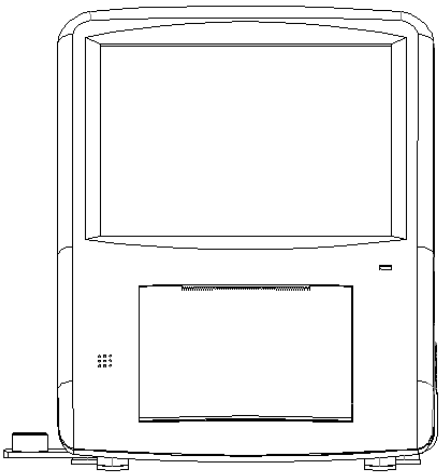
Instruction For Use

Ophthalmic Ultrasound

SK-2000AP



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Content

Preface

Dear User：

Thank you very much for choosing SK-2000AP, We feel deeply honored to get your trust. The operation instruction including the description, installation, usage, notice for use, maintenance, transportation and storage .This is an essential part to guide you use the instruments.

For your security and benefit, please read the operation instruction as well as the datum of the instruments carefully before using it. If the instruments in this manual are carefully followed , we are confident that this products will give you reliable and trouble-free usage.

Registration information

◆ Product Name：SK-2000AP Ophthalmic Ultrasound

◆Product Model： SK-2000AP

◆Production license number.： Chongqing Food and Drug Administration Production No. 20160050

◆ Product registration certificate number:

◆Technical requirements number of this product:

◆Production date of this product: see nameplate

◆The product life circle: 5 years

◆ Date of preparation of the manual: June 19, 2018

Please check following accessories before your using：

1. Please check the instrument accessories are consistent with the packing list or not.

2. Please read accompanying files carefully and keep properly.

The pictures provided in this manual are renderings. The specific configuration is subject to the packing list. If you have any questions, please contact manufacturer

Chapter 1 Summary

1.1 Machinary description

SK series ophthalmic A ultrasound biometry absorb the advantage of the international advanced model, have higher stability and reliability compare to similar products in domestic. Apply to measuring the axial length, anterior chamber depth, lens thickness and vitreous depth of eyes(SK-2000AP can measure corneal thickness.). The instruments have a low input power, even repeated irradiate a living organism; there is no accumulated biological effect and mechanical effect.

1.2 Usage information

1.2.1 For your security and benefit , please read the operation instruction and all the datum of the instrument carefully before using it. If you do not operate the instrument according to the operation instruction, Manufacturer will not take any responsibilities.

1.2.2 The instrument cannot be used in conjunction with high frequency surgical equipment.

1.2.3 The voltage must be up to the given standard. If the voltage is not steady, please install a constant voltage regulator. We will not take responsibility for the damage caused by the voltage.

1.2.4 Do not use in the inflammable ,hot, dusty and oxygen-enriched environment and pay attention to keep it clean and dry; to avoid being damaged by the environment (Damp, dusty, liquid, under the sun , and so on). Do not let the liquid or any other small objects run into the instrument ,otherwise these objects may make the inner parts of the instrument short-circuit , and even make the users get an electric shock or even cause a fire hazard.

1.2.5 Without the permission of us or our authorized distributor , do not open the box of the instrument, or we will not take the responsibility of consequence.

1.2.6 For better maintainence , please wait for at least 5 seconds to restart the device after turn off.

1.2.7 Turn off the main power when not using the instrument, do not being power-up state over 4 hours. Please keep the instrument clean.

1.2.8 Environment protection clause :it will pollute the environment if you discard the equipment and accessories which is breakdown . Recall or disposal according to the local laws and regulations.

1.2.9 A-probe is high precision instrument, please clean , sterilize the instrument and put it back to probe frame, and put the cable in a place to avoid damaging, or we will not take the consequence.

1.2.10 The applanating surface and adjacent 2-3 mm of the probe can be immersed into water or other no-corrosive,no-poisonous liquid.

1.2.11 About the instrument operation instruction （hereinafter called “operation instruction”）

1) The pictures given by the operation instruction are effect pictures, please in kind prevail.

2) If you have unknown any content or terms in operation instruction, or you experience technical problems in the process of using, please contact with the local agent or call +86-23-68643990.

3) We have the right of interpreting and revising this operation instruction.

1.3 Structure components

main unit, A-Scan probe（10M Hz）, pachymetry probe（20M Hz）, foot pedal, accessory,(measurement block, infiltration accessory, power cord).

1.4 Applicability

Apply to measuring corneal thickness(for SK-2000AP only) ,axial length, anterior chamber depth, lens thickness , vitreous depth of eyes.

A scan is used for the biometric measurement of axial length (including anterior chamber depth, crystal thickness and vitreous length);

P scan is used for the biometric measurement of corneal thickness.

1.5 Contraindication

People who have eye active inflammatory lesions(acute conjunctivitis, blepharitis, fungal keratitis, corneal ulcer, dacryocystitis, iridocyclitis and so on.) and babies cannot be tested by this device.

1.6 Precautions

To avoid injury and other hazards that may arise, please read the precautions carefully.

 **Warning: Do not press the cornea while measuring the axial length**

 **Warning: This device cannot be used on babies**

 **Warning: Disconnect the external power supply before wiping the device**

 **Warning: Disconnect the external power supply after turning off the device**

 **Warning: All the probes are push-pull connectors with a locking system that prevents incorrect installation. Do not force to install the connector.**

 To avoid being damaged by the environment (Damp, dusty, liquid, under the sun and so on). Do not let the liquid or any other small objects run into the instrument ,otherwise these objects may make the inner parts of the instrument short-circuit , and even make the users get an electric shock or even cause a fire hazard.

 **Let the device well grounded, it can only be used by clinicians and no need for allergy test.**

 **Instrument installation should be on a flat ground.**

 **Do not use the device in the inflammable, hot, dusty and oxygen-enriched environment and pay attention to keep it clean and dry.**

 **Use the special wire equipped with the device.**

 **Do not use sharp or hard objects to scratch or touch any exposed surface.**

 **This device cannot be used with high frequency surgical equipment.**

 **Cannot open outer case without the Manufacturer's permission, otherwise you will be at your own risk.**

 **Be sure to use a grounded power plug.**

 Federal law restricts this device to sale by or on the order of a physician or licensed professional practitioner.

 This device can be only operated by Medical Doctors, Nurse or Medical Technicians who have been trained for diagnosing patients.

The probe must be cleaned between the two patients to prevent cross-infection.

Manufacturer Medical suggests to do some preventive measures and cleaning steps, please check the section "How to prevent cross-infection between patients".

1.7 Operation instruction applicability

This operation instruction is a comprehensive version, apply to the following models.

The instrument models： SK-2000AP

1.8 Product features

1. Classified by protection against electric shock type ： class I equipment

2. Classified by protection against electric shock level: class B equipment

3. Classified by waterproofing grade: main machine is IPX0, waterproofing grade of probe is IPX7, waterproofing grade of foot pedal is IPX1.

4. Classification according to the degree of safety when using flammable anesthetic gas mixed with air or flammable anesthetic gas

mixed with oxygen or nitrous oxide: flammable anesthetic gas or oxygen or oxidized sub-mixed with air Use in the case of a nitrogen-mixed flammable anesthetic gas;

5. Classified by operation mode: intermittent load run continuously

6. Working voltage：ac.100-240V 50/60Hz

7. Input power ：15VA

8. The device does not have defibrillation applications part

9. The device does not have a signal output or input part

10. Non-permanent installation device

11. Device type: portable

12. Cartridge fuse model: T500mA 250V (internal)

13. Biocompatibility :material which contact with patient of A-probe and pachymetry probe meet the following requirements:

① Cytotoxicity: should be ≤grade Ⅰ

② Sensitization: should be no sensitization on the skin

③ Irritation: should be a very slight reaction.

14. Measuring accuracy : average relative error ≤0.05mm

15. Wastes such as A-super probes, P-ultrasound probes, and infiltration accessories after the equipment are used, the whole machine should scrap according to national and local environmental regulations.

1.9 Size and weight

Table 1 weight and size

model / size / weight	SK-2000AP
dimension （width×depth×height）（mm）	17.2*185*208
weight（kg）	1.3

1.10 Working environment

◆General clinical work environment

◆Temperature：5℃～30℃

◆Relative humidity： ≤80%

◆Atmosphere pressure: 700hPa～1060hPa

◆Power supply: 100/240V～ 50/60HZ

1.11 Transportation and storage

The instrument which was prepackaged can transport by usual vehicle. Please avoid mechanical collision and invert, free from exposure to the sun and rain.

Transportation environment temperature -40℃ - +70℃, atmospheric pressure 500hpa-1060hpa, relative humidity 10%-95%.

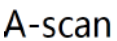
1.12 Symbolic interpretation

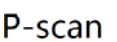
 Type B application part

 Dangerous voltage

 Caution!

 Power switch

 A-probe jack

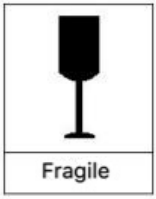
 P-probe jack

 Foot-pedal jack

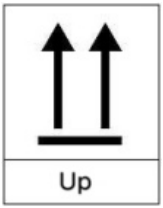
Power plug

SN	Series Number of products
	Should not be treated ashouseholdwaste
	Manual Instruction symbol
	Manufacturer information
	Manufacture date
CE	European certificate of conformity
EC REP	Authorized representative in the European Community

Explanation of symbols on the box：

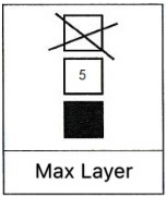


Fragile



Upward

Protect from moisture



Stacking limit

Caution: Federal law restricts this device to sale by or on the order of a physician or licensed professional practitioner.

Chapter 2 Instrument Introduction

2.1 Fundamental performance and parameter

No.	Technical index	Model
		SK-2000AP
1	Ultrasonic frequency	A-scan10MHz, Pachymetry 20MHz(Optional)
2	Measuring accuracy	Axial measurement≤0.05mm, corneal thickness≤0.01mm
3	Gain	99db
4	Probing depth	Axis measurement≥40mm, corneal thickness:0.15mm-1.5mm
5	Display screen	6.5 inch color touch-screen
6	Display resolution	≤0.1mm
7	Velocity	Typical sound velocity 1641,1532
8	Data output	Cornea, anterior chamber, lens, vitreous body, axial length, corneal thickness
9	Sets of data output	10 sets, average, standard deviation calculation
10	Formula	SRK-T,Hollady,Hoffer Q,SRK-2,Binkhorst Ⅱ,Haigis 6 usually used formulas
11	Examination Modes	Phakic、Dense、Aphakic、PMMA、Acrylic 、Silicone, Custom and Calibration

12	Test	Immersion 、Contact
13	Storage	Limit to 200 cases data
14	Print	Build-in thermal printer
15	Voltage	AC.100－240V 50/60Hz

2.2 Performance requirements

2.2.1 A-scan Performance

(1) A -probe nominal frequency: 10 MHz, the error does not exceed ± 15%;

(2) P-probe nominal frequency: 20 MHz, the error does not exceed ± 15%;

(3) The measurement range of A-probe axial length should not be narrower than 15 mm to 37 mm; among them, the measurement range of the anterior chamber depth is 1.98 mm to 6.9 mm, and the measurement range of the crystal thickness is 2.7 mm to 5.3 mm. The range is 5.7 mm to 30 mm.

(4) The measurement error of A super-eye length should be no more than 0.05 mm;

(5) The measurement range of P super-corner thickness should not be narrower than 0.3 mm to 1.5 mm;

(6) The measurement error of P super corneal thickness should be no more than 0.01 mm;

(7) The measurement of the length of the A-super-eye axis should show two significant digits after the decimal point. The measurement of the P-corner thickness should show three significant digits after the decimal point;

(8) A super has two measurement modes: manual and automatic, and the error of the two measurement methods is not more than 0.2 mm;

(9) It has an artificial crystal calculation function, and the calculation formula name should be given in the software settings and random files.

2.2.2 Appearance and structural requirements

(1) The outer casing of the measuring instrument should be free of mechanical damage and rust. The characters and signs on the panel should be clearly visible and firm.

(2) The plastic parts of the measuring instrument shall be free of blistering, cracking, deformation and overflow of the infusion.

(3) The operation and adjustment mechanism of the measuring instrument should be flexible and reliable, and the fasteners are not loose.

2.2.3 Software Function

a) it shall have the ability to input, store, inquire and print patient information and test records.

b) A ultrasonic function for biometric measurement of axial length (including anterior chamber depth, crystal thickness and vitreous length);

c) P ultrasonic function, used for the biometric measurement of corneal thickness;

2.2.4 Foot Switch

The foot switch shall meet the requirements of MEDICAL FOOT SWITCH.

2.2.5 Safety Requirements

General safety shall meet the requirements of EN 60601-1:2006/ A1:2013 or IEC 60601-1:2005 /A1:2012; Special security shall meet the requirements of IEC/EN 60601-2-37 2015.

2.2.6 Electromagnetic Compatibility Requirements

Electromagnetic compatibility shall comply with the relevant provisions of EN 60601-1-2:2015/ IEC 60601-1-2:2014 and IEC/EN 60601-2-37 2015.

2.2.7 Environmental Test Requirements

Measuring instrument should be in accord with EN ISO 14710-2009 climate Ⅱ, mechanical environment Ⅱ group requirements.

2.3 The principle of inspection.

A-scan principle

A-scan ultrasound shows the reflected signal at the interface of the human body as a vertical peak, forming a one-dimensional image. The ultrasonic propagation time represents the distance of the reflective interface. The farther the distance is, the more the peak position is. The peak height indicates the echo intensity, and the stronger the echo is, the higher the peak is. The obtained echo amplitude is called an echo map.

P-scan principle

Corneal thickness measurement, when the ultrasonic pulse hits the first interface, part of the sound wave is reflected, and the other part of the sound wave penetrates the first interface, and proceeds to the second interface, and then some ultrasonic waves are reflected by the second interface. Using the two reflections of the measured ultrasonic waves, the

distance between the two peaks produced is calculated to determine the thickness of the cornea.

Velocity

Sound wave has different velocity in different medium, sound velocity is associated with medium density and medium temperature. The velocity in anterior chamber and vitreous body is 1532m/s，the velocity in lens range from 1590-1670m/s according to different opacification degree, general use 1641m/s.

Detected Results Analysis

A-scan ultrasound allows for measuring the anterior chamber depth, lens thickness and vitreous depth of eyes (corneal thickness included in anterior chamber).The visual axis length from cornea to retina average in 22-24.5mm, age-related decreasing of anterior chamber depth, thickness of lens between 3.5-4.5mm, lens thickness is proportional to increase of age. Behind lens is vitreous body section, most in 16-18mm, but people who has high myopia usually larger than this range.

Important notes for A-scan: 1. Place the A-probe against patient eye lightly, don't press; 2.The direction of acoustic must through axle center of eye, or obvious measure errors will be made.

Algorithm

The calculation of IOL powers be implanted, usually using SRKⅡ for calculation, the formula as below:

$P=AL-2.5L-0.9(K_1+K_2)/2$

thereinto

P IOL degree

A Artificial crystal constant

L axial length

K_1 Horizontal corneal diopter

K_2 Vertical corneal diopter

When $19 \leq L < 20$ then $AL=A+3$

$20 \leq L < 21$ then $AL=A+2$

$21 \leq L < 22$ then $AL=A+1$

$22 \leq L \leq 24.5$ then $AL=A$

$L > 24.5$ then $AL=A-0.5$

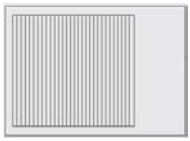
Chapter 3 Unpacking and checking

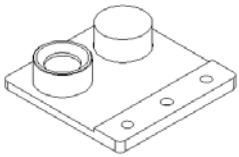
3.1 Packing

Open this instruments package carefully，outside packing is carton and inside protection packing is Pearl wool. Please check all accessories according to packing list before discarding the packing materials.

（1）SK ophthalmic A ultrasound biometry main machine

（2）Accessories





Power line A-probe foot pedal calibration cylinder P-probe (for SK-2000AP only)

(3) product qualification certificate, warranty, receipt and acceptance

3.2 Working environment

（1） Environment temperature：-5℃～40℃

（2） Atmosphere ：700hPa～1060h Pa

（3） Relative humidity：45%～85%

（4） AC.100－240V 50/60Hz

（5） Input power： 15VA

3.3 Installation environmen

In order to ensure the safe and stable operation of the equipment ,please ensure the installation environment：

(1) Install this instrument on the flat surface.

(2) This instrument must be installed in clean, quiet and dry environment.

(3) The equipment must use special ground wire.

If the equipment encounters low temperature during transportation, it is not recommended to open the switch immediately after unpacking.

 Warning: if the device is close to 0 ℃ degrees temperature, turn on the switch can cause serious damage. Open the package and place the device at room temperature for at least 8 hours to ensure that the internal components are gradually warming up

3.4 Installation

1) Front view of machine（figure 1）

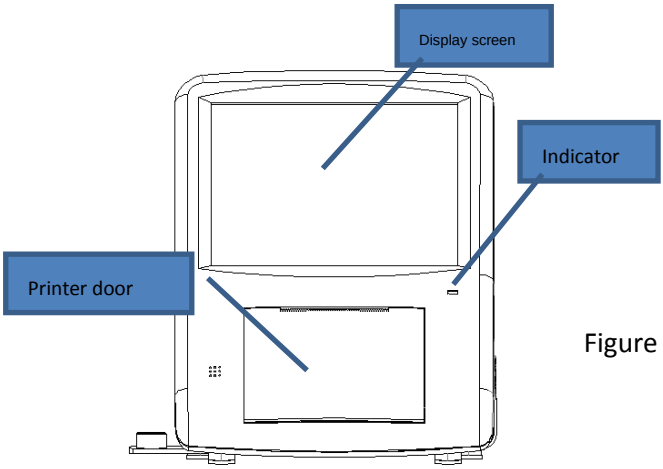


Figure 1

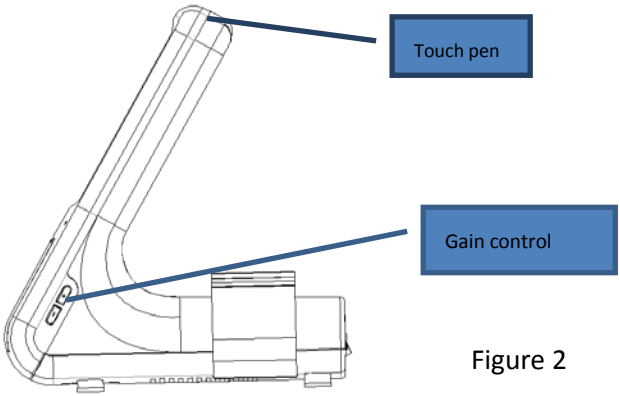
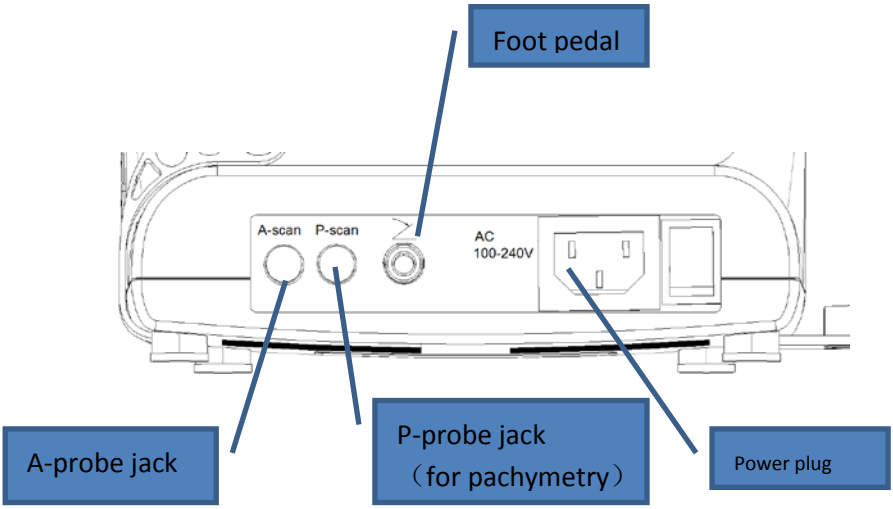


Figure 2

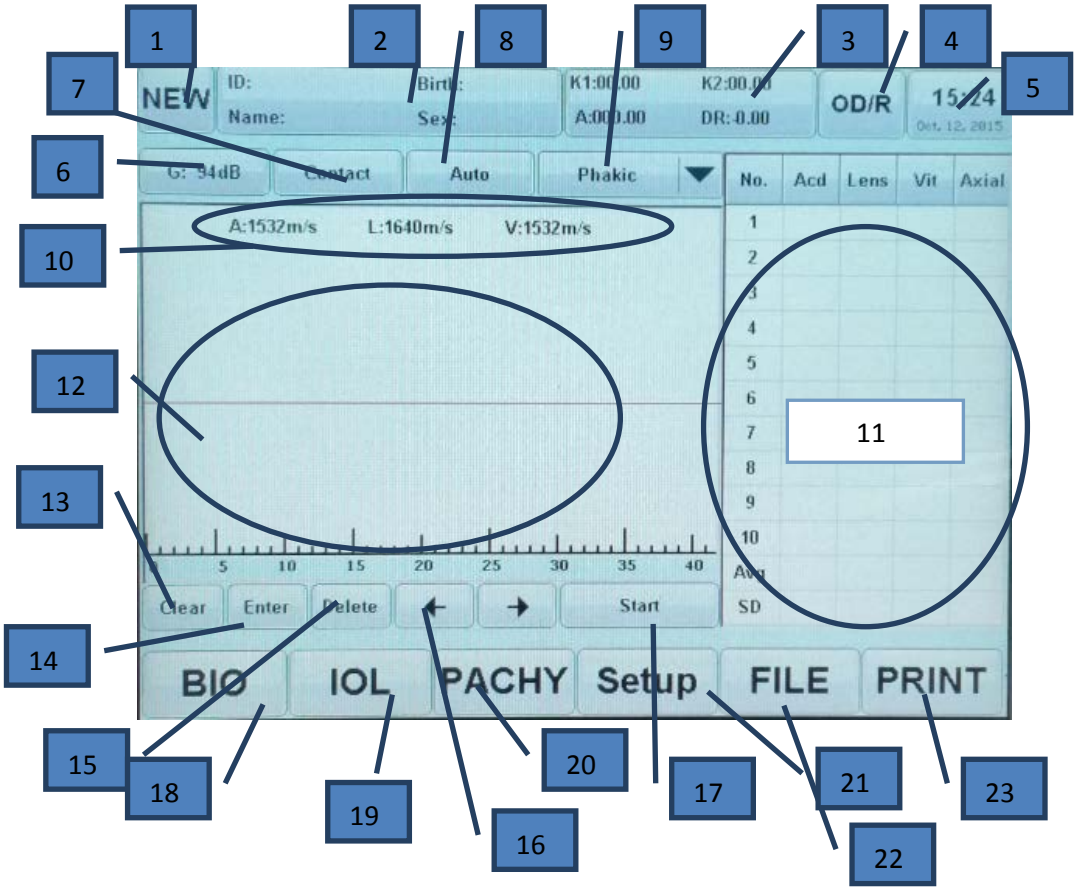
2) Side view of machine（Figure 2）

3) Rear view of machine（Figure 3）A-probe, P-probe and foot switch can be installed according to the arrow direction in figure 3 and disassembled according to the reverse arrow direction


Foot pedal
A-scan
P-scan
AC
100-240V
A-probe jack
P-probe jack
（for pachymetry）
Power plug

Chapter 4 Interface introduction and setup

4.1 Main screen



Functional Specification：

1. New icon：Press the icon then patient's information edit box will be shown accordingly, and clear all previous patients' data.

2. Patient information：Touching the area then the patient's information edit box will be shown accordingly, you can change the basic data.

3. Artificial lens calculation parameters input: Touch this area then it will display a input box to enter value.

4. Select eye: Switch between left/right eye by pressing the icon.

5. System setting: Set up the time for device, probe type and touch screen calibration.

6. Gain display: Show the gain value of current examination, you can change the value of the gain by pressing the button on the right side of machine.

7. Measurement mode: switch between contact and immersion mode by pressing it.

8. Data calibration mode: switch between auto and manual by touching it.

9. Lens type: Select different lens types from the drop-down list.

10. Tissue velocity: show the tissue velocity under current mode.

11. A-scan measurement data area: show at most 10 groups of measurement data and mean number, standard deviation.

12. A-scan echogram display area.

13. Clear icon: clear current patient's A-scan measurement data by pressing it.

14. Enter/switch icon: under manual examination mode, you can switch among A/L/V calibration point by pressing it.

15. Delete icon: delete the selected measurement data.

16. Left & Right move icon: move the calibration point under manual mode.

17. Start/Stop icon: start collecting data or stop collecting data by pressing it.

18. A-scan examination interface (main screen): enter A-scan examination mode by touching it.

19. Artificial lens calculation interface: enter artificial lens calculation interface after pressing.

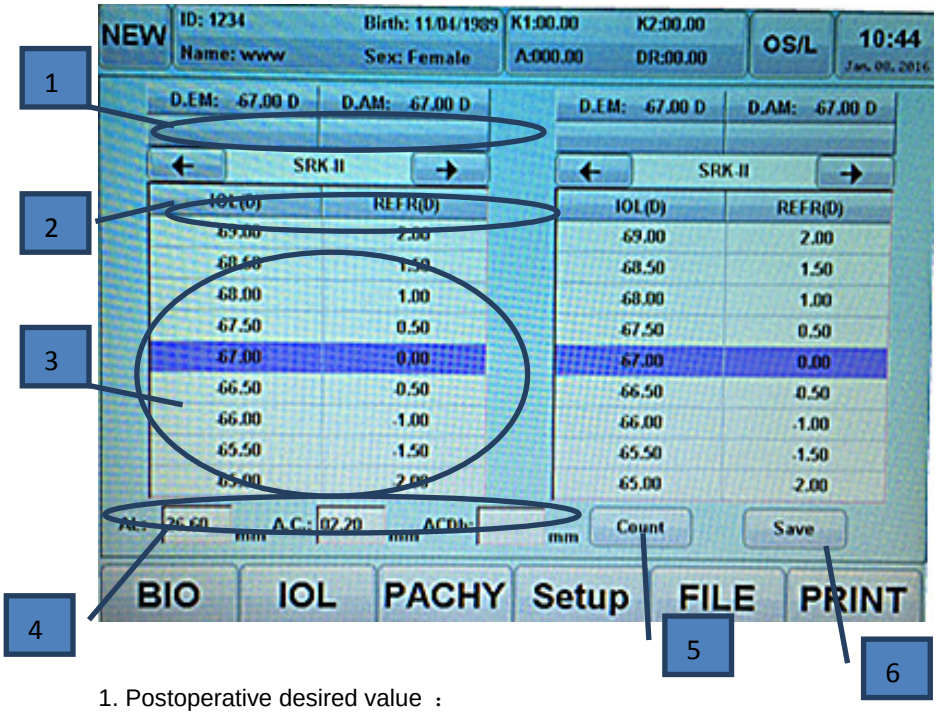
20. Pachymetry measurement: enter pachy measurement mode after pressing.

21. Parameter settings: enter IOL type setting and default value of IOL setting.

22. File interface: enter into query interface.

23. Print icon: Print examination results.

4.2 IOL calculation



1. Postoperative desired value ：

D.E.M The power of IOL which should be implanted to keep emmetropia after operation.

D.A.M The power of IOL which should be implanted to keep desired value after operation

2. IOL calculation formula: Select formula by using the [←], [→] icon.

3. IOL calculation value display area: The middle set of value which marked by dark color is calculated result of desired DR value.

4. Calculation input value:

AL----------the axial length of the tested eye

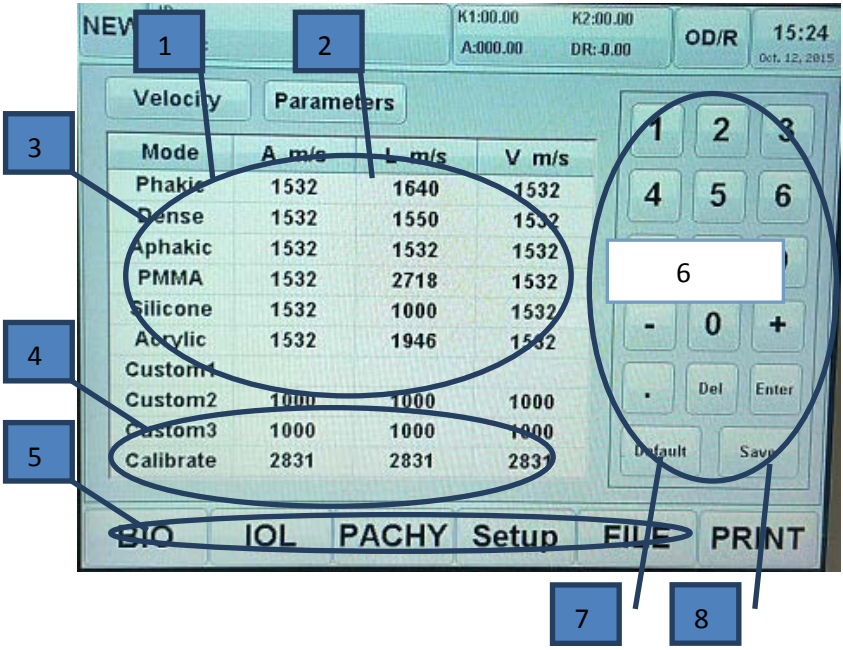
A.C.D.---------Anterior chamber depth(used in HAIGIS, determined according to measured data）

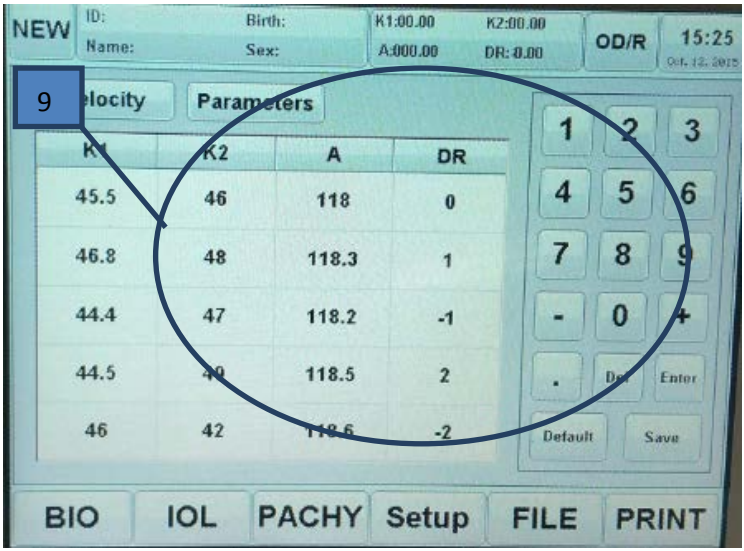
ACDb-------Anterior chamber depth after operation（used in Binkhorst-II, given by the IOL manufacturers)

5. Count icon: Press the icon to perform calculation. (Note: the calculation will not be performed automatically after changing parameter, need to press this icon).

6. Save icon: Save A-scan measurement results after click(Note: it will not save the IOL calculation result)

4.3 Parameter setting





1. Enter tissue velocity interface.

2. Enter IOL calculation pre-set parameter interface.

3. Tissue velocity versus different lens type display.

4. Customize lens type versus tissue velocity display.

5. The velocity of calibration cylinder type.

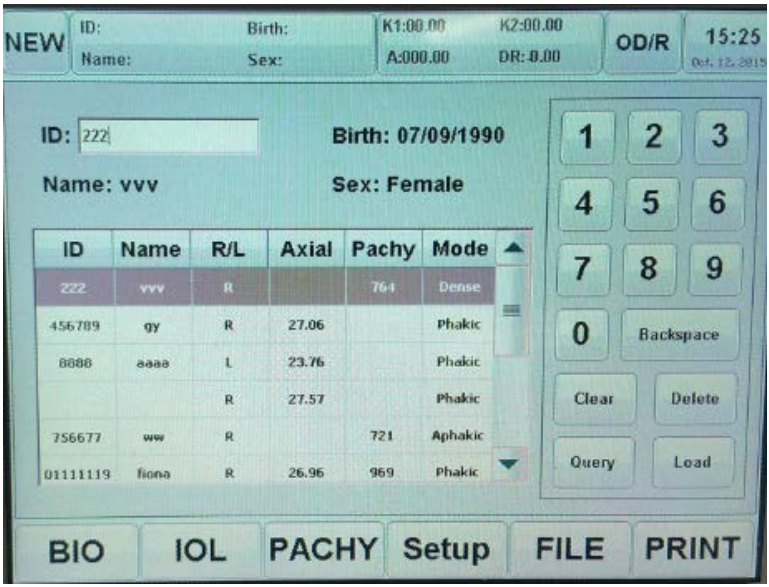
6. Keyboard area: One can modify the velocity value under any mode.

7. Restore default value: One can restore default value of selected area.

8. Save icon: Save the ultrasonic velocity value which be modified.

9. IOL calculation pre-set parameter area: Modify the pre-set value in this area

4.4 File management



1. ID input: Input the inquired patient's ID No.

2. Archived patient data display area.

3. Query information input keyboard.

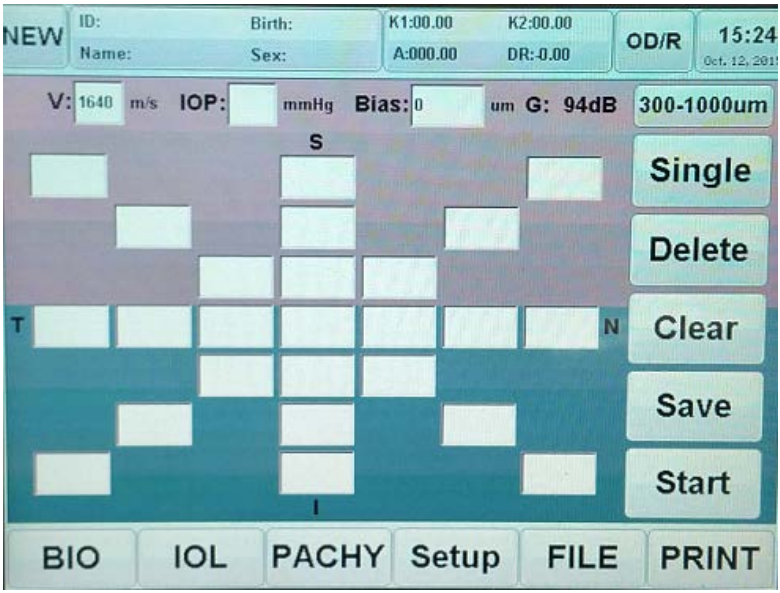
4. Clear : Touch this icon to clear all archived patient information.

5. Delete : Touch this icon to delete the selected patient information

6. Query : Input data in the ID box then click this icon to query patient information

7. Load : Click this icon to call the selected patient information

4.5 Corneal thickness measurement page



1. Corneal thickness measurement ultrasonic velocity：Click this icon to set the needed ultrasonic velocity.

2. IOP: Input the current patient's intraocular pressure reference value.

3. Measurement baseline: input corneal thickness baseline in this blank.

4. Gain control: one can change the value by pressing the button on the right side of device.

5. Measuring range: Select different corneal thickness measuring range by pressing it.

6. Measured data display area: show at most 10 groups of corneal thickness data.

7. Average: show the average value of corneal thickness.

8. Minimum: show the minimum value of corneal thickness.

9. SD: show measured data’s standard deviation.

10. Clear: clear all corneal thickness data of current examination.

11. Delete: delete the selected measured data.

12. Map mode: enter corneal multi-point measurement mode.

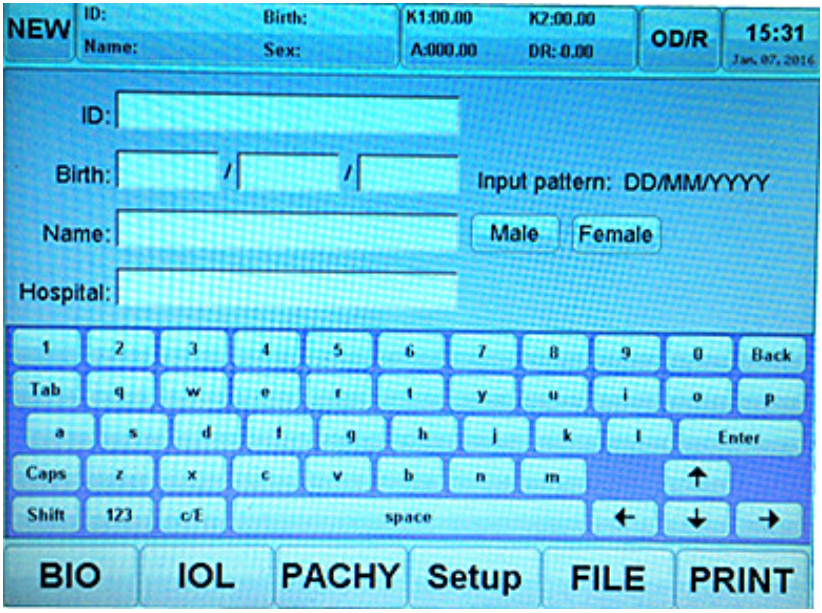
13. Save: save measured data.

14. Start: press to start corneal thickness data collection.

15. Multi-point mode data display area: measure at most 25 points of cornea's thickness data.

16. Single-point measurement mode: enter corneal thickness single-point measuring mode.

4.6 Patient data input

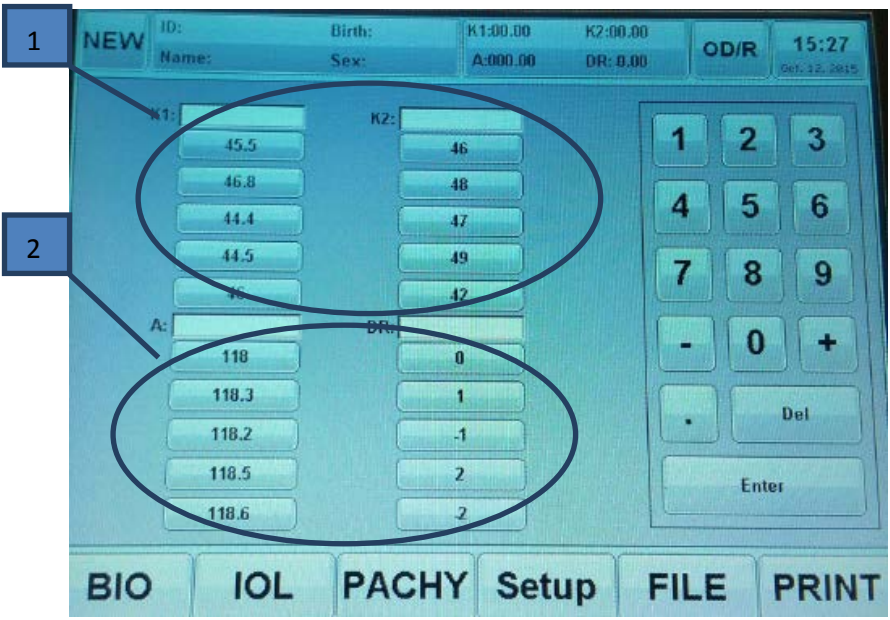


1. The current patient data area

2. Hospital name setup

3. Choose patient gender

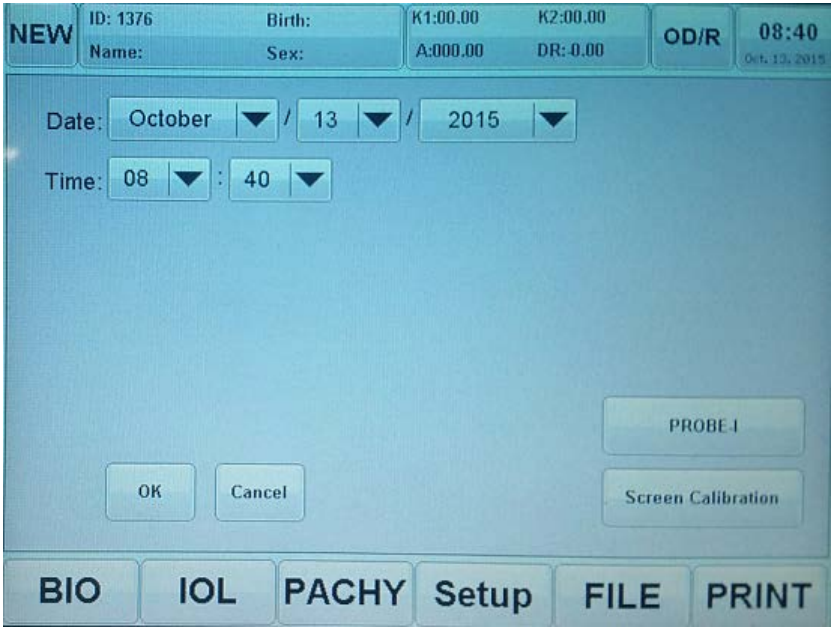
4.7 IOL calculation parameter input



1. Keratometer readings input: the data below is default value, it can be changed on parameter setting interface.

2. A-constant and desired value input：the data below is default value, it can be changed on parameter setting interface.

4.8 System setting input



1. System time setting area

2. Probe type setting

3. Touch screen calibration

Chapter 5 Operation instruction

5.1 Software description

1）Software Name: ophthalmic A-scan ultrasound measuring instrument software

2）Software Model: SK-2000AP

3） Software Release Version number: V1.0

4）Software Provider

The software is expected to be used in conjunction with the ophthalmologic A-scan ultrasonic diagnostic instrument as an embedded software component of the device.

5）Software Support

Manufacturer provides technical support, provides software operation training for software users, and continuously upgrades and optimizes the operating software.

5.2 A-Scan measurement

1) Confirm each wire connected well.

2) Turn on the power supply to enter the main screen.

3) Press "NEW" icon or directly touch the patient information area, input patient data.(One can skip this step if printouts are unnecessary).

4) Select lens type, measuring mode(contact mode or immersion mode) and gain value(gain value can be adjusted according to waveform changes in process of measurement) as needed.

5) Take down A-probe cover, clean the surface of A-scan probe tip with normal saline. The patient is placed in a supine position on a flat examination table, apply a drop of topical anesthetic to the eye that is to be measured prior to performing the A-Scan.

6) Separate the patient's eyelids, squat the patient's fixation center light red or face up, step on the foot switch or click the "Start" button on the screen to gently place the probe at the patient's corneal apex to measure

7) When there is a waveform that meets the calibration conditions, the system automatically freezes and emits a "beep" sound until the ten sets of waveforms are measured.

8) After measurement completed, one can reposition the calibration point manually according to measured data or delete the data in great error, re-collecting until get satisfactory data.

9) If one need to calculate IOL power after measurement completed, turn to IOL interface, or print examination result directly.

Notice：a. Immersion mode need a cup to be placed on patient's eyeball, probe to be placed in cup (figure 1).

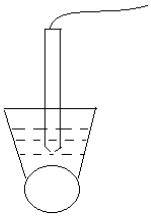


图1

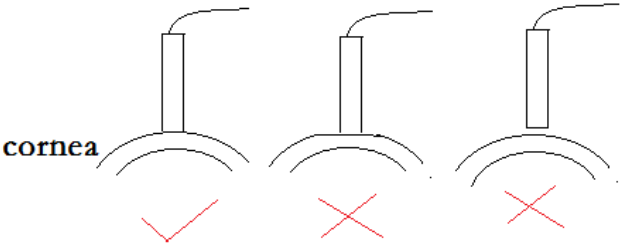


图2

b. Contact mode , probe need to be placed on cornea gently，pressing in or out of the corneal apex will cause data inaccurate (figure 2).

5.3 IOL Calculation

1) When A-scan measurement is completed , touch “IOL” to turn to calculation interface(can also calculate artificial lens formula on IOL interface)

2) Select the needed formula and contrast formula, press “count” icon for data calculation.

Notice：ACDb is used in Binkhorst-II formula，given by IOL manufacturers.

5.4 Corneal thickness measurement

1) When A-scan measurement is completed, click “PACHY” to enter corneal thickness measurement, corneal thickness measurements can also be performed alone .

2) The default corneal thickness measurement mode is single-point measurement mode, one can press “MAP” icon enter multi-point mode.

3) When measure corneal central thickness with single-point mode, probe need to be placed at the central point of cornea. When choose map mode, probe should place on the corresponding corneal position versus measured position display on the screen.

4) Choose the thickness range according to the patient's cornea condition during measurement, there are“150-350um”, “300-1000um”, “900-1500um”three ranges are available.

5) After setting the parameters, remove the probe cap and clean the surface of the P-ultrasound with saline. The patient to be tested will be in good condition for surface anesthesia.

6) Separate patient eyelid, instruct patient focus on red light in central probe or look upward, step on foot pedal or press the “Start” icon, then place the probe gently on the patient's cornea vertex(single-point mode)or the corresponding corneal position versus the point display on the screen(map mode), start measuring.

7) If echogram meets the criteria of the selected examination mode, it will immediately be frozen,save and a short “beep” sound will be emitted, until all 10 scans are captured.

8) Delete data in great error, re-collection until get satisfied data.

9) Touch “Save” to save the result, touch “Print” to print examination result.

Note：In corneal thickness measurement shouldn’t press in or out of corneal surface when contacted with cornea, like A-scan mode figure 2 shows.

5.5 Use of calibration cylinder

1) Turn on main machine power supply.

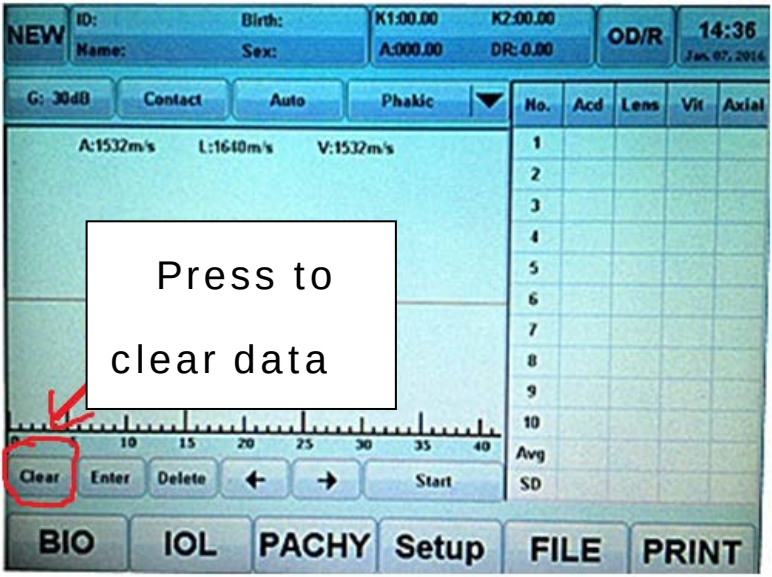
2) Enter main screen and select “calibrate” mode in lens type drop-down menu .

3) Place calibration cylinder on horizontal table, and drop 1-2 drops of water.

4) Place the probe onto the Calibration Cylinder. The probe should be placed perpendicularto the cylinder , step on foot pedal to collect the echogram.

5) When 10 groups of echogram collection completed, contrast echogram consistency, error be controlled within ±0.03mm.

Note：Calibration cylinder using environment are within 25°±5° interior.The data measured with the measuring block cannot be saved. After completing 10 groups of data, if the next test is needed, click the "Clear" button in the test interface as shown in the figure below. After clearing the data of the current test, the next test can be carried out



5.6 TOUCH SCREEN CALIBRATION

1) turn on the host power

2) click the system setting button

3) click the Screen Calibration button in the system Settings interface, and the following interface appears

4) Use the touch pen or finger to click the cross cursor in the corner of the screen to complete the screen correction.

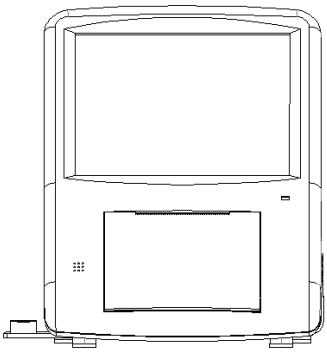
Chapter 6 Replace printing paper

6.1 Printing paper specification

Printing paper length is 57mm, diameter is 30mm. thermal printing paper.

Method to change printing paper

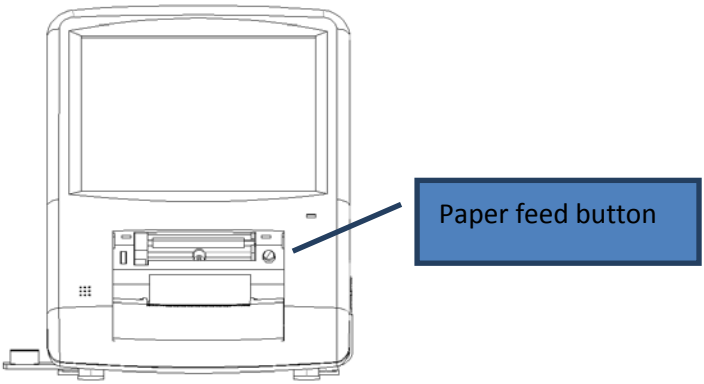
1) When device suggest “No Paper”, need to change printing paper.
2) Open the door of paper repository.



3) Take down the original printing paper .

4) Assemble new printing paper (notice the front and back side of the paper).

5) Make printing paper aligning paper entrance slot, press paper feed button, press the button again to stop when the paper come out.



6) Close the door of paper repository firmly.

Chapter 7 Equipment maintainence

7.1 Daily Maintenance

 Warning: disconnect the ac power supply before wiping the device.

 Warning: disconnect the ac power supply after each shutdown.

The environment should be clean and dry, and the room should be well ventilated. The surface of the instrument should be gently wiped with a clean dry towel to avoid dust contamination. After the equipment has been used for a period of time, cotton swabs and 75% medical alcohol are used to scrub the surface parts to sterilize them.

 Warning: touch screen is easy to damage. Use a damp cloth only. Do not use solvents or alcohol.

7.2 Maintenance during operation

When the instrument is running, there should be no strong sound, light, electricity or magnetism around it. Keep this device from this kind of environment when working.

7.3 Probe maintenance

The probe is fragile and should be handled with care. If it falls onto a hard surface it will be damaged.

Periodic inspection:

Check the probe connection and the probe itself for cracks. Cracks can cause liquid to penetrate.

The probe should be inspected regularly to ensure that the surface of the probe that is in contact with the patient is not damaged.

Do not use if you suspect a problem with the probe. Contact your local distributor or the after-sales service department of manufacturer

Do not sterilize the probe using the high pressure method.

7.4 Maintenance during loing-term parking

Before long-term decommissioning, the instrument should be cleaned and wiped, then covered, wrapped, or packed in a clean cloth or polyethylene film.

To protect the casing, do not use abrasive cleaning tools. If possible, remove stains before drying.

7.5 How to prevent cross infection in patients

The probe must be cleaned between the two patients in order to prevent cross infection.

The probe can be cleaned with alcohol commonly used in hospitals, and then rinsed with saline. Follow the label's operating instructions when cleaning. Other FDA approved disinfectants can also be used.

The probe cannot be completely submerged - the front of the probe can only be placed in a disinfectant for disinfection. The probe has a maximum immersion depth of 5 cm.

 **Connector cannot be submerged. Do not autoclave probe or wire.**

After washing, thoroughly clean the end of the probe with saline and wash away any remaining liquid.

Follow the instructions on the disinfectant label.

Wipe the surface with a medical gauze.

7.6 Common trouble shooting

Fault Phenomenon	Cause	Solution
Can't freeze data in measuring	Lens mode selection is not correct	Re-select lens mode
	Gain value too high or too low	Adjust gain value
	Can't reach automatic calibration conditions	Choose manual calibration mode
Can't collect data	Foot pedal collection not connected or damaged	Re-connected or replace foot pedal, or use function icon on the screen to collect
No normal reflection echogram	Probe not connected or damaged	Re-connected or replace probe

Generally, the faulty user can eliminate it by himself. If there are other faults, please contact the company to solve it.

7.7 Parts replacement

The hospital can repair or replace the data of parts by itself (the model specified by our company must be used)

(1) foot switch (model: tfs-1);

(2) A ultrasonic probe (10 MHz);

(3) P ultrasonic probe (20 MHz);

(4) printing paper (57 mm long and 30 mm to 40 mm in diameter);

If the user needs, can provide relevant technical drawings, circuit diagrams for maintenance.

7.8 Waste disposal

During the normal operation and maintenance of the equipment, the components or other wastes that have been replaced shall be properly disposed according to the requirements of local laws and regulations, and shall not be discarded at will. When the equipment reaches the end of its life, it should be recycled according to the requirements of local laws and regulations. So as not to cause pollution to the environment.

7.9 Responsibilities of manufacturer

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

-- assembly, addition, commissioning, alteration or maintenance are carried out by authorized personnel;

-- the electrical facilities in the room are in compliance with relevant requirements;

--The equipment is used according to the instructions.

Chapter 8 Probe sound output publishment

8.1 Tissue irradiated by ultrasounic energy

SK-2000AP equipment can only be used for ophthalmology, A scan.

 Warning: this device cannot be used for infants.

 The warning part (as low as possible) :

When used according to the recommended method, the energy is weakened by the organization between the converter and the focus. The value shown here is the value at focus. The intensity is highest at the focal point.

In addition to the duration of exposure, the user has no control over the ultrasonic energy. However, in order to reduce exposure, the measurement time can be as short as possible.

8.2 Sound output publishment

P-ultrasound output publishment	A-ultrasound output publishment
1、Maximum power（mW） 0.53	1、Maximum power（mW） 0.091
2、p_(Mpa) 1.83Mpa	2、P_(Mpa) 2.08
3、Iob(mW/ cm^2) 0.456	3、Iob(mW/ cm^2) 0.94
4、Ispta (mW/ cm^2) 1.1	4、Ispta (mW/ cm^2) 1.12
5、System setup	5、System setup
6、Lp (㎜) 11	6、Lp (㎜) 5
7、Wpb6(㎜) (Ⅱ)： 1.49 （⊥）： 1.52	7、Wpb6(㎜) (Ⅱ)：1.59 （⊥）：3.05
8、prr(kHz) 0.6	8、prr(kHz) 0.6
9、srr(Hz) Not Applicable	9、srr(Hz) Not Applicable
10、Output beam size（cm^2）0.0456	10、Output beam size（cm^2）0.0962
11、fawf(MHz) 18	11、fawf(MHz) 8.5
12、APF Not Applicable	12、APF Not Applicable
13、Boot mode A-scan mode	13、Boot mode A-scan mode
14、AIF Not Applicable	14、AIF Not Applicable
15、Initial mode A-scan mode	15、Initial mode A-scan mode

16、Sound output freeze YES	16、Sound output freeze YES

Chapter 9 EMC Information requirements

For this device, special precautions regarding electromagnetic compatibility (EMC) are required and must be installed and used in accordance with the electromagnetic compatibility information specified in this manual.

Portable and mobile RF communications equipment may have an impact on this equipment.

In addition to cables (transducers) sold as spare parts for internal components, the use of accessories and cables (transducers) outside of the regulations may result in increased emissions or immunity to emissions from equipment or systems.

Equipment or systems should not be used in close proximity or stacked with other equipment. If they must be used close to or stacked, they should be observed to operate properly in the configuration in which they are used.

Guide and manufacturer's statement - electromagnetic emission **The equipment** 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:：		
Emission test	**compliance**	**Electromagnetic environment - guide**
Rf launch	One group	The Ophthalmic Ultrasound A-scan (SK-2000AP) uses RF energy only for its internal functions, so its RF emissions are low and there is little chance of interference with nearby electronic equipment.
Rf launch	Class A	Ophthalmic ultrasound A-scan(sk-2000ap) is suitable for use in all non-domestic and facilities not directly connected to the domestic residential public low-voltage power supply network.
Harmonic radiation	Not applicable	
Voltage fluctuation / flicker emission IEC 61000-3-3	Not applicable	

Guidance and manufacturer's statement - electromagnetic **immunity** **The ophthalmic ultrasound A-scan (sk-2000ap)** 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：

Immunity test	IEC60601 Test level	Compliance level	Electromagnetic environment - guide
Electrostatic discharge （ESD） IEC61000-4-2	±8kV Contact discharge ±15kV Air discharge	±8kV Contact discharge ±15kV Air discharge	The ground 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	±2kV Power cord ±1kV Input/output line	±2kV Power cord ±1kV Input/output line	The network power supply should have the quality used in a typical commercial or hospital environment.
Surge IEC61000-4-5	±1kV Line to line ±2kV Line to ground	±1kV Line to line ±2kV Line to ground	The network power supply should have the quality used in a typical commercial or hospital environment.
Power supply input line voltage sag, short - term interruption and voltage variation IEC61000-4-11	< 5% U_T, duration 0.5 cycle (on U_T, > 95% sag) 40% U_T, duration 5 cycles (on U_T, 60% sag) 70% U_T, 25 cycles (on U_T,	< 5% UT, duration 0.5 cycle (on UT, > 95% sag) 40% UT, duration 5 cycles (on UT, 60% sag) 70% UT, 25	The network power supply should have the quality used in a typical commercial or hospital environment. If the user of the ophthalmic ultrasound A-scan (SK-2000AP) needs continuous operation during power

	30% sag) < 5% U_T, 5s (on U_T, > 95% sag)	cycles (on UT, 30% sag) < 5% UT, 5s (on UT, > 95% sag)	interruption, it is recommended that the ophthalmic ultrasound A-scan (SK-2000AP) be powered by an uninterruptible power supply or battery.
Power frequency magnetic field （50/60Hz） IEC 61000-4-8	3 A/m	3 A/m	The power frequency magnetic field should have the horizontal characteristics of the power frequency magnetic field in a typical place in a typical commercial or hospital environment
Note： U_T refers to the ac network voltage before the test voltage is applied.			

Guidance and manufacturer's statement - electromagnetic **immunity** **The ophthalmic ultrasound A-scan (SK-2000AP)** 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	**IEC60601 Test Level**	**Compliance level**	**Electromagnetic environment - guide**
RF transmissio	3 V（Valid values）	3 V（Valid values）	Portable and mobile **RF** communications

n IEC61000-4-6 RF radiation IEC61000-4-3	150kHz - 80MHz 3 V/m 80MHz - 2.5GHz	3 V/m	equipment should not be used closer to any part of the equipment, including cables, than the recommended isolation distance. This distance is calculated by the formula corresponding to the transmitter frequency Recommended isolation distance d =1.2 150kHz-80MHz d =1.2 80MHz-800MHz d =2.3 800MHz-2.5GHz In the formula： P——The maximum rated output of a transmitter in watts (W) according to the transmitter manufacturer； d——is the recommended isolation distance in meters (m). The field strength of a fixed **RF** transmitter is

			determined by surveying the electromagnetic field a, which should be lower than the compliance level in each frequency range.[b] Interference may occur near devices marked with the following symbols. 

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

Note 2： These guidelines may not be suitable for all situations, and electromagnetic propagation is affected by the absorption and reflection of buildings, objects and the human body.

[a] Fixed transmitters, such as base stations for wireless (cellular/cordless) telephones and ground mobile radios, amateur radios, am and FM radio broadcasts, and television broadcasts, are not theoretically predictable.In order to assess the electromagnetic environment of a fixed RF transmitter, the survey of the electromagnetic field should be considered.If the measured field strength of **the ophthalmic ultrasound A-scan(SK-2000AP)** is higher than the applicable radio frequency compliance level, **the ophthalmic ultrasound A-scan(SK-2000AP)** should be observed to verify that it can operate normally.Additional measures may be necessary if abnormal performance is observed, such as reorienting the direction or position of **the ophthalmic ultrasound A-scan(SK-2000AP)**.

[b] In the whole frequency range of 150khz-80mhz, the field intensity should be lower than 3V/ M.

Recommended isolation distance between portable and mobile RF communication equipment and ophthalmic A-type ultrasonic measuring instrument (SK-2000AP)

An ophthalmic ultrasound A-scan (sk-2000AP) is expected to be used in an electromagnetic environment where radio frequency radiation harassment is controlled.Depending on the maximum rated 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 **ophthalmic ultrasound A-scan (sk-2000AP)** as recommended below.

Maximum rated output power of transmitter (W)	Corresponding distance to different frequencies of the transmitter/m		
	150kHz - 80MHz d = 1.2	80MHz - 800MHz d = 1.2	800MHz - 2.5GHz d = 2.3
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

Note 1: at 80MHz and 800MHz frequency points, the higher frequency band formula is adopted.

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

The following cables must be used to meet electromagnetic emissions and immunity requirements:

Cable name	length
power cable（10A）	＜3 m
other	/

Chapter 10 Warranty statement

Commitment: The factory can provide the necessary information for the repairable parts of the equipment specified by the manufacturer.

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

Before contacting our company, we suggest you do the following work:

- The device name and model you are using
- The factory number of the device you are using
- An accurate description of the information displayed on the screen
- What happened and what were you doing when it happened
- What steps have you taken to solve this problem.

2.This product is free of charge for one year from the date of purchase, subject to the operation of this instruction manual.

3.In the normal use state according to the instructions for use and the operating precautions in the machine, if the machine malfunctions, please contact the company immediately.

4.The following content is not covered by the warranty：

- Damage caused by failure to use, maintain or store the instruction manual.
- Damage caused by unauthorized removal/modification without the authorization of Manufacturer
- Damage caused by accident, wrong use, or irresistible natural factors.

Note：

1. Medical accident caused by irregular operation or not following operation procedure, Manufacturer will not take any medical liability.

2. The final interpretation right of this operation instruction belong to manufacturer, these information are subject to change without prior notice.