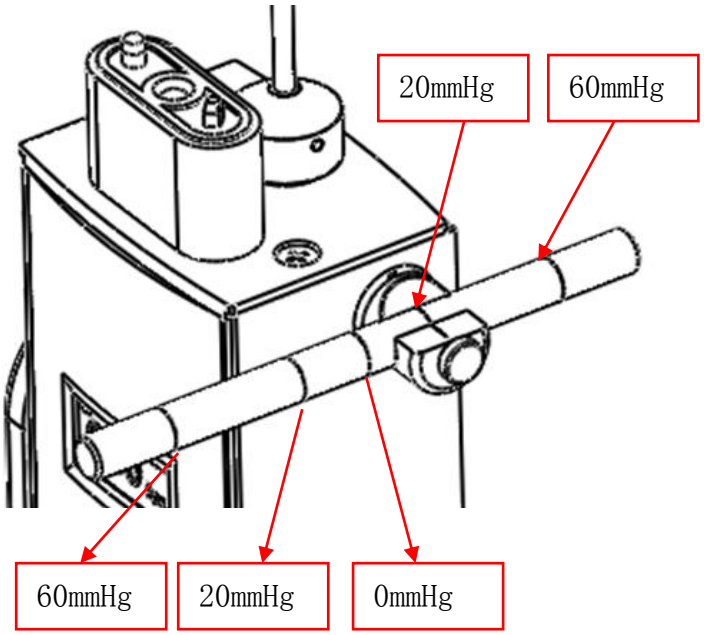
6.1.1 Check procedure when the calibration rod is set to 20

This is the most important inspection procedure because it is important to measure intraocular pressure in this area. It is recommended to perform this check every day.

This check is using a calibration rod. This calibration rod has 5 scales. The middle scale corresponds to 0mmHg, the next left and right scales correspond to 20mmHg, and the outermost scale corresponds to 60mmHg.

Slide the calibration rod along the holder until the 20mmHg reference mark is fully aligned with the scale line on the holder.

Make sure that the longer part of the calibration rod is facing the inspector.



Calibration position 19.5mmHg

Rotate the measuring knob forward until the LED screen reads 19.5 mmHg.

Then continue to rotate the knob slowly until the measuring arm moves forward.

Check that the screen reading is between 19.5 mmHg and 20.5 mmHg.

Calibration position 20.5mmHg

Rotate the measuring knob backward until the LED screen reads 20.5 mmHg.

Then continue to rotate the knob slowly until the measuring arm moves backward.

Check that the screen reading is between 19.5 mmHg and 20.5 mmHg.

6.1.2 Check procedure when the calibration rod is set to 60

Calibration position59.0mmHg

Rotate the measuring knob forward until the LED screen reads 59.0 mmHg.

Then continue to rotate the knob slowly until the measuring arm moves forward.

Check that the screen reading is between 59.0 mmHg and 61.0 mmHg.

Calibration position61.0mmHg

Rotate the measuring knob backward until the LED screen reads 61.0 mmHg.

Then continue to rotate the knob slowly until the measuring arm moves backward.

Check that the screen reading is between 59.0 mmHg and 61.0 mmHg.

6.2 Maintenance

6.2.1 This instrument can only be cleaned by manual non-immersion, as follows:

- Wipe the outer surface with a clean and Non-shedding cloth.
- Do not let the cloth soak in liquid.
- Carefully dry the surface manually with a clean, non-shedding cloth.
- Safe disposal of used cleaning materials

6.2.2 Repair drawings are available upon request.

6.2.3 When not in use for a long time, remove the battery and place the tonometer and accessories in the box and store them in a dry and ventilated place.

6.2.4 The tonometer should be calibrated first when it has not been used for more than one month.

6.3 Trouble Shooting Analysis

Fault phenomenon	Reason Analysis	Troubleshooting	Remarks
The display is not bright.	The battery is exhaustion.	Replace the new battery according to the instructions in this manual.	
Measurement data blinking	Not calibrate Zero	Re-calibrate Zero according to the method of this manual	

6.4 Transportation, Storage and Work Environment

The following environmental conditions are recommended for applanation tonometers work.

For transportation and storage, it is recommended to keep the tonometer in its original manufacturer's package.

Before use, the tonometer should be adapted to the indoor ambient temperature for more than 4 hours.

Storage Temperature：-10℃～＋55℃

Relative humidity：10%-95%

Atmospheric pressure：700hPa～1060hPa

Work Environment Temperature：＋10℃～＋35℃

Relative humidity：30%-90%

Atmospheric pressure：800hPa～1060hPa

7. Device Symbols

7.1 Device Symbol Explanation

Type B Application part

DC

Attention! Access to random files

Power on-off

Measuring unit switch

Measuring lock switch

Battery positive

Should not be treated as house hold waste

Recycling Materials

One-time use

Low battery reminder

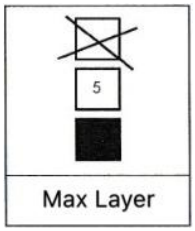
Data lock

Check the instruction manual

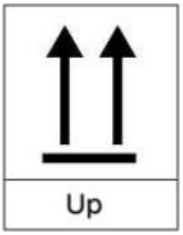
European certificate of conformity

7.2 Outer Package Symbols Explanation

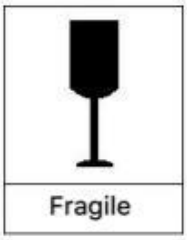
The package transport must be avoid rain.



The package transport piece stacks up to max 5 layers.



The package transport piece should be vertically up when transported.



The transport package contains fragile items and should be handled with care.

8. Equipment Electromagnetic Compatibility

8.1 Equipment Grouping Classification

The applanation tonometer (model: SK-R\SK-T\SK-Q) is classified into Group 1 Class A equipment according to the national standard GB4824.

8.2 Basic Performance

The test conditions specified in the applanation tonometer in 36.202 of EN 60601-1-2:2015 shall meet the following conditions:

1)The parameters can be normally displayed as expected, and the normal functions of each button should not be invalid;

2)After the immunity test, the equipment should still meet the requirements of Patient leakage current,Patient assisted current and Earth leakage current in the EN 60601-1: 2014 .

8.3 Electromagnetic Emission

Guide and manufacturer's statement - electromagnetic emissions		
The applanation tonometer (model: SK-R\SK-T\SK-Q) is expected to be used in the electromagnetic environment specified below, and the purchaser or user should ensure that it is used in this electromagnetic environment:		
Emission experiment	**Compliance**	**Electromagnetic environment - Guide**
Radio frequency emission CISPR 11	Group 1	The tonometer (model: SK-R\SK-T\SK-Q) uses RF energy only for its internal function. Therefore, its RF emissions are low and there is little chance of interference with nearby electronic equipment.
Radio frequency emission CISPR 11	Class A	The tonometer (model: SK-R\SK-T\SK-Q) is suitable for use in all facilities not directly connected to non-domestic and public low-voltage power supply networks for residential homes/Used in hospital
Harmonic emission	Not applicable	

IEC 61000-3-2		dedicated low voltage power supply grid.
Voltage fluctuation / flicker emission IEC 61000-3-3	Not applicable	

8.4 Electromagnetic Immunity

Guide and manufacturer's statement - Electromagnetic Immunity			
The applanation tonometer (model: SK-R\SK-T\SK-Q) is expected to be used in the electromagnetic environment specified below, and the purchaser or user should ensure that it is used in this electromagnetic environment:			
Immunity test	**IEC 60601Test level**	**Compliance level**	**Electromagnetic environment - Guide**
Electrostatic discharge IEC61000-4-2	±6 kvContact discharge ±8 kvAir discharge	±6 kvContact discharge ±8 kvAir discharge	The floor should be wood, concrete or ceramic. If the floor is covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient burst IEC61000-4-4	±2 kv to Power cord	±2 kv to Power cord	The network power supply should have the quality used in a typical commercial or hospital environment.
Surge IEC61000-4-5	±1 kv Line to ground ±2 kvLine to ground	±1 kvLine to ground ±2 kvLine to ground	The network power supply should have the quality used in a typical commercial or hospital environment.
Voltage dip, short interruption and voltage change on the power input line IEC61000-4-11	＜5%UT,last 0.5 cycles（On the UT,>95% of dip）40% UT;last 5 cycles（On the UT，60% of dip）70%UT;last 25 cycles（On the UT，30% of dip）; ＜5UT,last 5s（On the	＜5%UT,last 0.5 cycles（On the UT,>95% of dip）40% UT;last 5 cycles（On the UT，60% of dip)70% UT;last 25 cycles（On the UT，30% of dip）;	The network power supply should have the quality used in a typical commercial or hospital environment.If the user of the applanation tonometer (model: SK-R\SK-T\SK-Q) needs continuous operation during the power interruption, the intraocular pressure value can

	UT，>95% of dip); Notes：UT is the AC network voltage 220V before the test voltage is applied.	＜5 UT,last 5s（On the UT，>95% of dip) Notes：UT is the AC network voltage 220V before the test voltage is applied.	be read directly through the scale on the measuring knob (Model: SK-R \SK-T\SK-Q).
Power Frequency Magnetic Field（50HZ） IEC 61000-4-8	3 A/m	3 A/m	The power frequency magnetic field should have the characteristics of the power frequency magnetic field level in a typical place in a typical commercial or hospital environment.

8.5 Electromagnetic Immunity--For Non-living Support Equipment and Systems

● Guide and manufacturer's statement -Electromagnetic Immunity			
The applanation tonometer (model: SK-R\SK-T\SK-Q) is expected to be used in the electromagnetic environment specified below, and the purchaser or user should ensure that it is used in this electromagnetic environment:			
Immunity test	**IEC 60601Test level**	**Compliance level**	**Electromagnetic environment - Guide**
Radio Frequency Conduction IEC61000-4-6 Radio Frequency Radiation IEC61000-4-3	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 RF communications equipment should not be used closer to any part of the applanation tonometer(model: SK-R\SK-T\SK-Q), including cables, than the

			recommended isolation distance.This distance should be calculated from the formula corresponding to the transmitter frequency. 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 In the formula: p-According to the transmitter's maximum output rated power, in watts (W); d-Recommended isolation distance, in meters（m）. The field strength of a fixed RF transmitter is determined by surveying the electromagnetic field and should be lower than the compliance level in each frequency range. Interference may occur near the device that marks the following symbol. 
Notes 1：At 80MHz and 800MHz frequencies, the formula for the higher frequency band is used. Notes 2:In these guidelines may not be suitable for all situations, electromagnetic propagation is affected by the absorption and reflection of buildings, objects and human bodies.			
a)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 not theoretically predictable in terms of field strength. In order to assess the electromagnetic environment of a stationary RF transmitter, an electromagnetic field survey should be considered.If the measured field strength of the tonometer (model: SK-R\SK-T\SK-Q) is higher than the above-mentioned radio frequency compliance level,the applanation tonometer (model: SK-R\SK-T\SK-Q) should be observed to verify that it is functioning properly.If normal performance is not observed, additional measures may be necessary, such as repositioning the orientation or position of the applanation tonometer (model: SK-R\SK-T\SK-Q).

b)The field strength should be less than 3V/m over the entire frequency range from 150 kHz to 80 MHz.

8.6 Recommended Isolation Distance for Portable and Mobile RF Communication Equipment and Applanation Tonometer (model: SK-R\SK-T\SK-Q)

——For Non-living support devices and systems

Recommended isolation distance for portable and mobile RF communication equipment and applanation tonometer (model: SK-R\SK-T\SK-Q)

The tonometer (model: SK-R\SK-T\SK-Q) is expected to be used in an electromagnetic environment where radio frequency disturbance is controlled.Depending on the maximum output power of the communication device, the purchaser or user can prevent electromagnetic interference by maintaining the minimum distance between the portable and mobile RF communication device (transmitter) and the applanation tonometer(model: SK-R\SK-T\SK-Q) as recommended below.

Maximum rated output power of the transmitter(W)	Corresponding distance to different frequencies of the transmitter/m		
	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	0.35	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;

Here P is the maximum output rated power of the transmitter provided by the transmitter manufacturer in watts (W).

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

Notes 2:In these guidelines may not be suitable for all situations, electromagnetic propagation is affected by the absorption and reflection of buildings, objects and human bodies.

8.7 Installation Environment

Applanationtonometers (models: SK-T, SK-R, SK-Q) are used in all facilities where non-domestic and domestic residential public low-voltage power supply networks are not directly connected/used in hospital dedicated low voltage power supply grid.Power outlets should have reliable protective grounding and use with supplied power cords, components and accessories.If the floor is covered with synthetic material, the relative humidity should be at least 30%. Other equipment used in the vicinity of this equipment shall comply with electromagnetic compatibility requirements.

Possible effects of portable and mobile RF communication equipment on the applanation tonometer (model: SK-R\SK-T\SK-Q),pls see “8.6Recommended isolation distance for portable and mobile RF communication equipment and applanation tonometer (model: SK-R\SK-T\SK-Q)”.

Applanation tonometers (models: SK-T, SK-R, SK-Q) are limited used tocomponents and accessories supplied by the manufacturer. Meet the requirements of 36.201 and 36.202 in YY0505 when using these power cords, components and accessories.

Warning：In addition to the accessories and cables sold by the manufacturer,use of accessories and cables outside of the regulations may result in increased emissions or reduced immunity of the equipment.

Warning：The device may be disturbed by its use near the device labeled  and/or exhibit performance degradation associated with basic performance and safety.

Warning：This device can detect the minimum value of human intraocular pressure: 0.5mmHg.Operation of the device or system lower than the minimum amplitude or value described above may result in inaccuracies.

8.8 List of Accessories

Item NO.	Accessories name	Model No.	Parameter
1	Button battery	CR2450	⎓3V

9. After-sales Service, Company Information

9.1 Performance Pledges

1. Warranty time, from the date of acceptance, the manufacturer will guarantee 1 year free warranty for main unit and 6 months for the accessory.

2. After the warranty period, if product has faulty,besides the cost of accessories,the door-to-door repair will charge the corresponding travel expenses.

3. Repair parts are guaranteed to arrive within five working days, and each one day later, the warranty period is extended by three days.

4. The service life of the equipment is 5 years from the date of installation and commissioning. After the service life of the instrument expires, it should be disposed of according to the national and local environmental regulations. During the design life of the equipment, the manufacturer guarantees that the user will replace the original partsto ensure the normal use of the equipment.

5.Equipment maintenance must be maintained by the factory's professional or authorized person by the factory.

Manufacturer's Responsibility

——Assembly, addition, commissioning, modification or repair shall be carried out by personnel approved by the manufacturer;
——The electrical facilities in the room shall comply with the requirements in this manual;
——The product should be used in accordance with the instruction manual.