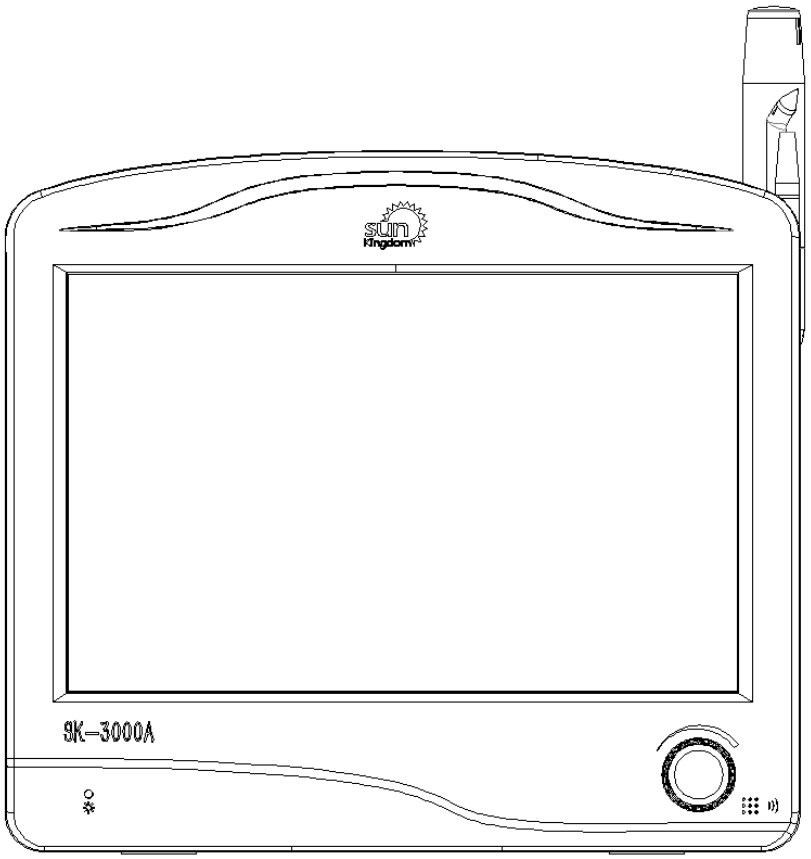
Instruction For Use

Ophthalmic Ultrasound

SK-3000A



Chongqing Sunkingdom Medical Instrument Co., Ltd
File No.: IFU- EN-OU-3000A
Version: V200518

Content

PREFACE

Dear User：

Thank you very much for choosing SK-3000A Ultrasound AB Scanner manufactured by Chongqing Sunkingdom Medical Instrument Co.(hereinafter called Sunkingdom), 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-3000A Ophthalmic Ultrasound

◆ Product Model：SK-3000A

◆ Operators Manual Model：SK-3000A

◆ Manufacturer Name：Chongqing Sunkingdom Medical Instrument Co.,Ltd.

◆ Manufacture Address：35-2, Yingtian Guangdian Gonggu, Caijiagang Industry Zone,Beibei District,Chongqing, China.

◆ Product registration address：No. 1 Xinmao Road, Beibei District, Chongqing (Free Trade Zone)

◆ Production license number of this product.：Chongqing Pharmaceutical Supervision Equipment Production License No. 20160050

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

◆ After-sale service address： 35-2, Yingtian Guangdian Gonggu, Caijiagang Industry Zone,Beibei District,Chongqing, China.

◆ After-sale service phone No.：+86-23-68102805

◆ Date of production: See nameplate

◆ Product life circle 5 years

◆ Date of preparation of instruction: 19 June 2018

Before use, you are advised to do the following carefully:

1. Check carefully whether the instrument and packing list are consistent, and whether the instructions and accessories are complete.

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

The pictures in this instruction are the effect pictures. The specific configuration is based on the packing list. If you have any details, please consult Sunkingdom Medical.

Consultation tel: +86 23-68683990

CHAPTER 1 SUMMARY

1.1 Machinery Description

SK-3000A Ultrasound AB Scanner takes the advantage of the international advanced model, have higher stability and reliability compare to similar products in domestics. Apply to measuring the axial length to choose right IOL power, capturing eye(anterior & posterior chamber) and orbit image to diagnosis eye disease. 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, Sunkingdom 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 maintenance , 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, B-probe both are 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 front surface and adjacent 2-3 mm of A- 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 or objection to 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 +86-023-68643990

3) Sunkingdom reserves the right to explanation and modification for the operation manual.

1.3 Structure Components

Components includes main unit, A-Scan probe（10M Hz）, B-scan probe（10M Hz）, pachymetry probe（20M Hz）, foot pedal, power cable, calibration cylinder.waterproofing grade of main unit is IPX0, waterproofing grade of probe is IPX7, waterproofing grade of foot pedal is IPX1.

1.4 Applicability

Apply to measuring corneal thickness, anterior chamber depth, lens thickness , vitreous depth，axial length for ophthalmology, Calculate the intraocular lens implanted into the eye, and generate the ultrasound images of the eye and orbit to examine the eye diseases.

Ultrasound A is suitable for measuring axial length, anterior chamber depth, lens thickness and vitreous length.

B-mode ultrasonography is suitable for examining eye diseases.

P-ultrasonography is suitable for measuring corneal thickness

1.5 Product Contraindication

[Product contraindication] Active ocular inflammatory lesions (such as acute conjunctivitis, blepharitis, keratitis, corneal ulcer, dacryocystitis, iridocyclitis etc) and the infants can not use the product.

1.6 Points for Attention

 In order to avoid personal injury and other possible dangers, please read the precautions carefully.

 Warning: When measuring the length of the eye axis, be careful not to press the cornea.

 Warning: This device cannot be used for infants.

 Warning: Before wiping the equipment, the external power supply should be disconnected.

 Warning: disconnect the external power supply after shutting down the equipment each time.

 Warning: All biometric probes are push-pull connectors with locking systems to prevent incorrect installation. Do not forcibly install connectors.

 When using, make sure the equipment is grounded reliably. In order to avoid the damage of the equipment by the environment (humidity, dust, liquid, direct exposure to sunlight, etc.), it should be placed in a dry place. Do not splash liquid or other sundries into the equipment, otherwise it may cause short circuit of the internal components of the equipment and then cause electric shock or fire.

 The instrument is well grounded and can only be used by clinicians without sensitivity test..

 Installation of instruments should be carried out on flat and inclined ground.

 Keep the working environment clean and dry, avoid overheating and dusty environment.

 Use the special wires equipped with the instrument when it leaves the factory.

 No sharp instruments or hard objects shall be used to mark or touch any exposed part of the surface.

 Warning: This device can not be used with high frequency surgical equipment.

 Warning: Do not open the case without permission of the company, otherwise the consequences are at your own risk.

 Warning: Be sure to use grounded power plugs.

 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.

1.7 Operation Instruction Applicability

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

The instrument models：SK-3000A

1.8 Products Features

1) According to the types of electric shock protection: Class I equipment;

2) According to the degree of protection against electric shock: type B application part;

3) According to the degree of protection against liquid intake: the main machine is a common type of equipment; pedal switch: IPX1; probe: IPX7;

4) According to the degree of safety in the use of flammable anesthetic gas mixed with air or flammable anesthetic gas mixed with oxygen or nitrous oxide: it should not be used in the case of flammable anesthetic gas mixed with air or flammable anesthetic gas mixed with oxygen or nitrous oxide;

5) Classified by operation mode: intermittent loading and continuous operation;

6) rated voltage and frequency of equipment: ~100-240V 50/60Hz;

7) The input power of the equipment is 80VA;

8) Whether the equipment has the application part of protection against the effect of defibrillation discharge: no;

9) Whether the equipment has the signal output or input part: Yes;

10) Permanent installation equipment or non-permanent installation equipment: non-permanent installation equipment;

11) Equipment type: portable;

12) Safety Pipe Model: F1AH250V;

13) The biocompatibility of the equipment: the materials contacted with patients by A-scan probe, B-scan probe and Pachymetry probe meet the following requirements;

① Cytotoxicity; should be≤ II.

② sensitization; there should be no skin sensitization.

③Stimulation; should be a very slight reaction.

14) Detection accuracy: average relative error ≤ 0.05 mm

15) Wastes such as A-scan probe, B-scan probe and Pachymetry probe and infiltration accessories after the equipment is used shall be disposed of in accordance with national and local environmental regulations

1.9 Size and Weight

Table 1 weight and size

Model / size／weight	SK-3000A
dimension （wide*height*length）（mm）	300*93*255
weight（kg）	3.6

1.10 Working Environment

- General clinical work environment
- Temperature：5℃～40℃

- Relative humidity： ≤85%
- Atmosphere pressure: 700hPa～1060hPa
- Power supply：AC 100-240V 50/60Hz

1.11 Transportation & Storage

The packaged instrument can be transported by ordinary means of transportation. Rain and snow splashing and mechanical collision should be avoided during transportation. It should not be exposed to sunlight. Transportation ambient temperature:-40。C -+70。C, atmospheric pressure: 500 hPa - 1060 hpa, relative humidity 10% - 95%.

The packaged instruments should be stored in clean rooms with good ventilation, dry and non-corrosive gases at ambient temperatures ranging from 0℃～55℃, relative humidity not more than 85%, atmospheric pressure ranging from 500 hPa to 1060 hPa.

1.12 Symbolic Interpretation

Instrument external marking instructions：


Type B Application Section


Dangerous voltage


Caution!


Switch on and off the power supply

A-scan
A-scan probe socket

P-scan
Pachymetry probe socket

B-scan
B-scan probe socket


Pedal switch socket

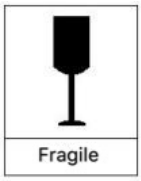
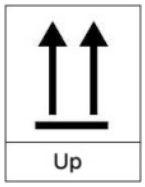
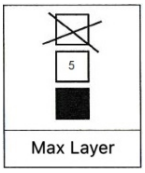

USB interface


Network interface

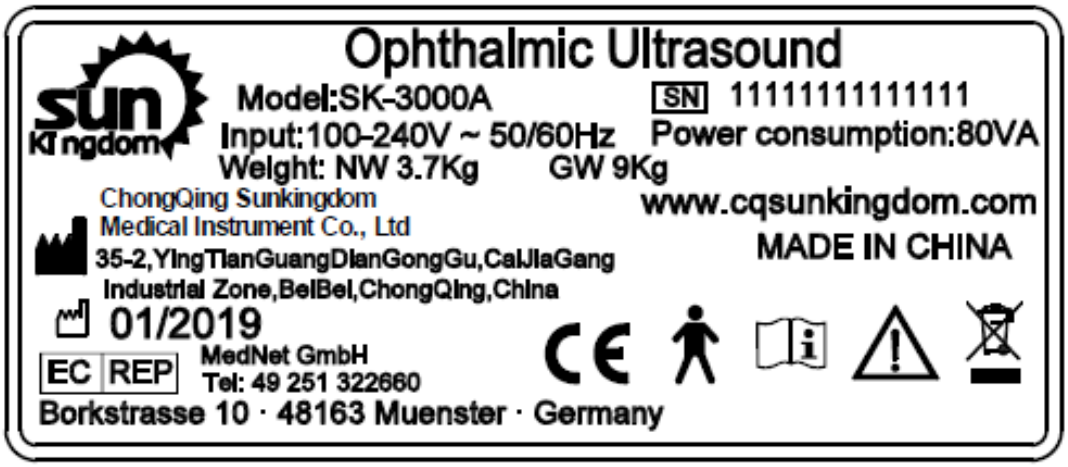
Video 
Video output interface and printer interface

AC 100-240V	Power jack
	Should not be treated as household waste
	Manual Instruction symbol
	Manufacturer information
	Manufacture date
AC 10 V	European certificate of conformity
SN	Series Number of products
EC REP	Authorized representative in the European Community

Symbol Interpretation on packaging box：

	It indicates that fragile articles are contained in transport packages and should be handled with care.
	It indicates that the transport package should be vertically upward when it is transported.
	It shows that the transport package is afraid of rain.
	It shows that the transport package can be stacked up to five layers.

1.12 Label



This label information is stick on main body of Ophthalmic ultrasound

CHAPTER 2 INSTRUMENT INTRODUCTION

2.1 Basic Performance and Parameters

No	Category	Technical index	Parameters	Note
1	A-Scan and Pachymetry	Ultrasonic frequency	10MHz(20MHz)	20MHzis for Pachymetry
2		Definition	≤0.05mm	axial lengths measurement
3			≤0.01mm	Cornea measurement
4		Display resolution	≤0.01mm	
5		Probing depth	≥40mm	Limit Axis Range 13-39 mm
		Gain	0-99db	
6		Velocity	Typical sound velocity 1640m/s，1532m/s	You can choose manually or pre-set the sound velocity
7		Data output	Cornea,anterior chamber,lens,vitreous body,axial length	
8		Sets of data output	10 sets	Average, standard deviation calculate
9		Formula	SRK-T,Hollady,Hoffer Q,SRK-2,Binkhorst Ⅱ,Haigis	6 usually used formulas
10		Lens type	Phakic,Dense,Aphakic,PMMA, Acrylic,Silicone	Selection of Six Common lensConditions
11		Measurement method	Auto and Manual	
12		Test mode	Immersion,Contact	
13	B-scan	Probe frequency	10MHz	
15		Scanning resolution	axial direction ≤0.2, side direction≤0.4	Standard B-scan
16		Display resolution	≤0.06mm	
17		Probing depth	≥60mm	
18		Blind zone	≤ 4 mm	
19		Lengthways geometric position accuracy	≤5%	
20		Horizontal geometric	≤ 10 %	

		position accuracy		
21		Gain range	0～99db	
22		Scan angle	≥53°	
21		Grey scale	256	
22		fps	≥12 frames per second	

2.2 Performance Requirements

(1) A/B Ultrasound Performance

The nominal frequency of A-scan probe is 10MHz and the error range is±15%.

The nominal frequency of B-scan probe is 10MHz, and the error range is±15%.

The nominal frequency of the Pachymetry probe is 20MHz, and the error range is±15%.

B-scan detection depth: 10M B-mode ultrasound probe (≥50)

Lateral Resolution of B-scan: 10M B-mode Ultrasound Probe ≤ 0.4mm

Axial resolution B-scan: 10M B-mode probe≤0.2

Transverse Geometric Position Accuracy of B-scan: 10M B-scan Probe ≤ 10%

Longitudinal Geometric Position Accuracy of B-scan: 10M B-scan Probe≤ 5%

Blind zone of B-scan: 10M B-scan probe≤4

The measuring range of the length of A-scan eye axis should not be less than 15 mm to 35 mm.

The error of measuring the length of A-scan eye axis should be no more than 0.05 mm.

The measurement range of Pachymetry corneal thickness should not be less than 0.3 mm to 1.2 mm.

The measurement error of Pachymetry thickness should be no more than 0.05 mm.

A-scan Axis length measurements should show two significant digits after decimal points, and Pachymetry corneal thickness measurements should show three significant digits after decimal points.

A-scan has two measuring modes, manual and automatic. The error of the two measuring modes is not more than 0.2 mm.

It has the function of calculating intraocular lens and the name of calculating formula should be given in software settings and attached files.

(2) Appearance and structural requirements

The shell of the diagnostic instrument should be free from mechanical damage and rust. The words and marks on the panel should be clearly visible and firm.

The plastic parts of the diagnostic instrument should be free from foaming, cracking, deformation and overflow of fillings.

The operation and adjusting mechanism of the diagnostic instrument should be flexible, reliable and the fastener should not be loosened.

The front side of the B-scan probe of the diagnostic instrument should be marked correctly to indicate the scanning plane, and the marking should be on the scanning plane.

(3) Foot pedal

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

(4) Safety requirements

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

(5) EMC requirements

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

(6) Environmental test requirements

The measuring instrument should meet the requirements of Climate Environment Group II and Mechanical Environment Group II in EN ISO 14710-2009

2.3 Theory

A-scan theory

A-scan ultrasound show reflected signal which is from interface in human body as vertical peak, form an image. The ultrasonic wave transmission time represents distance of reflecting interface, the further the distance, the later position of peak .the height of peak represent echogenicity, the stronger of echo, the higher of peak. The echo amplitude obtained is A-Scan ultrasound echogram.

B-scan theory

B-scan ultrasound send out a set of ultrasonic to human body, scanning according to a certain direction, transfer the interface echo to echo spot in different brightness , all these light spot form a 2D series section images.

Pachymetry theory

Pachymetry cornea thickness measurement :When the ultrasonic pulse strikes the first interface, one part of the acoustic wave is reflected, the other part of the acoustic wave penetrates the first interface and continues to move to the second interface, and then another part of the ultrasonic wave is reflected by the second interface. The corneal thickness can be calculated by measuring the distance between the two peaks produced by the two reflections of ultrasound.

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,placing the A-probe against patient eye lightly, and don't press it;

2.The direction of acoustic must through axle center of eye, or obvious measure errors will be made.

The mark on the B-probe represent the direction of sound beam and the upside of image.B-scan ultrasound mainly do width scanning ,equivalently equatorial diameter, so when you want to scan peripheral part, you must change the probe direction or patient gaze direction , to make the lesion area in the center of image.

The method to get high definition B-scan image :

1. Lesion area located in the central zone;

2. Sound beam must perpendicular to detected interface;

3. Adjust the gain , keep enough strength and low decibel to get the best resolution image.

Algorithm

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

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

There into

P IOL degree

A IOL constant

L axial length

K_1 Horizontal corneal diopter

K_2 Vertical corneal diopter

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

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

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

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

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

CHAPTER 3　DEVICE INSTALLATION INSTRUCTION

3.1　Packing

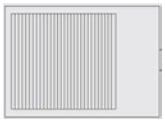
Open this instruments package carefully，outside packing is carton and inside protection packing is Pearl wool .Please check all accessories according to packing list before discarding the packing materials.

（1）SK-3000A Ultrasound AB Scanner main machine

（2）Accessories

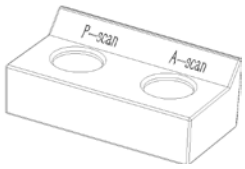

Power line


A-probe


Foot pedal


B-probe


P-probe



Calibration cylinder

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: 80VA

3.3　Installation Environment

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

(1)　Install this instrument on the flat surface.

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

(3) Must install special ground wire .

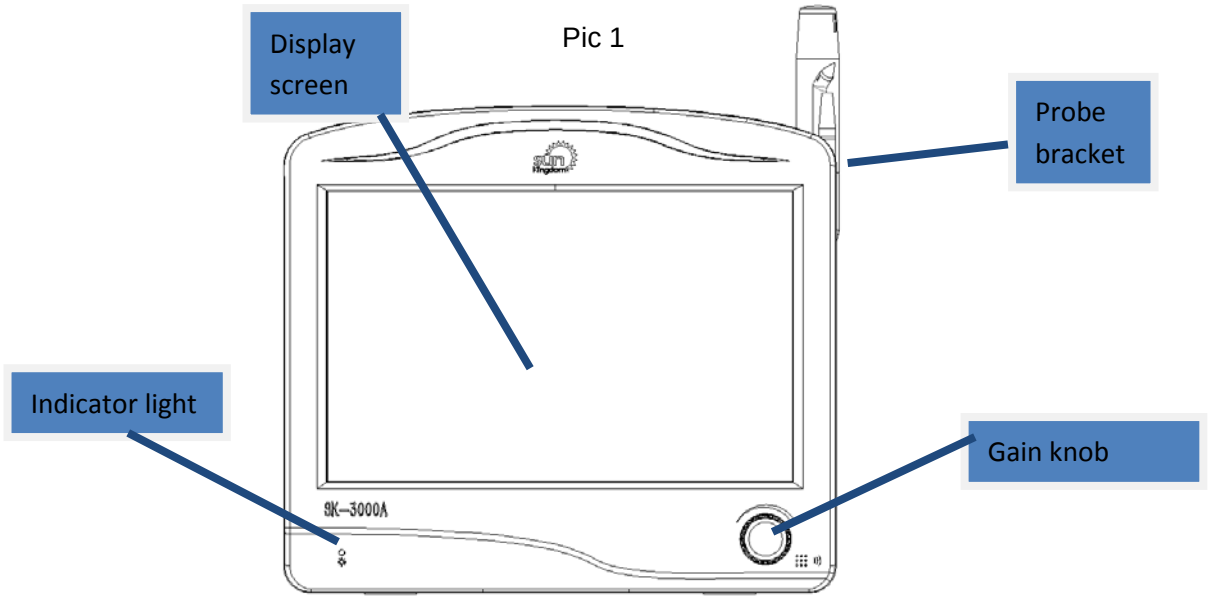
If the equipment encounters low temperature during transportation, it is not recommended to open the switch immediately after unpacking.

Warning: Switching on the switch can cause serious damage if the equipment is at a temperature close to 0 C° . Open the package and place the equipment at room temperature for at least 8 hours to ensure that the internal parts are gradually warmed up.

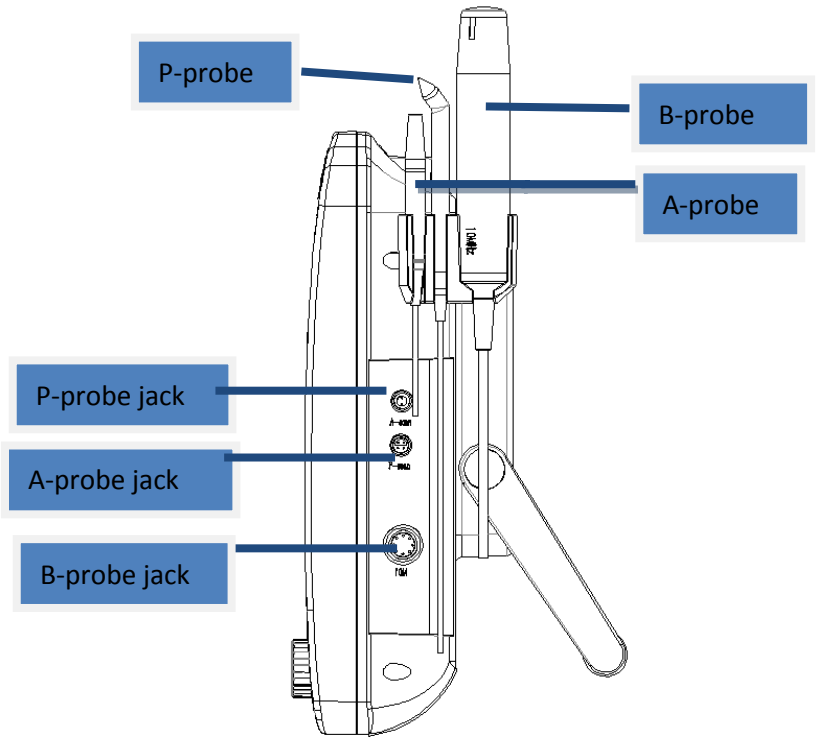
3.4 Device Installation

1) Front view of machine（pic 1）

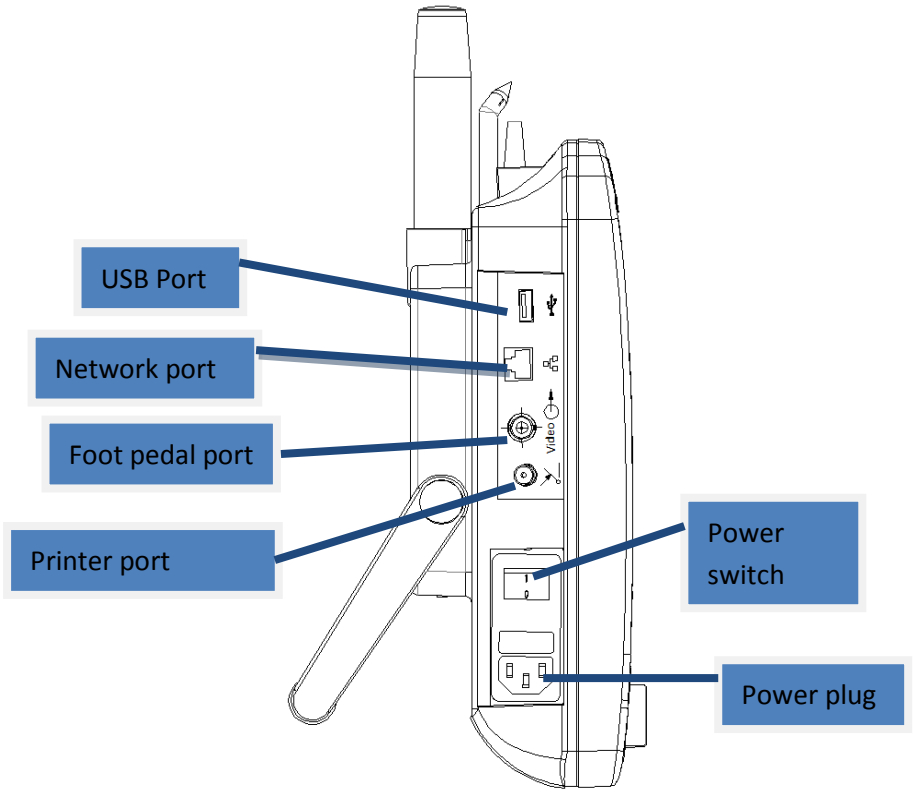
Pic 1



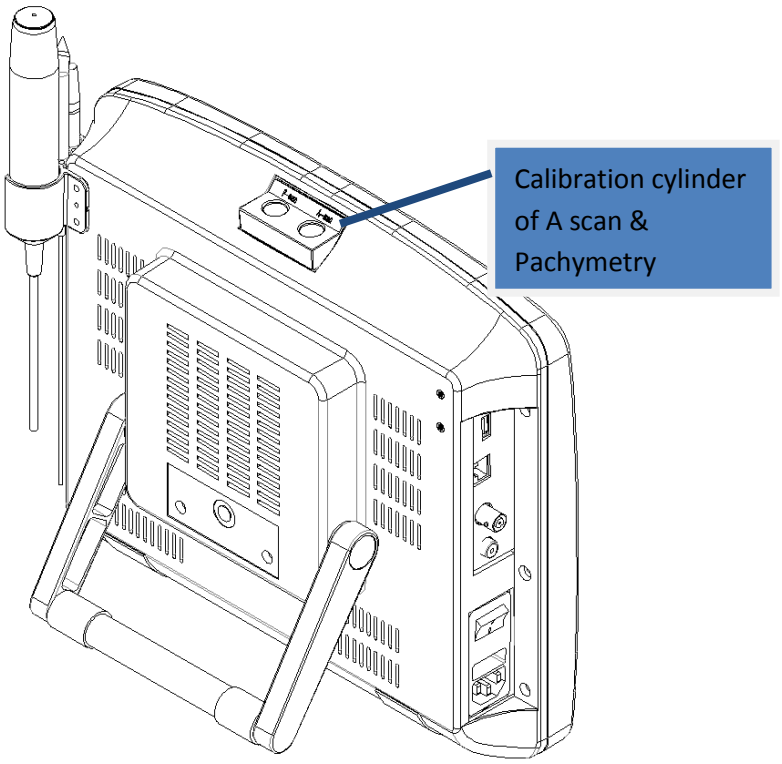
2) Side view of machine（Pic2,Pic3,Pic4）


P-probe
B-probe
A-probe
P-probe jack
A-probe jack
B-probe jack

Pic 2

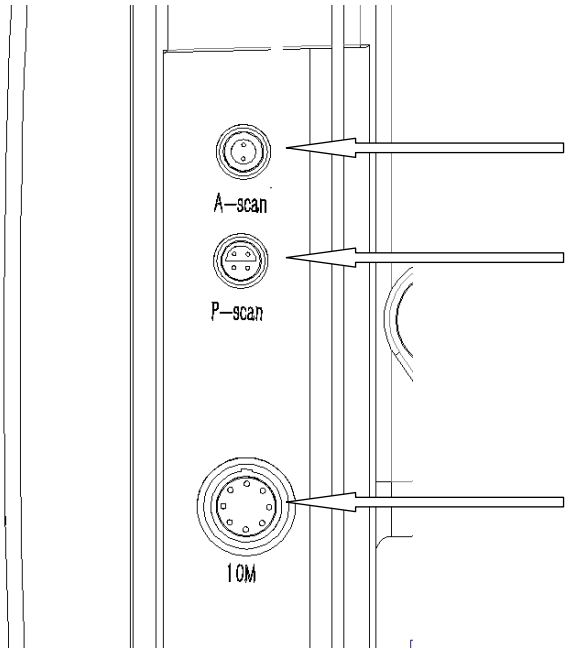

USB Port
Network port
Foot pedal port
Printer port
Power switch
Power plug
Video

Pic 3



Pic 4

3) Probe disassembly and installation diagram (Pic. 5). A, P and B ultrasonic probes can be installed in the direction of arrow in Pic. 5, and disassembled in the opposite direction of arrow in Pic. 5.

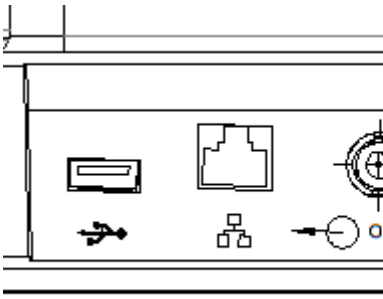


Pic 5

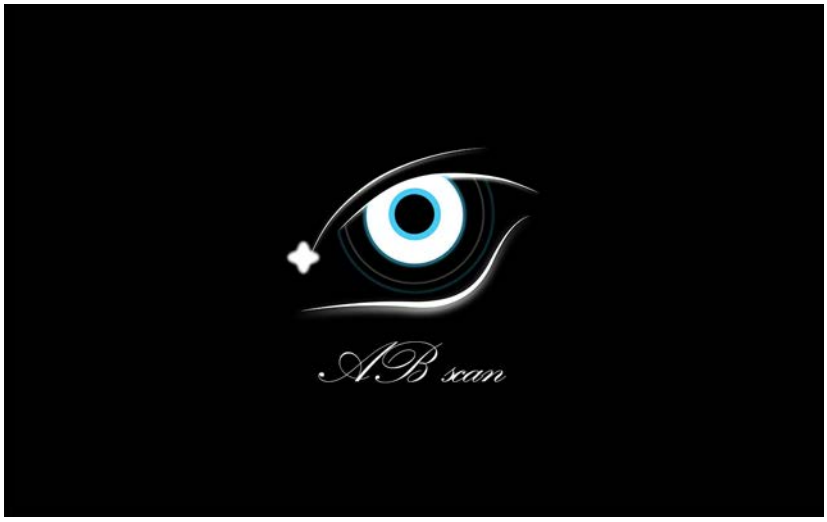
3.5 Device Start-up and Termination

Equipment startup:
Turn on the power switch next to the power cord on the left side of the device, turn the switch to position "I" and start the device.

Power supply: 100 to 240V AC power switch



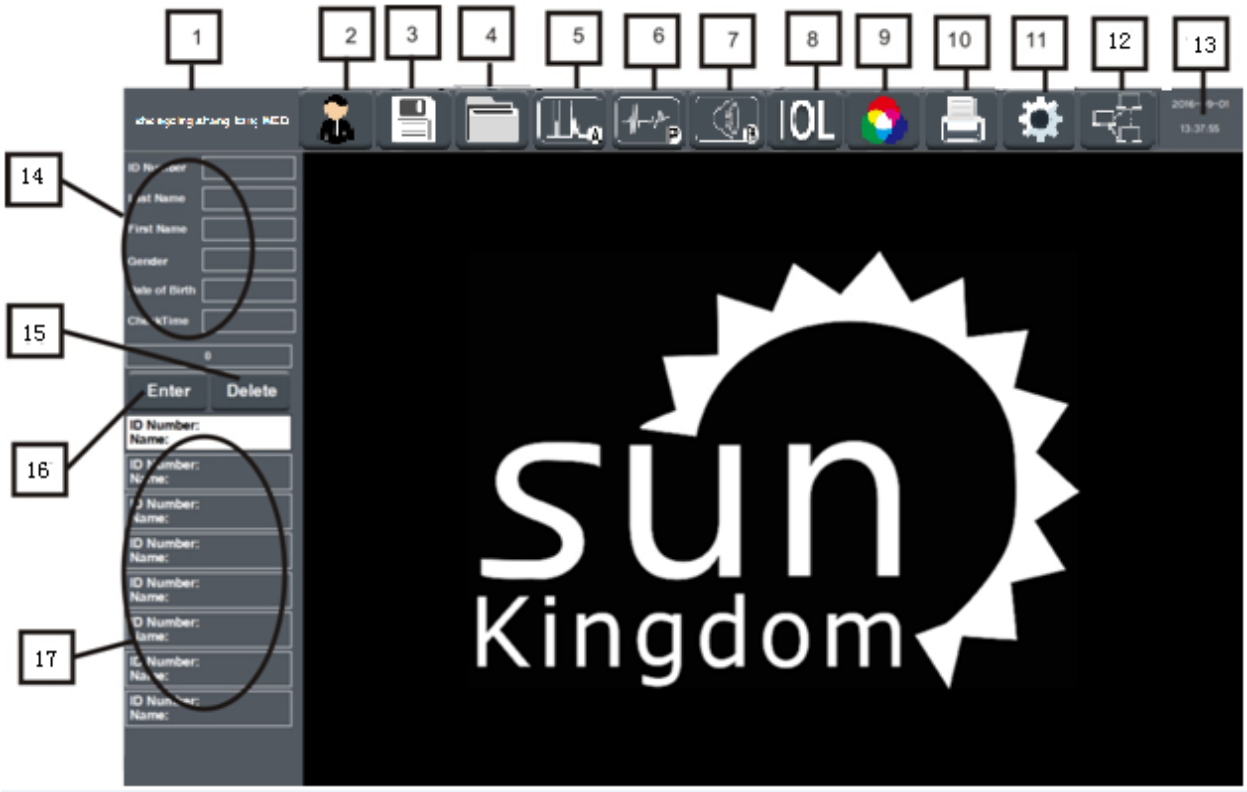
On the front screen, the touch screen will light up. Displays the first screen.



Equipment termination:
Put the switch of the power switch next to the power line on the left side of the equipment to the position "O", and the operation of the equipment can be safely terminated.

CHAPTER 4 INTERFACE INTRODUCTION AND SETUP

4.1 Main Screen Introduction

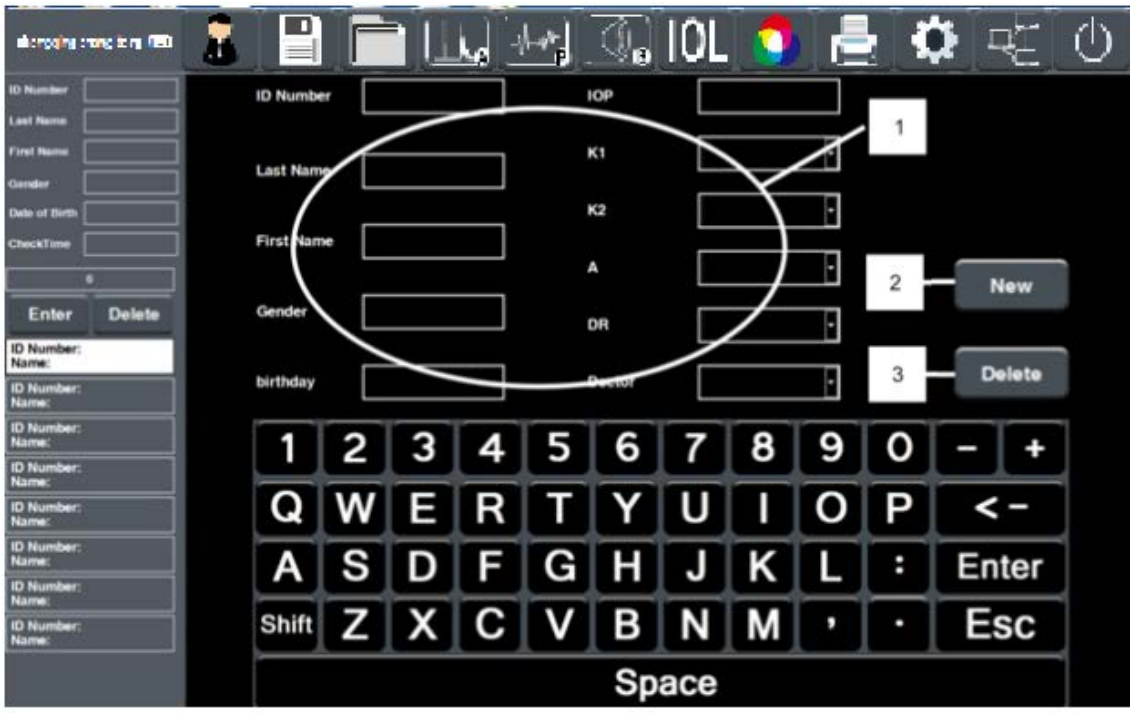


Button Functional Specification:

1. Hospital name display zone
2. New: Click to enter the patient information input interface
3. Save: save data and upload data to PC
4. Database:Click to enter data query interface
5. A-scan mode: Click to enter A scan checking interface
6. Pachymetry mode:Click to enter Pachymetry checking interface
7. B-scan mode: Click to enter B scan checking interface
8. IOL calculation: Click to enter IOL calculation interface
9. B-scan image post-processing: Click to enter B scan image post-processing interface
10. Print : Click to print the test result (Click Print on PC , one can preview test report)
11. Setting : Click to enter setting interface.
12. Online state: Blue means PC and PLC connect well, blank means PC and PLC offline
13. System time display zone (In PC software , this zone is software close icon.)
14. Patient information display zone
15. Delete: Select a patient , then click the Delete , this patient will remove to waiting area
16. Enter: Select a patient, click the Confirm to enter checking state
17. Patient waiting list

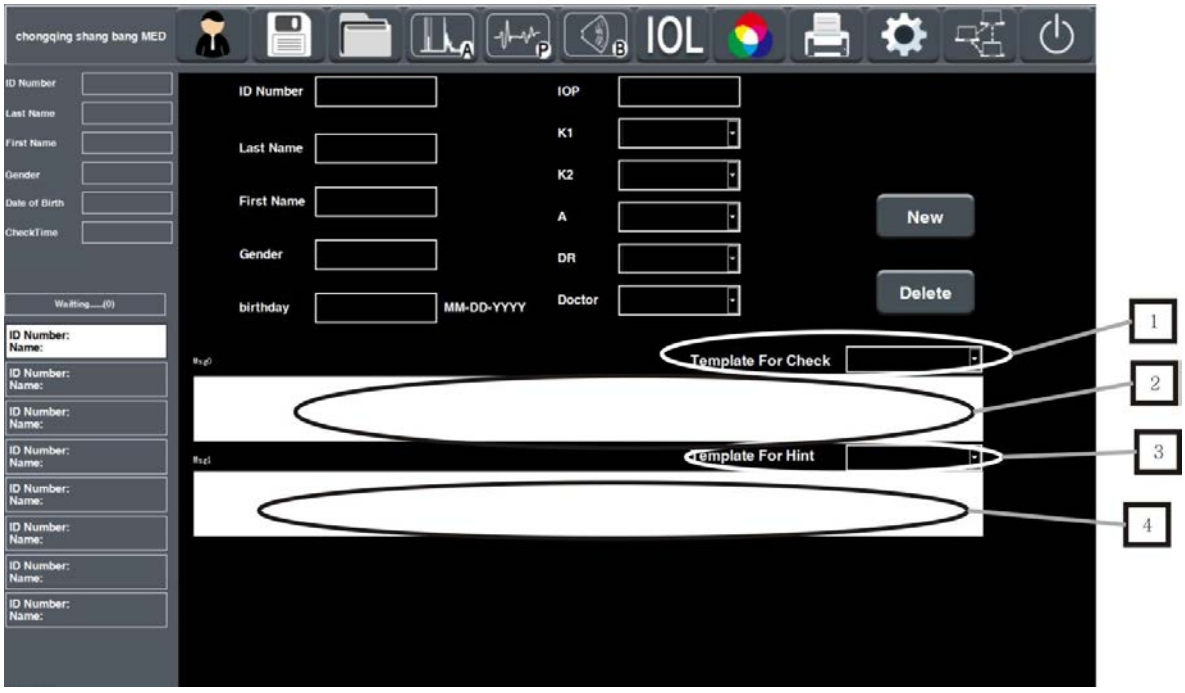
4.2 New Create Interface

PLC new create patient information interface



1. Input patient basic information
2. New: New create
3. Delete: Delete doctor name

PC new create patient interface



1. Selection Menu of ultrasonography description: you can choose corresponding preset ultrasonography description from drop-list menu according to what you see on the screen.

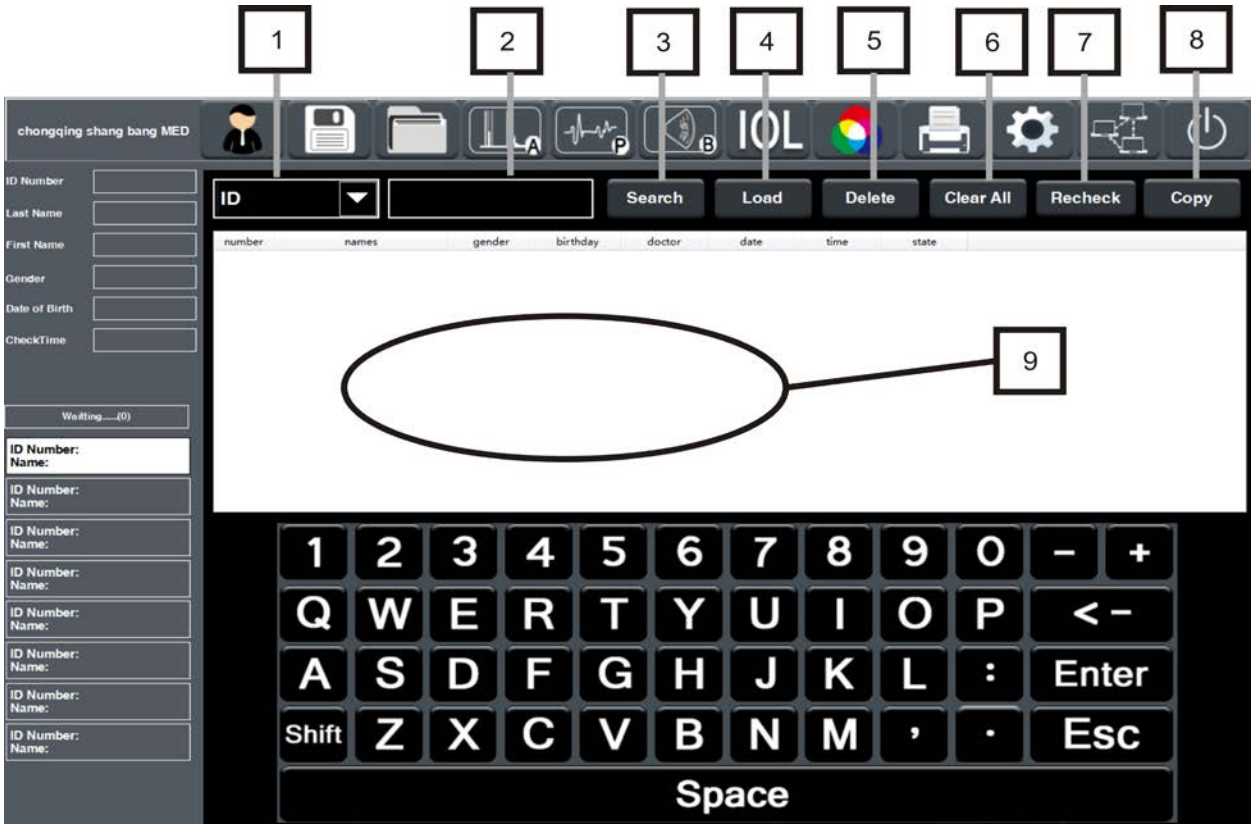
2. You can edit the ultrasonography in this area.

3. Selection Menu of diagnostic template: you can choose preset diagnostic opinion from drop-list menu.

4. Diagnostic opinion edit area.

Note : After checking , save test data , enter database interface . Choosing a patient, click Load then you can enter New create interface to input ultrasonography description and diagnostic opinion.

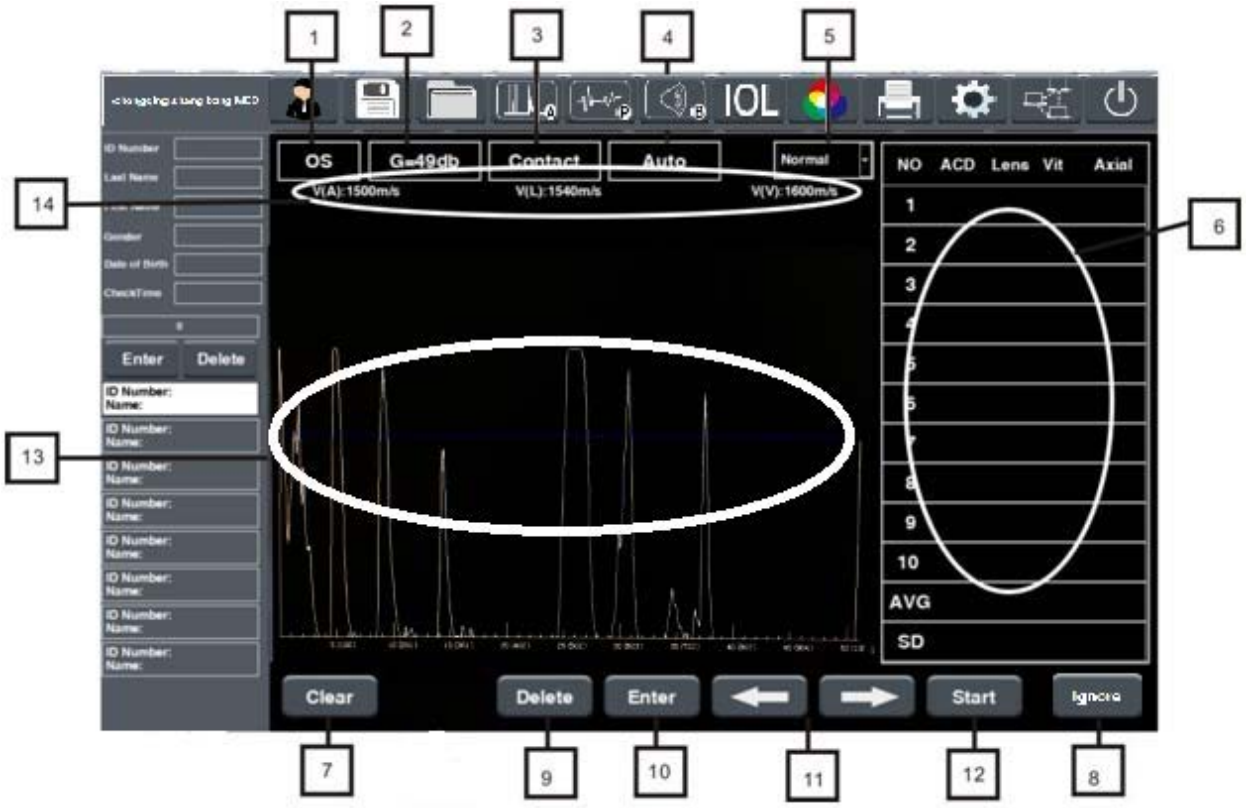
4.3 Database Interface



1. Query condition selection in database
2. Keyword input box
3. Search: Click to proceed query action
4. Data load: to load patient related information

5. Data delete:to delete patient related information
6. Clear all: Clear whole database
7. Recheck: Click to recheck the patient , after clicking , the database will add a column automatically.(PC interface don't have this option)
8. Copy: Insert the U-disk into PLC (USB-disk must be FAT32),select need to be imported data from database, click "copy", selected data will be imported into USB-disk(now the data just can import to USB-disk one by one) . Then , Insert this U-disk into PC, click "Copy" on PC interface, the data be imported into PC to check (Just can import one by one).
9. Patient test data list.

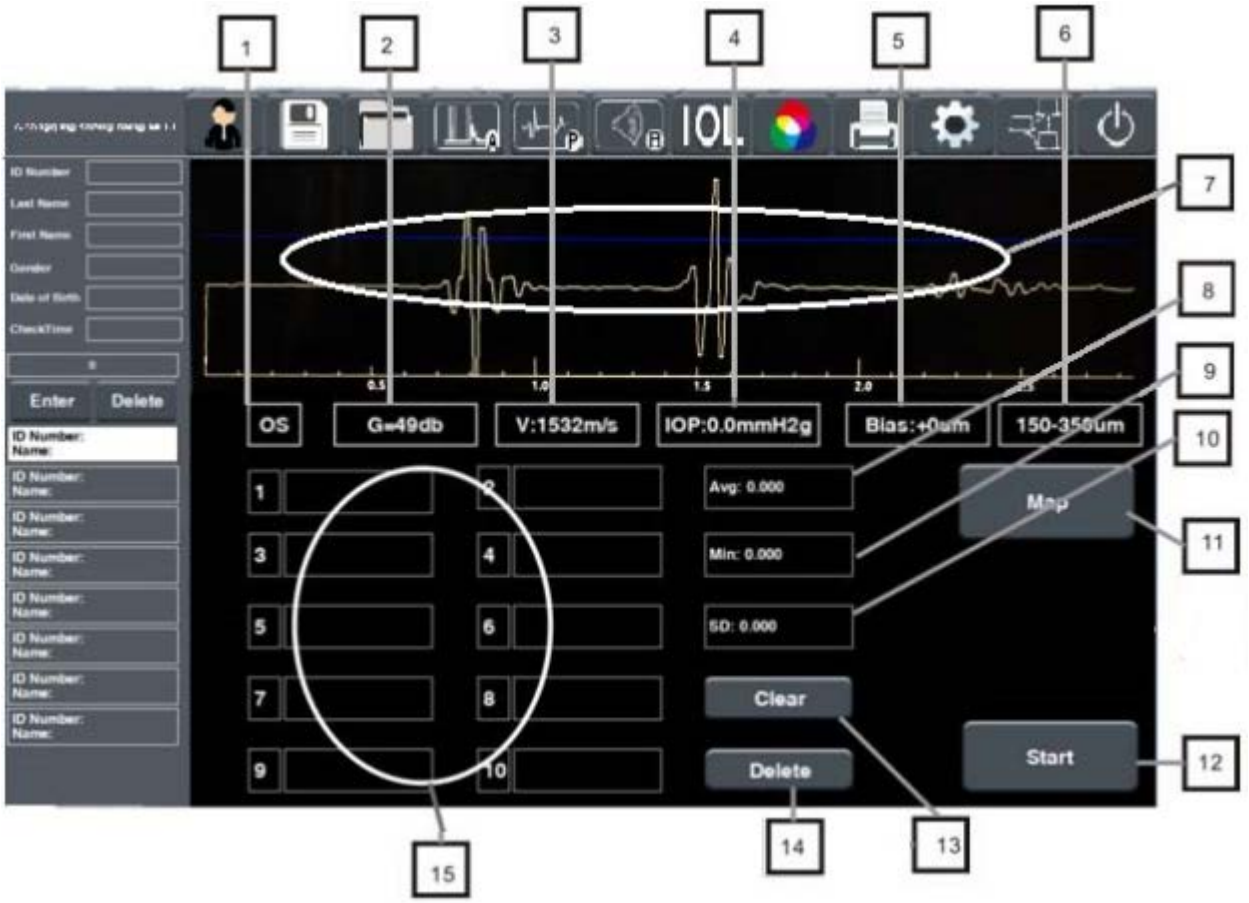
4.4 A-scan Test Interface

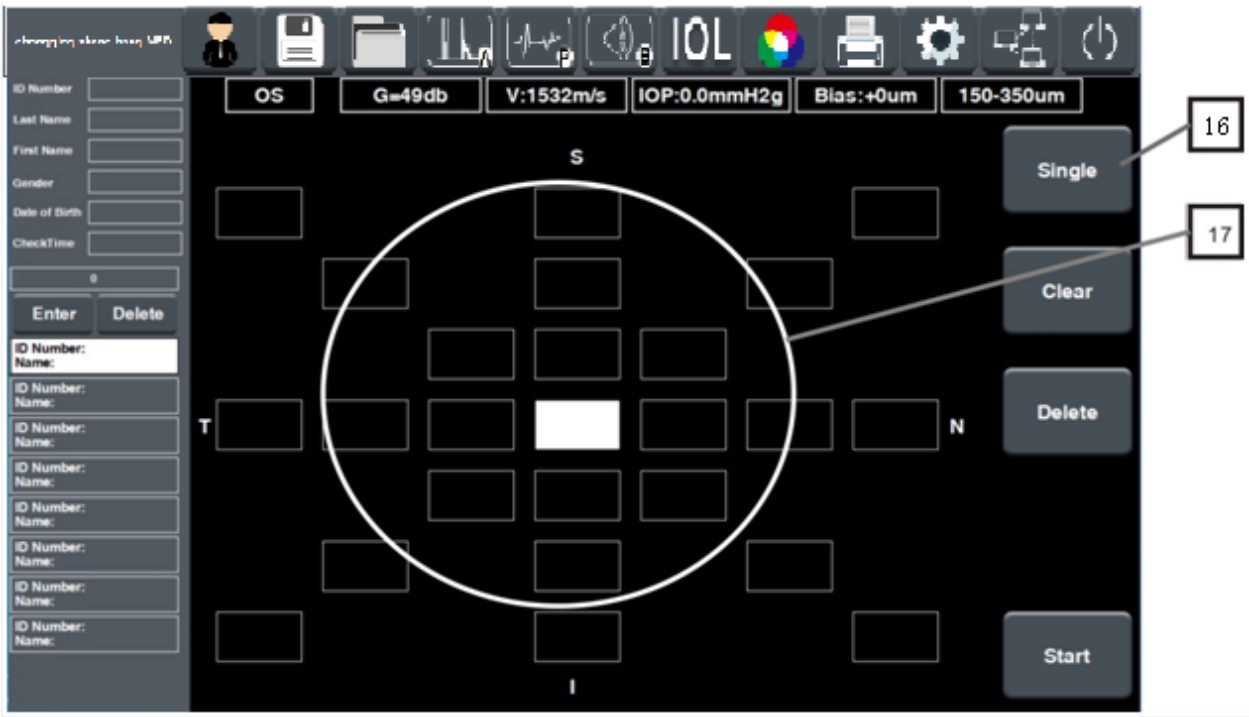


1. Eye: Switch left eye and right eye.
2. Gain value: show the gain value of current test, you can change the value through gain knob.
3. Test mode: Switch between contact mode and immersion mode.

4. Data calibration mode: switch between manual and auto.
5. Lens type: select lens type from drop-down list.
6. A-scan tested data display : show at most 10 groups of measurement data and mean number, standard deviation.
7. Clear: Click to clear current patient A scan test data.
8. Ignore: Select a set of A scan test data,click “Ignore” then the set of data don’t count in average value , standard deviation and IOL calculation. Click the “ignore ”again,the set of data recover to normal , and participate in calculation. If you need ignore multi-group data, select one set , click ignore , then select another set , click ignore.
9. Delete: Delete selected test data.
10. Enter /shift : under manual examination mode, you can switch among A/L/V calibration point by pressing it.
11. Left & Right move icon: move the calibration point under manual mode
12. Start/Stop : start collecting data or stop collecting data by pressing it.
13. A-scan echogram display area.
14. Tissue velocity: show the tissue velocity under current mode.

4.5 P-scan Test Interface





1. Eye: Switch left eye and right eye.

2. Gain value: show the gain value of present test, you can change the value through gain knob.

3. Corneal thickness measurement ultrasonic velocity：Click this icon to set the needed ultrasonic velocity. （When test on Pachymetry cylinder , the velocity set as 2381m/s）

4. IOP: the current patient IOL reference value .

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

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

7. Pachymetry echogram display area.

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

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

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

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

12. Start: start corneal thickness data collection.

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

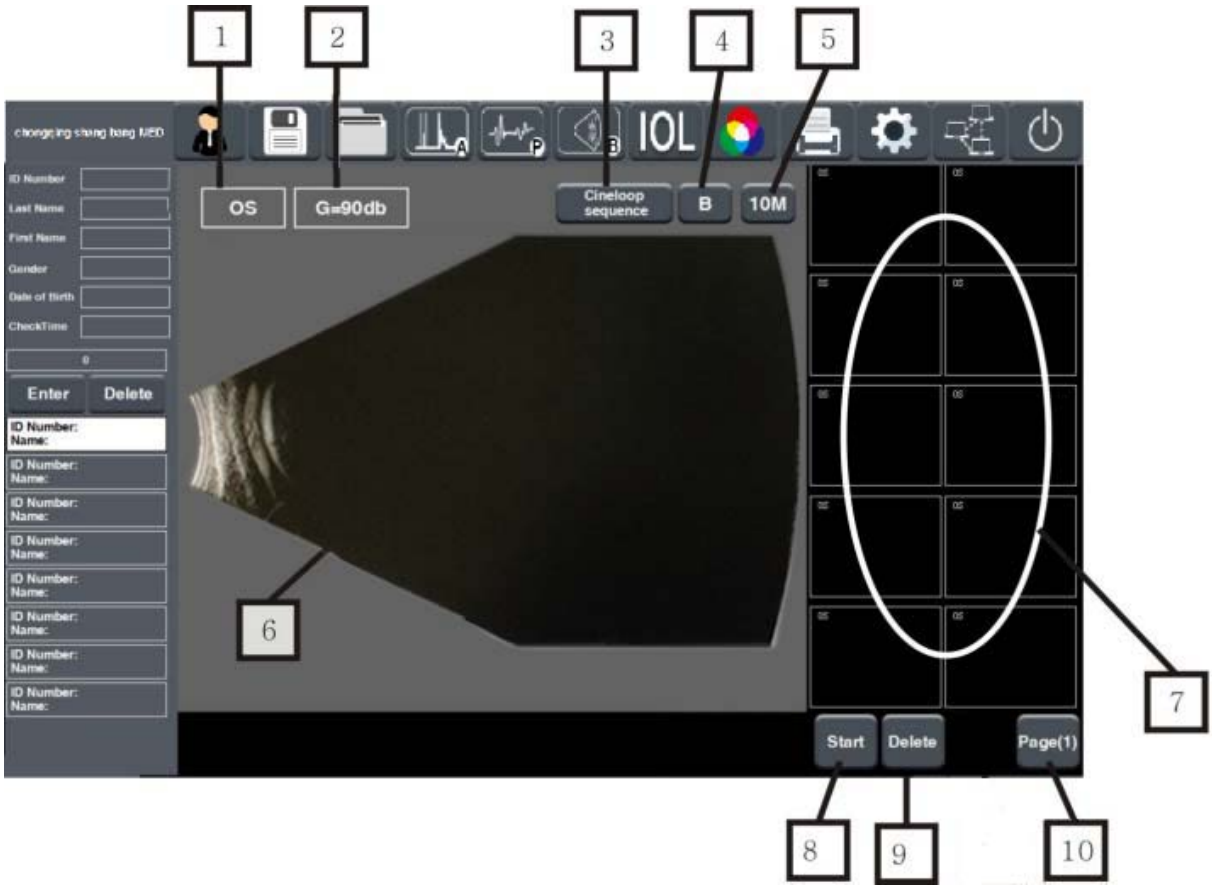
14. Delete: delete the selected data.

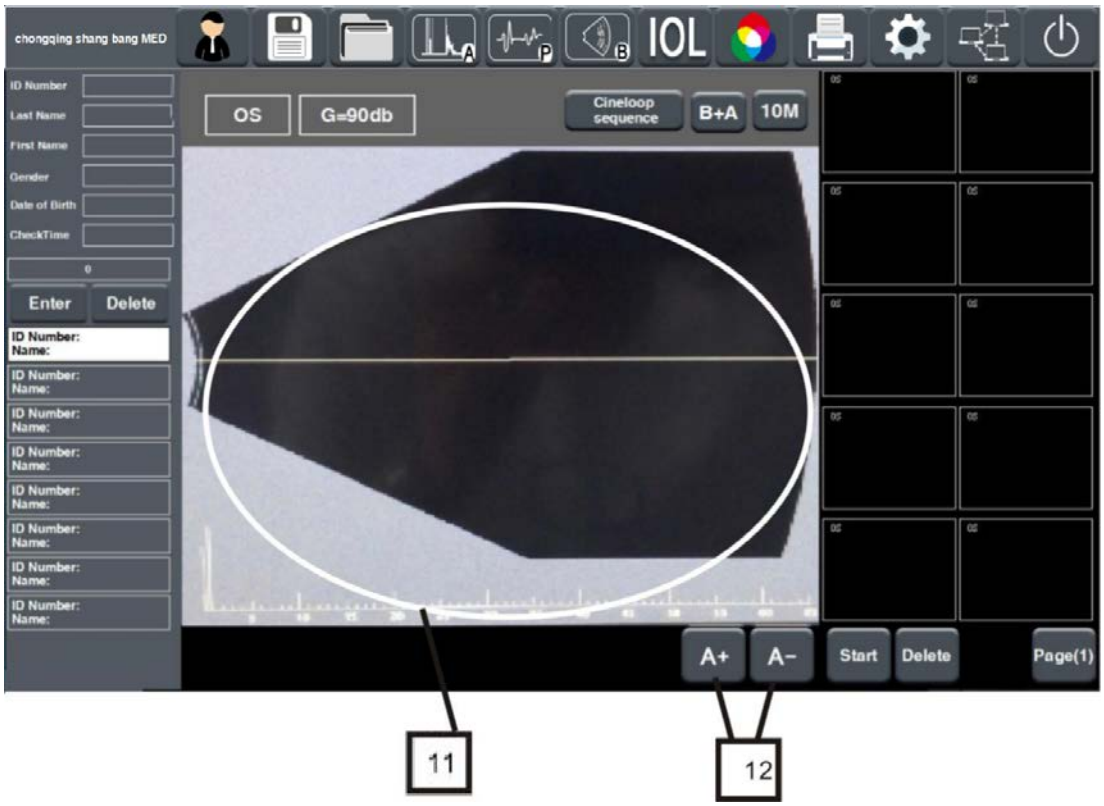
15. Measured data display area: show at most 10 sets of corneal thickness data.

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

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

4.6 B-scan Test Interface





1. Eye: Switch left eye and right eye.

2. Gain value: show the gain value of present test, you can change the value through gain knob.

3. B-scan ultrasonography cineloop: click to playback the B scan ultrasonography (PC don’t have this option)

4. Test mode: switch between B-scan mode and B+A scan .

5. Probe type:switch between 10M and 20M.

6. B-scan echogram display area.

7. Echogram storage area.

8. Start/Stop : start collecting B-scan data or stop collecting data by pressing it.

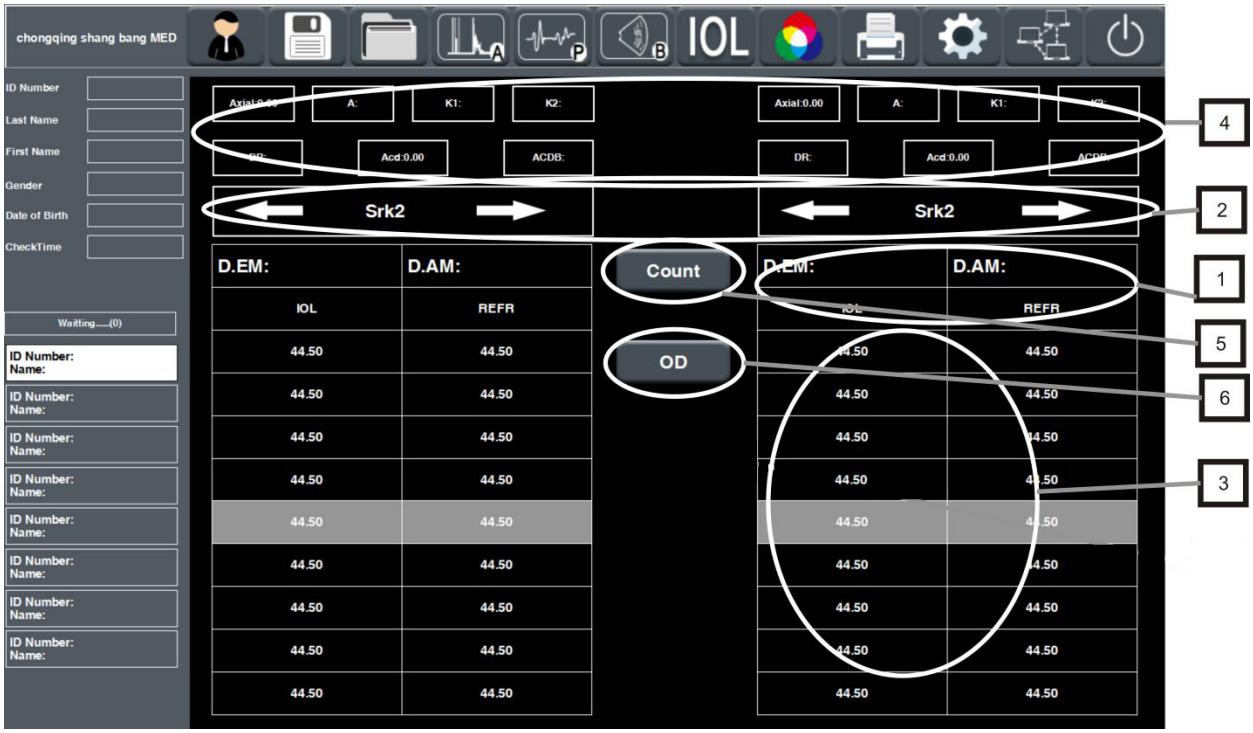
9. Delete: Delete the selected images.

10. Paging turning : Click to do page turning.

11. B+A echogram display area.

12. In B+A mode,A scan echogram baseline adjust icon.

4.7 IOL Calculation Interface



1. Postoperative desired value display:

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 grey color is calculated result of desired DR value.

4. Calculation input value:

Axial---------- axial length of the tested eye

A----------Constant

K1, K2----------Corneal radius

DR----------The value postoperative expected to retain

ACD----------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. Eye:Switch left eye and right eye.

4.8 B-scan Image Post-processing

1. Length measurement, click to measure length (a. Select the measuring point on the image which need to mark length, you can make the start point more accurate by click the direction icon on this interface, click the central icon to confirm the start point;

b. Select end point ; c. Draw a line between start point and end point , and read the length value.)

2. Contrast button, to adjust the contrast ration.

3. Angel measurement, click to measure the angel (a. select the measure starting point on the image which need to mark the angel, locate the starting point accurately by adjust the direction icon, then click the central button to fix the point ; b, click the screen choose a point to draw one edge;c, click screen to choose another point to draw another edge;d, read the angel.)

4. Sharpen, click to focus on the blurry edge, to improve definition or focus degree of a certain part in the image.

5. Area measurement, click to measure the area.（a, Select the measurement starting point on the image boarder , locate the starting point accurately by adjust the direction icon, then click the central button to fix the point ;b, select measurement points along the image boarder, drawing a closed area boarder ;c, read the area

value.

6. Pseudo color, to do pseudo color processing , click again to cancel the processing.

7. Nidus mark, mark the nidus by click the screen ,locate the position accurately by adjust the direction icon, then click the central button to fix the point, then there is a arrow will appear and direct to the nidus.

8. Clear, when doing length measurement, angle measurement ,area measurement, nidus mark operation , you can click this button to cancel the wrong mark .

9. B-scan scanning angle selection: click the down arrow, there is a drop-down menu pop-up for selection, ”No Display” means don’t display , 1--12 correspond to 1--12 o’clock.

10. Zoom in: click to zoom in the image, click one time , get twice size , at most make it three times larger .

11. Image zoom in , zoom out , and gray adjustment.

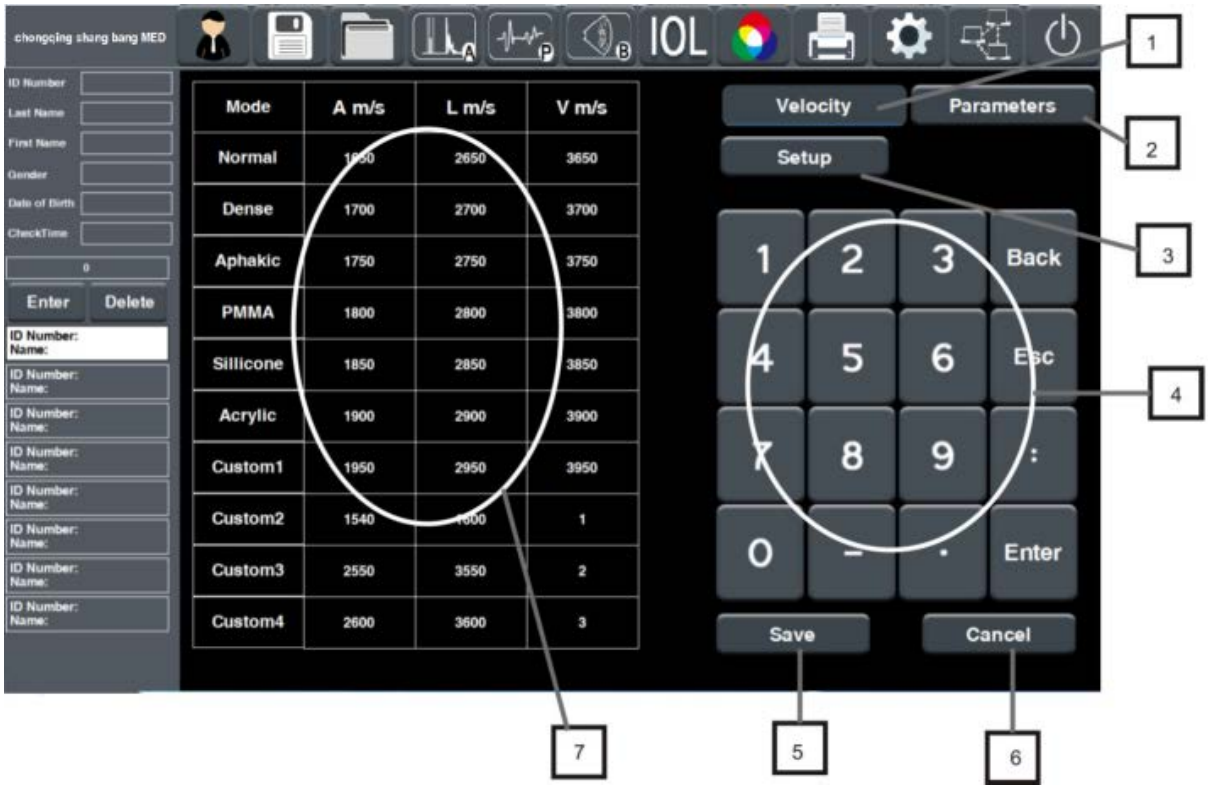
12. Delete: Use for deleting selected image.

13. Page turning: use for page turn.

14. Direction icon: adjust the points when measure length, angel, area, nidus, and move the image after zoom in .

4.9 Setting Interface

PLC setting interface


chongqing shang bang MED
IOL
ID Number
Last Name
First Name
Gender
Date of Birth
CheckTime
Enter
Delete
ID Number:
Name:
Mode
A m/s
L m/s
V m/s
Normal
Dense
Aphakic
PMMA
Sillicone
Acrylic
Custom1
Custom2
Custom3
Custom4
1700
2700
3700
1750
2750
3750
1800
2800
3800
1850
2850
3850
1900
2900
3900
1950
2950
3950
1540
2550
3550
2
2600
3600
3
Velocity
Parameters
Setup
1
2
3
Back
4
5
6
Esc
7
8
9
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0
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.
Enter
Save
Cancel
1
2
3
4
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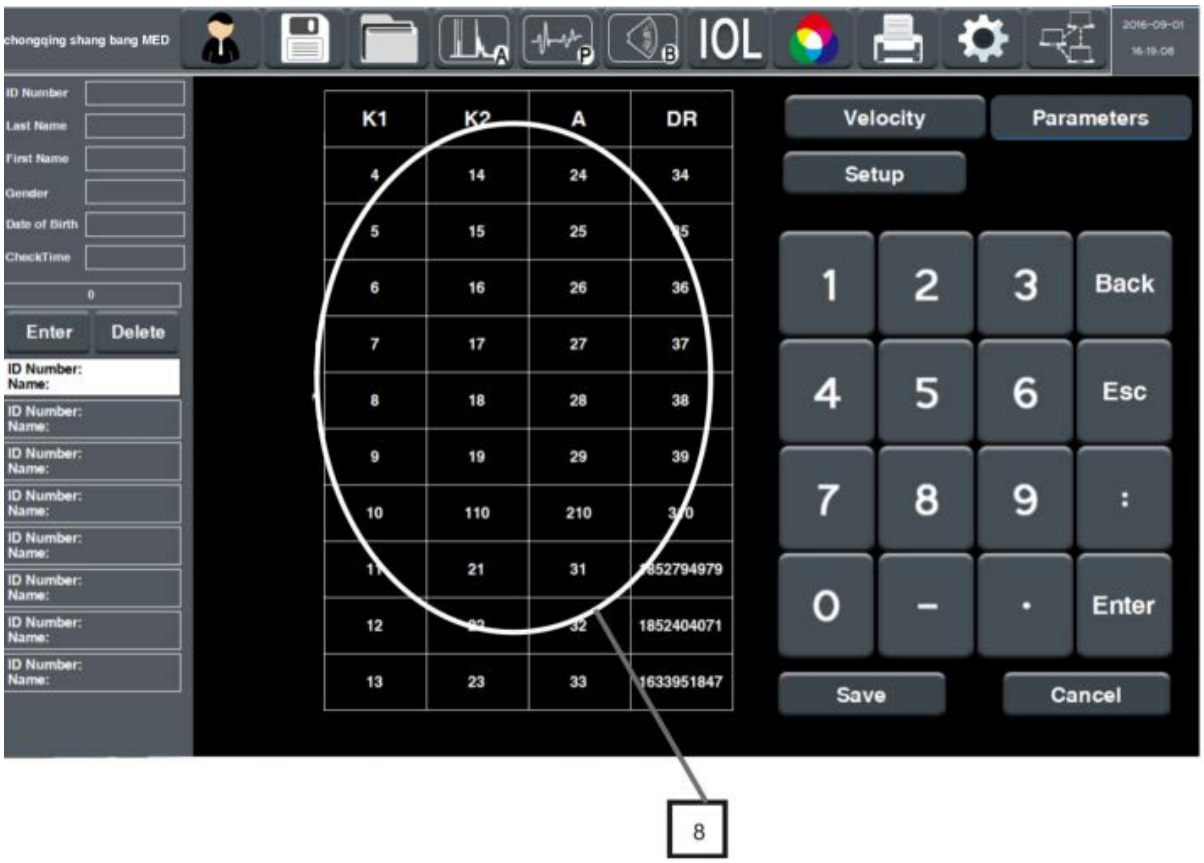
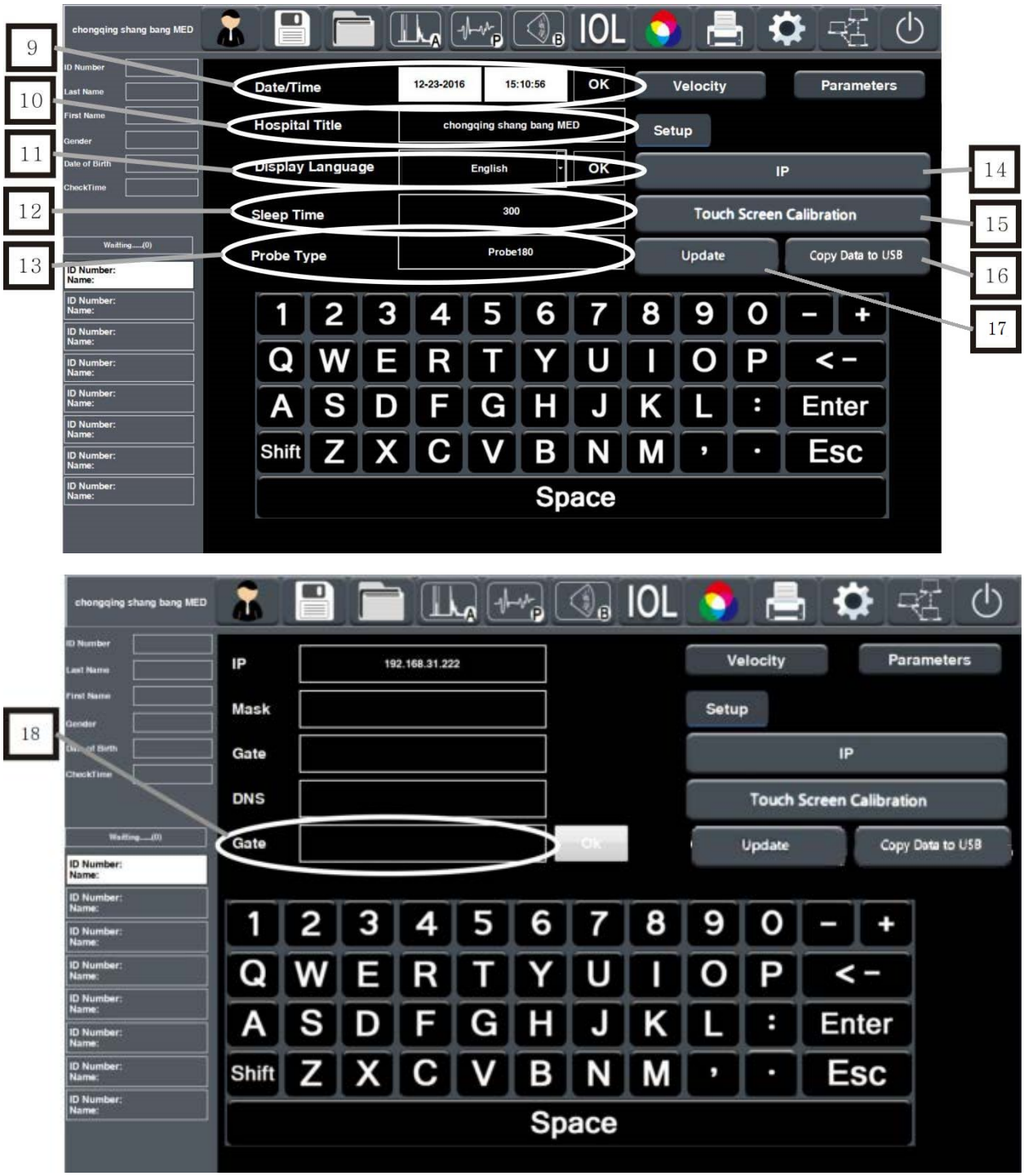
6
7


chongqing shang bang MED
IOL
2016-09-01
16:19:08
ID Number
Last Name
First Name
Gender
Date of Birth
CheckTime
Enter
Delete
ID Number:
Name:
K1
K2
A
DR
4
14
24
34
5
15
25
6
16
26
36
7
17
27
37
8
18
28
38
9
19
29
39
10
110
210
11
21
31
1852794979
12
32
1852404071
13
23
33
1633951847
Velocity
Parameters
Setup
1
2
3
Back
4
5
6
Esc
7
8
9
:
0
–
.
Enter
Save
Cancel
8



1. Velocity（For velocity in different types of lens）
2. IOL calculation preset parameters setting
3. System setting
4. Keyboard zone
5. Save, can save parameter setting.
6. Cancel
7. Tissue velocity versus different lens type and customize type display zone: you can

modify the preset value.

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

9. System time

10. Hospital name set, click Save button on the top of screen, the set will be saved.

11. System language setting.

12. Probe sleep time setting.

13. Probe type selection

14. IP setting of PLC: click the button to set the PCL IP address , PLC and PC should be set in same network segment.

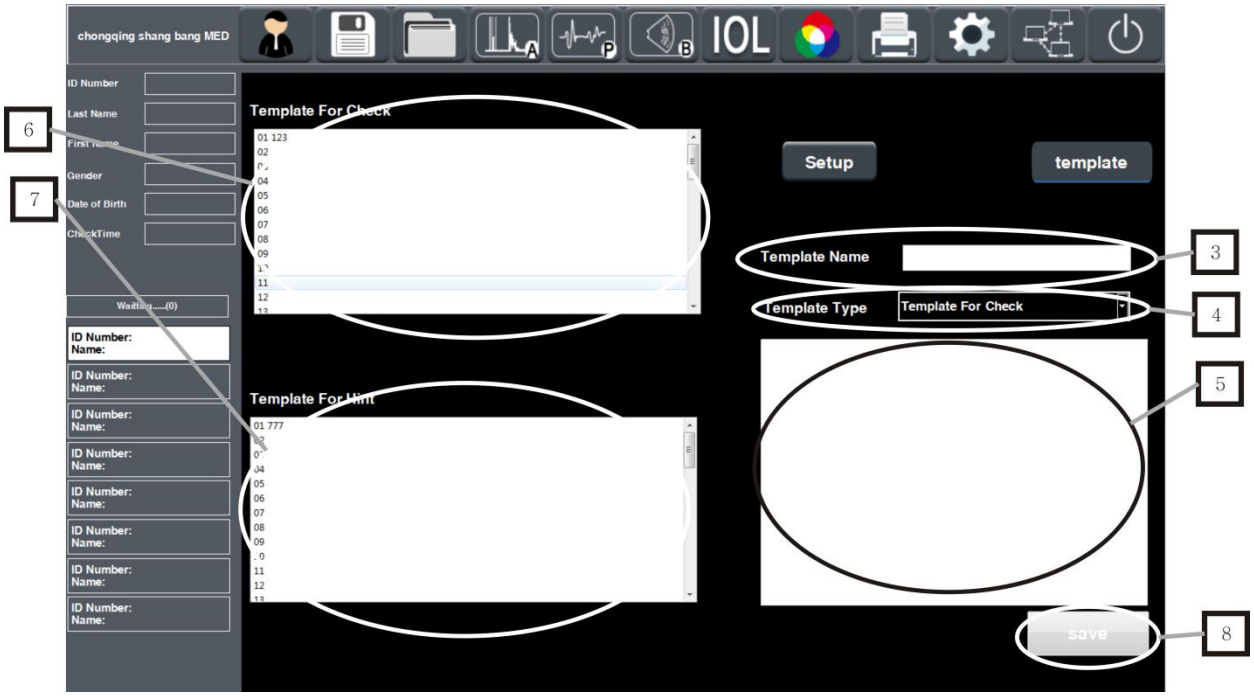
15. Touch screen calibration

16. Database back up: insert USB-disk into PLC(USB-disk must be FAT32),click this button to back up the database into USB-disk .

17. Update: User can put the upgrade file into the “update” folder , then copy the folder into USB-disk(USB-disk type must be FAT32), then insert the USB into PLC , click “update ” to do upgrade.

18. Machine S/N number: every machine has it’s own unique code.

PC setting interface



1. Diagnostic template setting button

2. IP setting of PC: click to enter IP setting of PC ,PLC and PC should be set in same network segment.

3. Diagnostic template name edit

4. Diagnostic template type selection

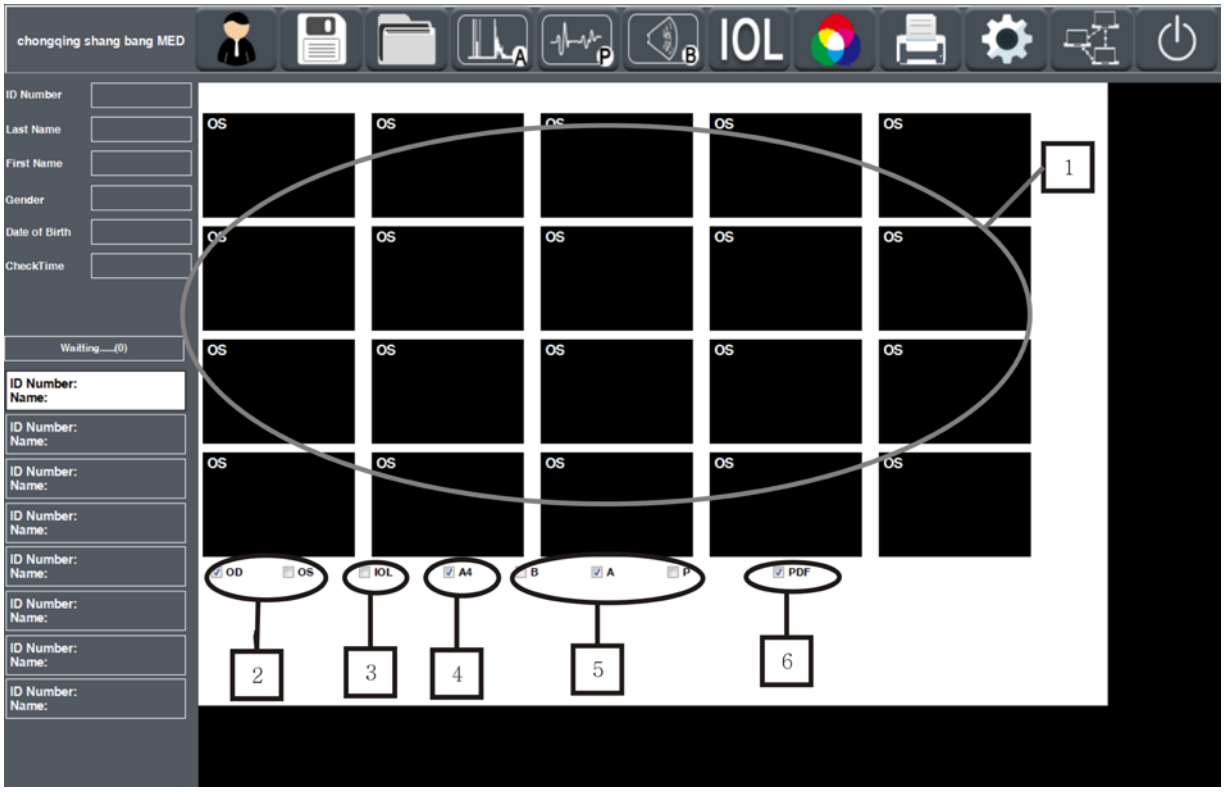
5. Diagnostic template content edit

6. Input ultrasonography description list

7. Input diagnostic opinion list

8. Save button

4.10 Print Selection Interface of PC



1.Choose B-scan ultrasound pictures. Click to select the B-scan ultrasound pictures that need to be printed or exported.

2. OD/OS selection.

3. Select IOL to print.

4. Paper selection, if ticked, is A4 paper, if not ticked, is A6 paper.

5. Test mode selection, tick to print the corresponding check results.

6. Export the PDF option, select the report that needs to be exported, tick the PDF option, click the print button, you can export the check results to PDF format, export the path to the pdfs folder in bin folder, if there is no pdfs folder under bin file, you can create a new pdfs folder.

CHAPTER 5 OPERATING INSTRUCTION

5.1 Software Instruction

5.1.1 Software Name: Ophthalmology AB-scan ultrasound testing system software, software model: SK-3000A

5.1.2 Software Release Number: V1.1.4 date: 2018.02.01

5.1.3 Software Provider

Name of Operating Software Provider: Chongqing Sunkingdom Medical Instrument Co., Ltd.

Operating Software Provider Address: Yingtian Guangdian Gonggu 35-2, Caijiagang Town, Beibei District, Chongqing

The software is expected to be used in conjunction with AB-scan ophthalmic ultrasound diagnostic instrument, and is an embedded software component of the equipment.

5.1.4 Software Support

Chongqing Sunkingdom Medical Instrument Co., Ltd. provides technical support and training for software users, while continuing to upgrade and optimize the operation software.

5.2 PC Software Installation

1) Double click to install the software

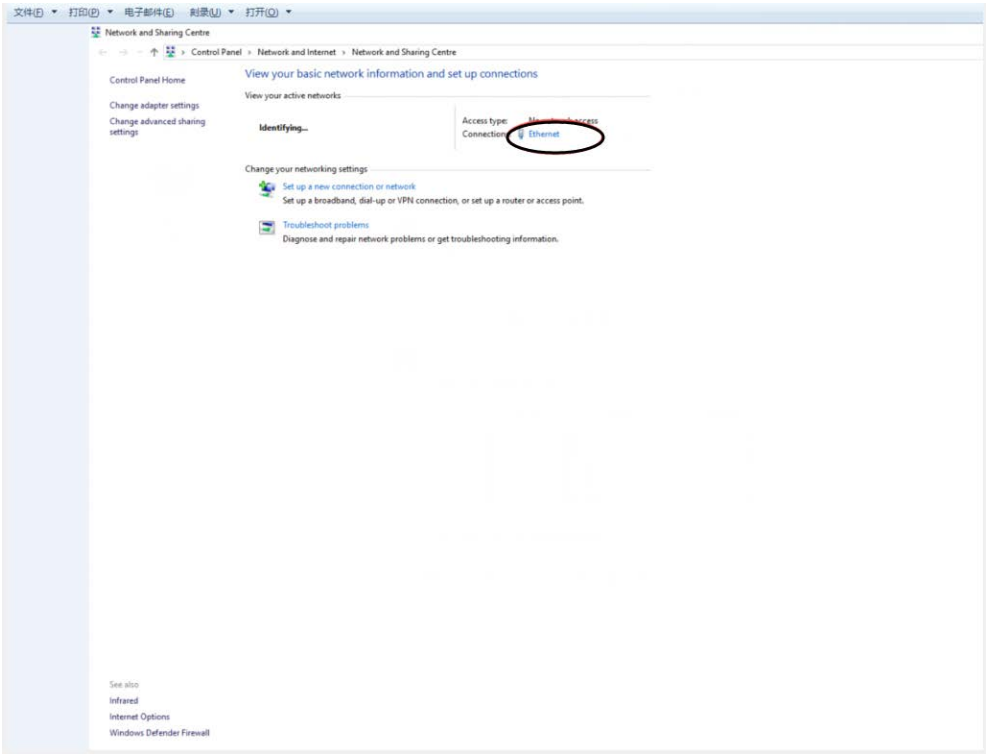
2) Click Next follow the installation steps.

3) Choose Local Disk (C:) as install file path .

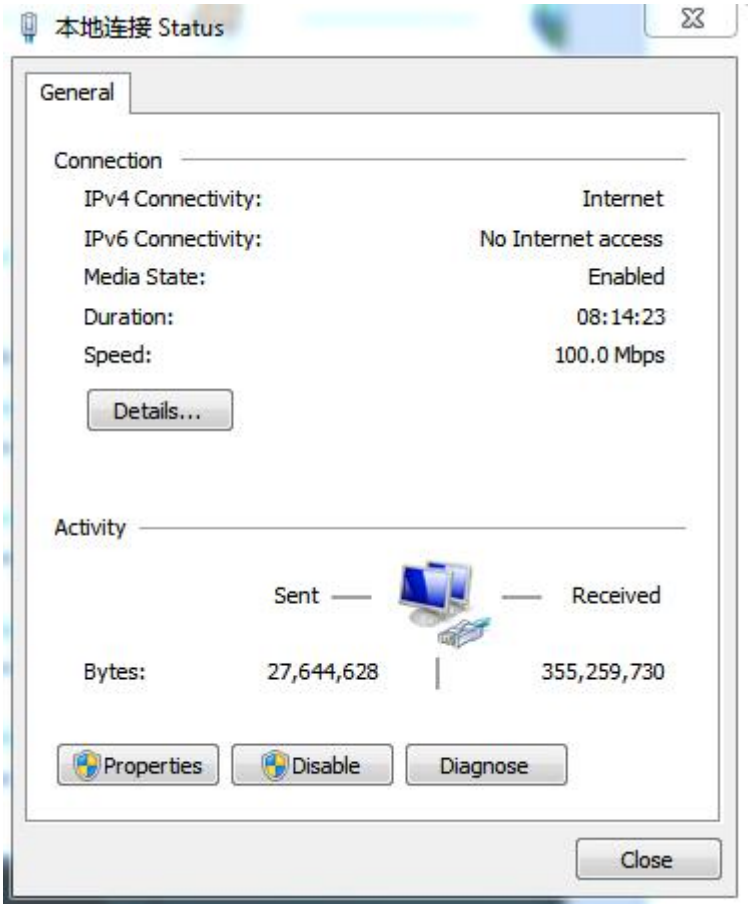
5.3 IP Settings of Upper Computer Software

5.3.1 IP settings of direct connection between PC and PLC(Open the PLC , connect PC with cable)

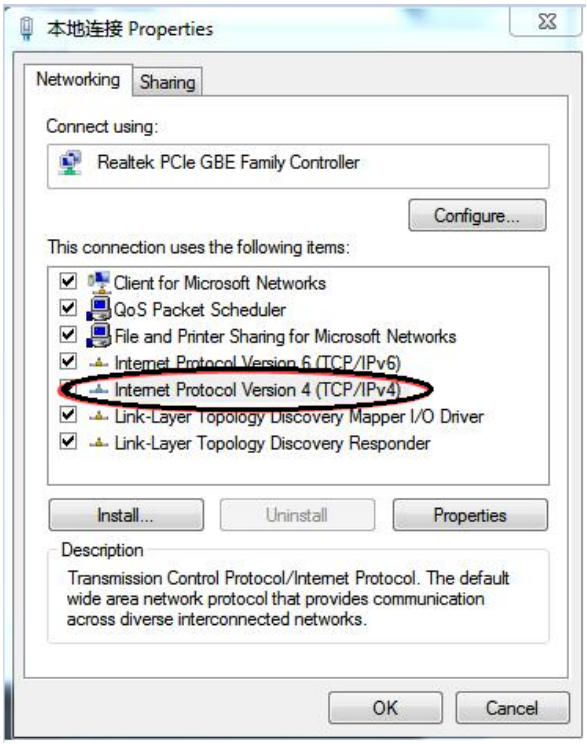
1) Open Network and sharing center, click Local connectivity, as below picture show.



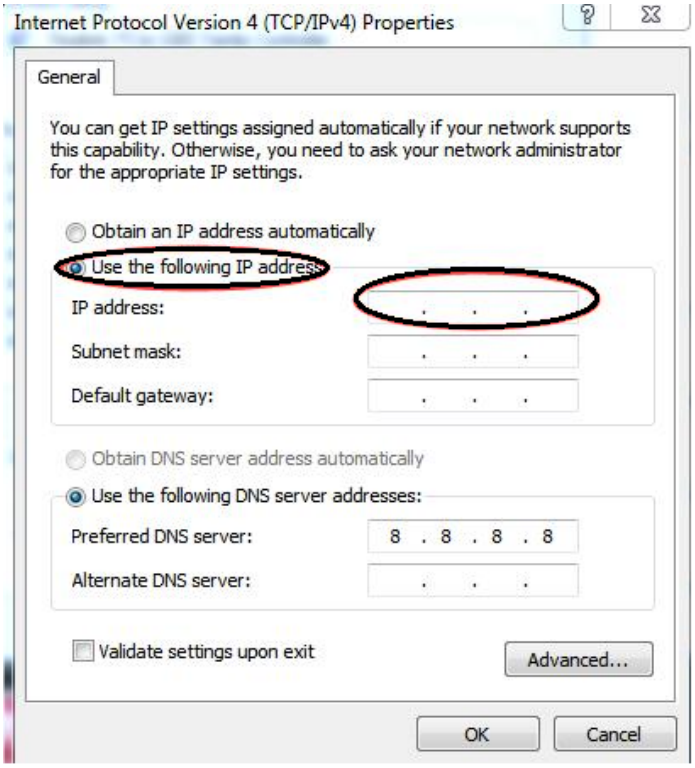
2) Click Properties



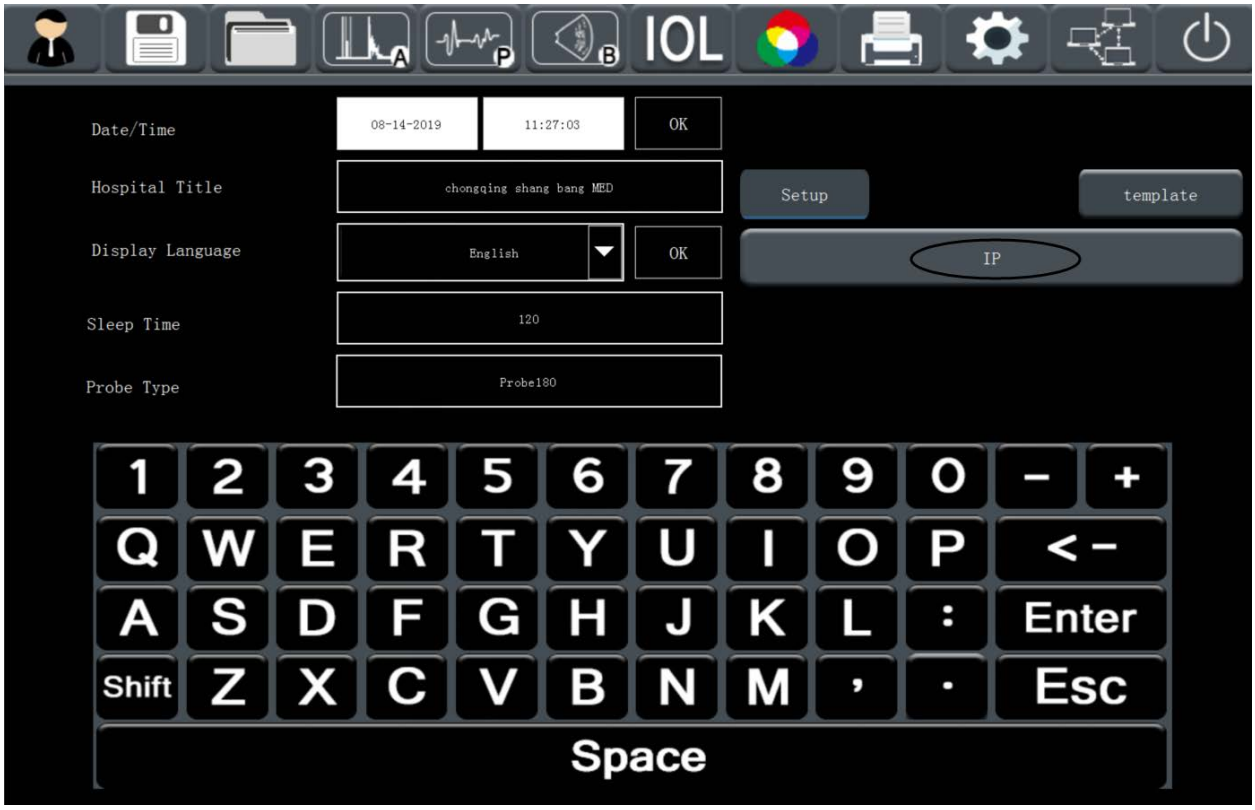
3) Double click “Internet protocol version 4（ICP/IPv4）”



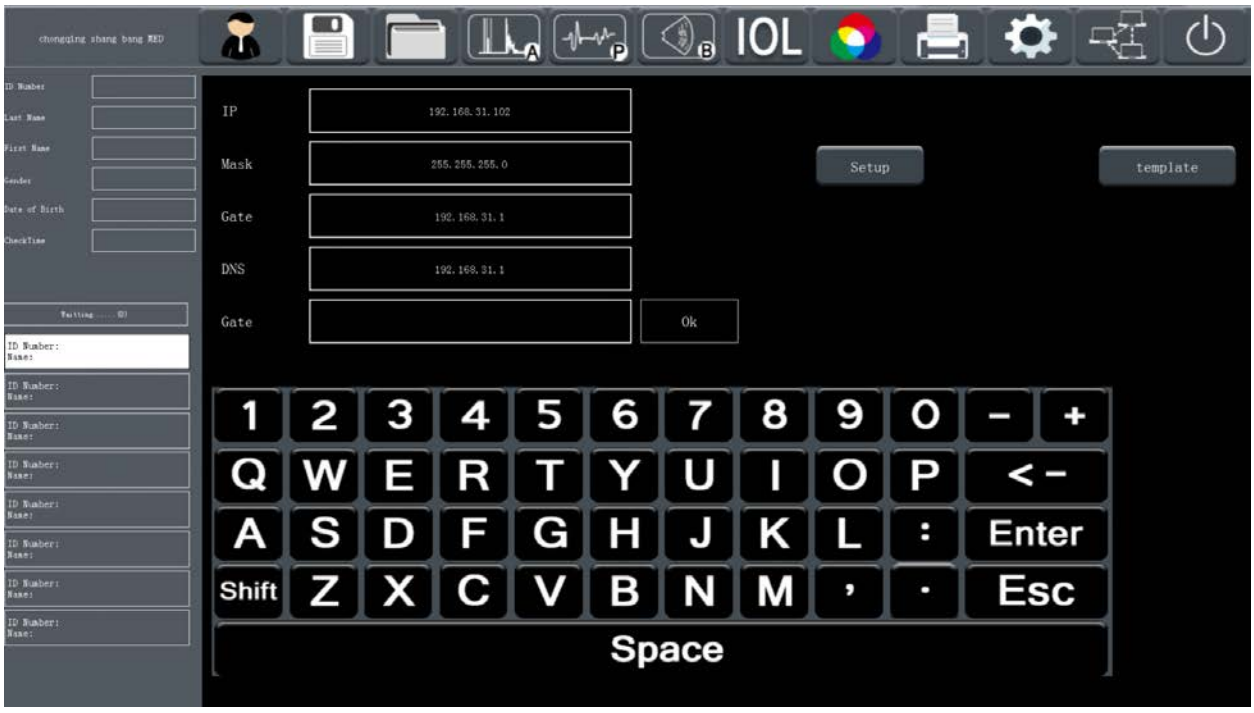
4) Select ”Use the following IP address”, input the IP address(PLC and PC should be set in same network segment, check the IP address of PLC in IP setting of PLC.)



5) Open the PC software, click”Setup”, enter IP setup, see in below image.



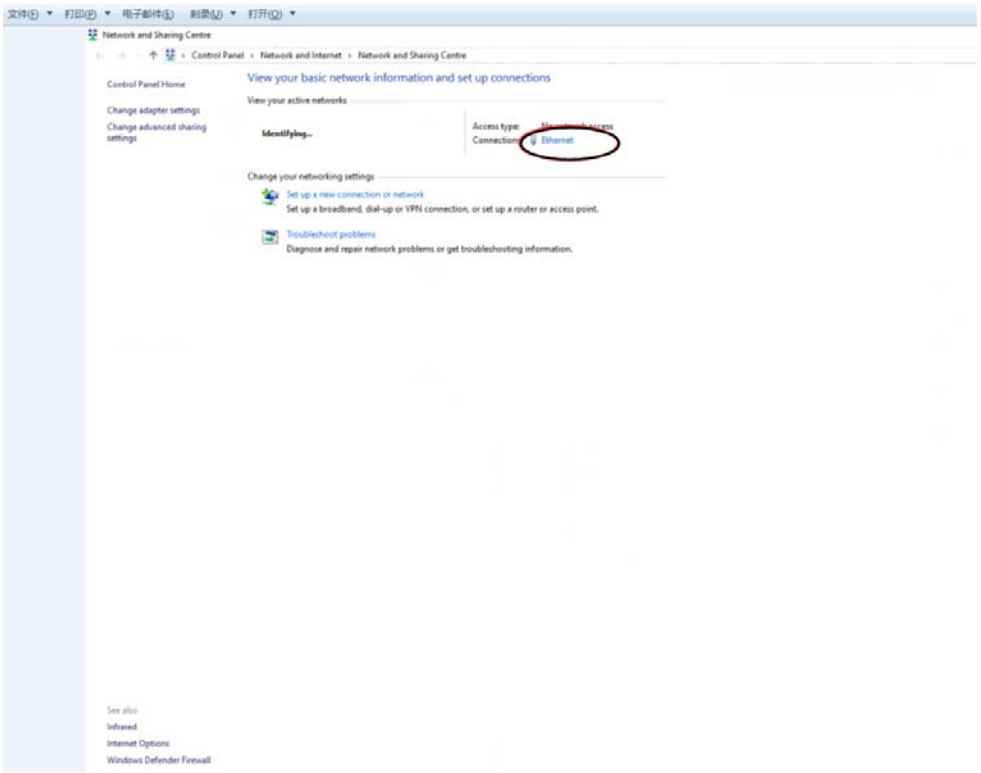
6）Input the IP value, Mask value, Gate value, DNS value in PLC IP setup to corresponding position in PC software, click“OK”，finish setting.



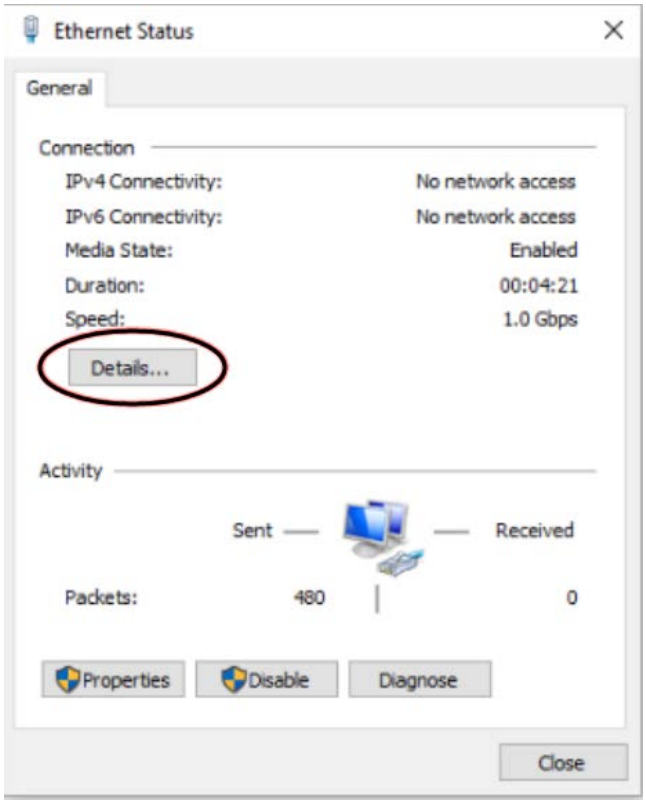
5.3.2 IP Settings of PC and PLC Connected by Router

1）Before setting up IP, connect the PC and PLC to the router with the network cable, respectively.

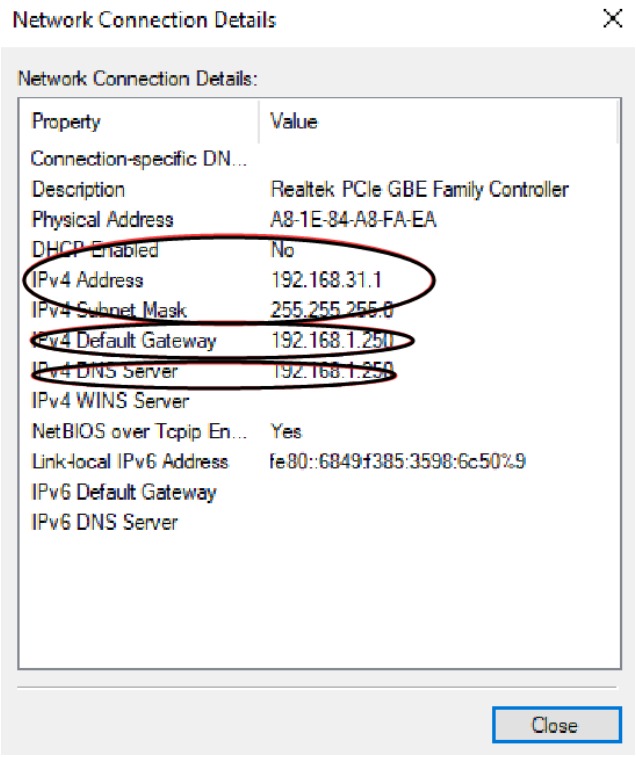
2）Open the computer's “network and sharing center” and click on the local connection, as shown below



3）Click “details” , as shown below

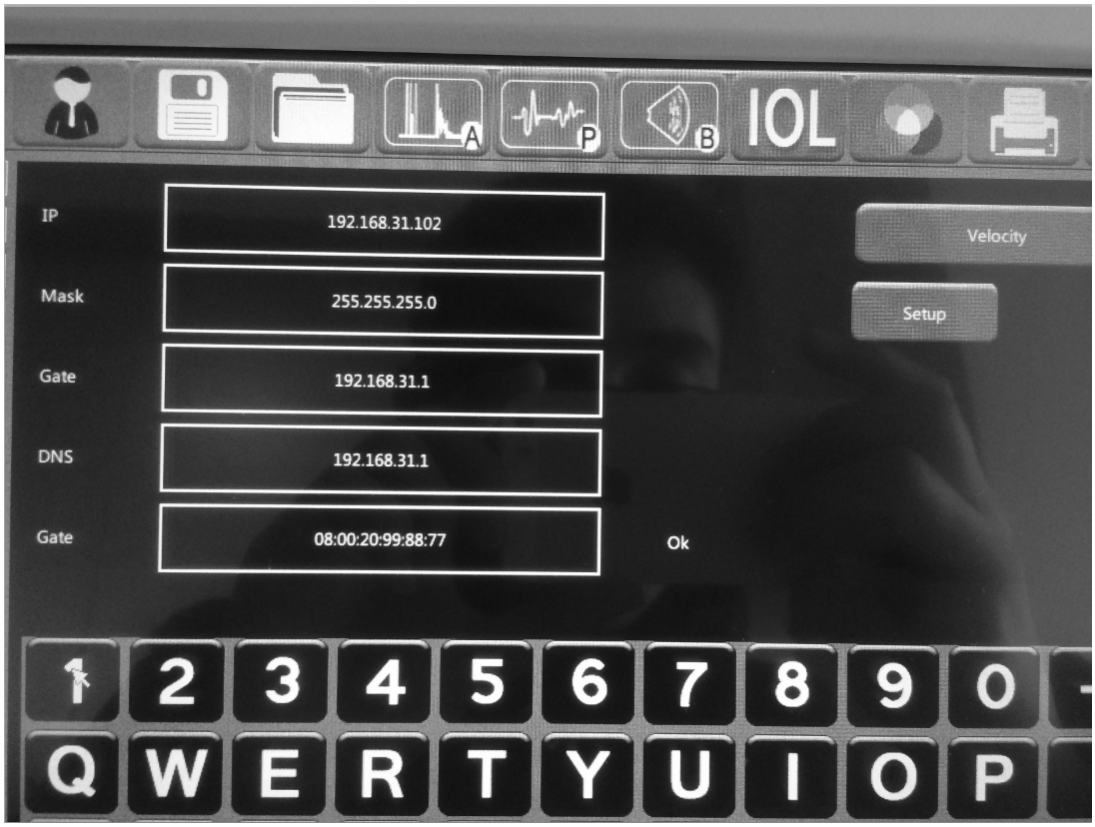


4）Record the values of "IPv4 address", "IPv4 subnet mask", "IPv4 default gateway", "IPv4 DNS server"

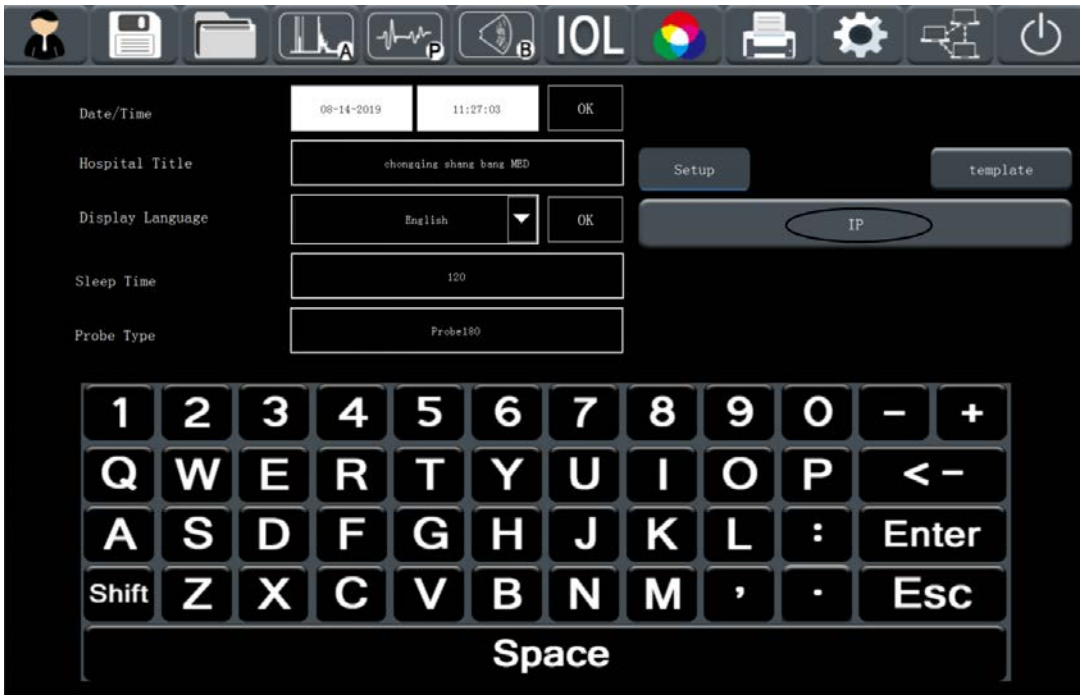


5）Open PLC, click “setup”, then click “IP”, as show below.

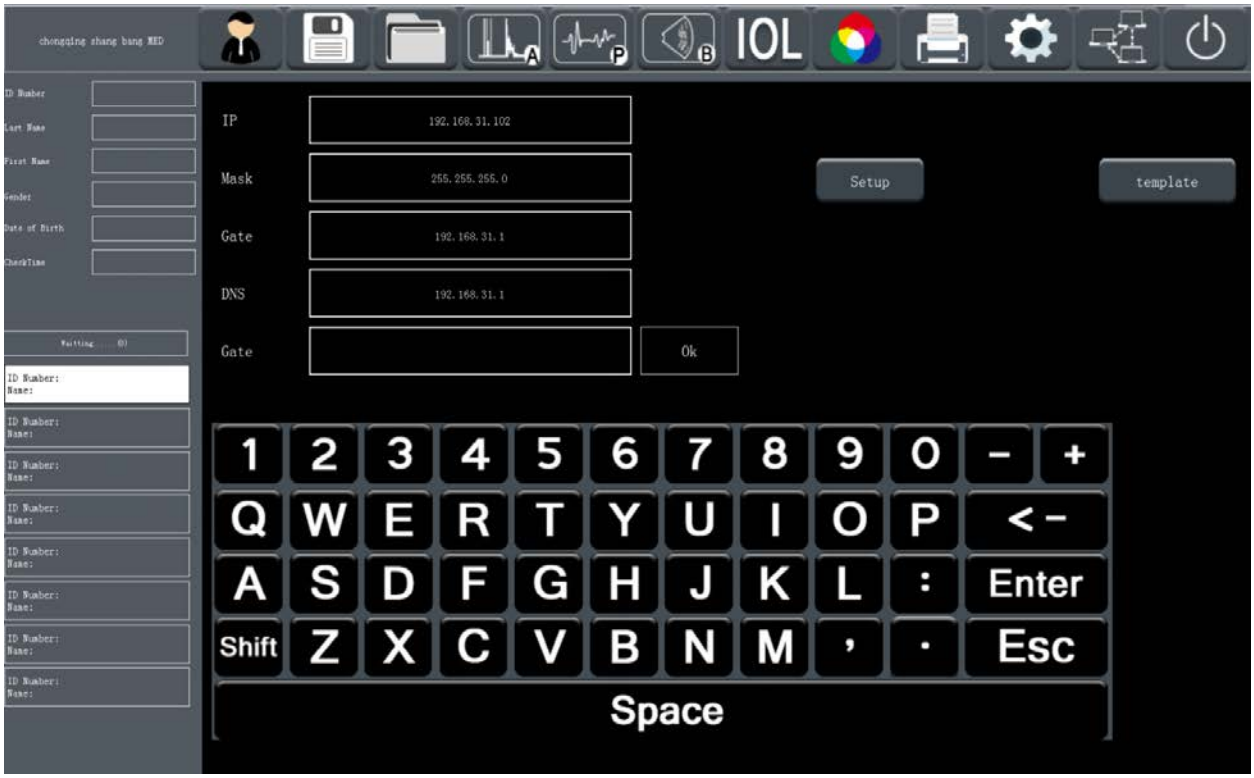
6）PLC’s IP fills in the address of the same network segment as IPv4 address, Mask fills in the value of IPv4 subnet mask, Gate fills in the value of IPv4 default gateway, DNS fills in the value of IPv4 DNS server, click "ok"



7）Open PC software, click “setup”, enter “IP”, as show below



8）Input the IP value, Mask value, Gate value, DNS value in PLC IP setup to corresponding position in PC software, click“OK”，finish setting.



5.4 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 cap, 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 patient eyelid，instruct the patient focus on the red light in central probe or look upward，step on foot pedal or press the “Start” icon ,then place the probe tip gently on the patient's corneal vertex to 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 records are captured.

8) After measurement completed, one can re-position 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 (pic 1).

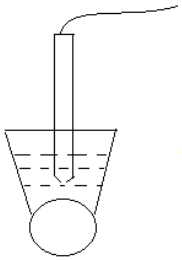


图1

Pic 1

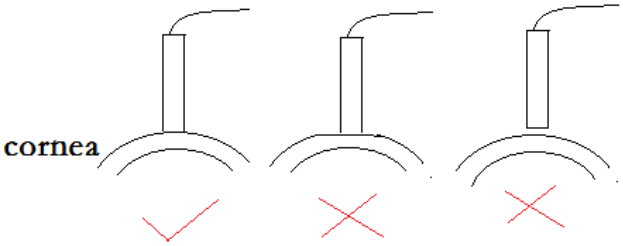


图2

Pic 2

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

5.5 IOL Calculation

1) When A-scan measurement is completed, click “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.

5.6 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 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 set parameter, take down the probe cover, clean the surface of Pachymetry 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 P-scan.

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) Click “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.

5.7 B-scan Measurement

1) Connect all lines well.

2) Open the main machine power to enter home interface.

3) Click “New” to input patient information.

4) Click B-scan mode to do B-scan testing.

5) Select the B-scan probe type, test mode (B-scan mode / B+A mode), adjust the gain value (also can adjust during test process)

6) Take down the probe cap, clean the surface of B-scan probe tip with normal saline,patient lying flat on the examination bed, apply appropriate ultrasound couplants on eyelid .

7) Step on foot pedal one time or click Start , put the probe on the eyelid vertically , at the same time , observe the screen and adjust the position of probe until you can see the retina , lens clearly ,step on the foot pedal again , or click “Stop” to finish a test.

8) After testing , you can delete bad images and re-test until capture perfect B-scan ultrasonoscopy.

9) After testing, if you want playback the ultrasonoscopy, just click “Cineloop sequence” to make it.

10) If you want to do post-processing, please enter the B-scan image post-processing interface.

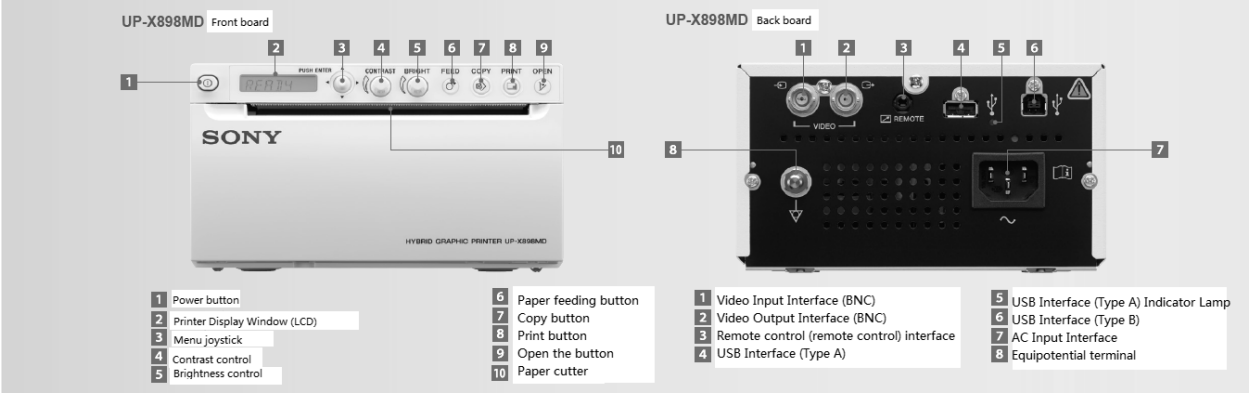
5.8 Use Of Calibration Cylinder

1) Turn on main machine power supply.
2) Enter main screen and select “calibrate” mode in lens type drop-down menu .when calibrate with p scan , set the velocity as 2381m/s.
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 vertically to the cylinder , step on foot pedal to collect the echogram.

Note：Calibration cylinder using environment are within 25°C±5°C interior, the data measured by cylinder can’t be saved , if you need do next test ,just clear all data.

CHAPTER 6 PRINTER INSTRUCTION & REPLACE PAPER

6.1 Printer Button

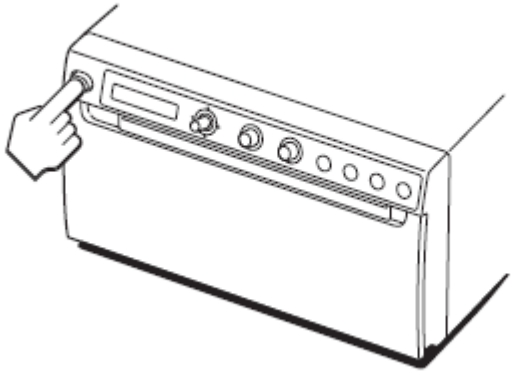


6.2 Printing Paper Specification

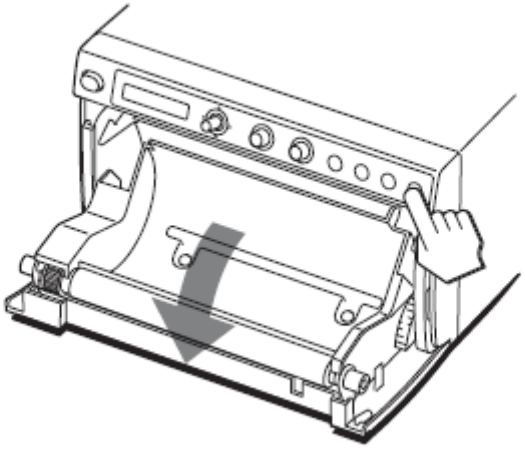
Printing paper width is 110mm,thermal printing paper.

6.3 Method to Change Printing Paper

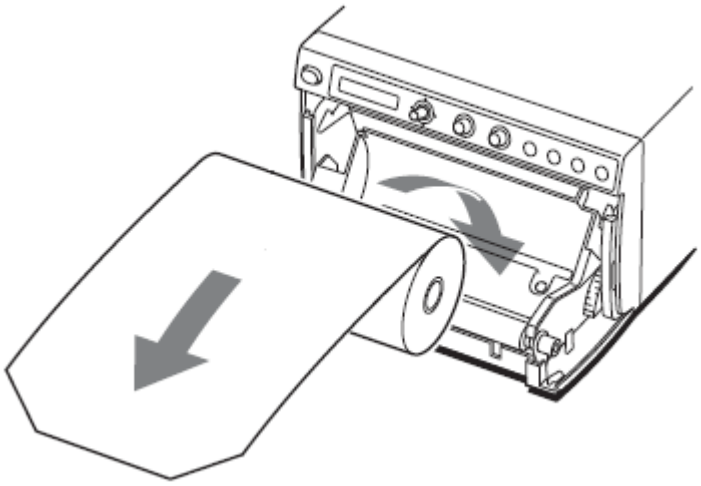
1) Press power switch button ,open the machine ,when there is no paper inside ,the LCD is in Orange and show message “EMPTY.”



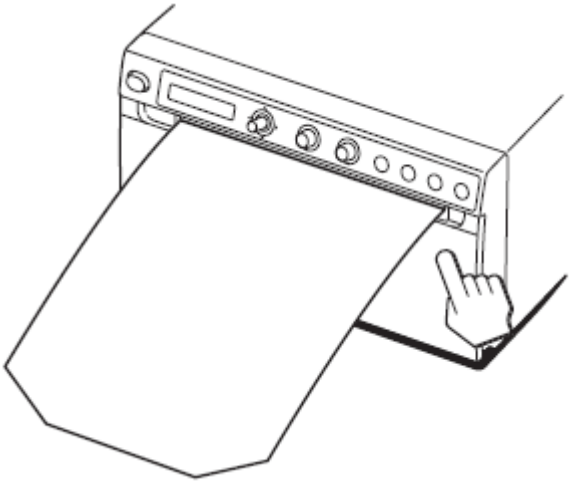
2) Press OPEN button to open the paper box.



3) Tear off the printer paper's label, reserve 15--20cm length paper out, then roll the paper into paper repository. (notice: keep the front side upward , if not , the print can't success.)



4) Pull the plate to close it.



CHAPTER 7 EQUIPMENT MAINTENANCE

7.1 Daily Maintenance

 Warning: The AC power supply should be disconnected before wiping the equipment.

 Warning: The AC power supply should be disconnected every time the equipment shuts down.

The use environment should be kept clean and dry, and the room should be well ventilated. The surface of the instrument should be wiped gently with a clean dry towel to avoid dust contamination. Ultrasound A, B and P probe belong to high precision instruments. After use, they should be cleaned, disinfected and put back into the probe rack.

 Warning: Touch screen is easily damaged. Only use wet cloth to wipe. Solvents or alcohol should not be used.

7.2 Maintenance in Process Of Working

When working , there should be no interference from strong noise , light , electricity and magnetism. Keep this device from this kind of environment when working, or the performance of device would be affected.

7.3 Maintenance of Probe

The probe is fragile and should be operated carefully. If it falls on a hard surface, it will be damaged.

Regular inspection:

Check the connection of the probe and whether there are cracks in the probe itself. Cracks can lead to liquid infiltration.
The probe should be checked regularly to ensure that the membrane is not damaged.

If you suspect that there is a problem with the probe, please do not use it. Contact the local distributor or the after-sales service department of Chongqing Sunkingdom Medical Instrument Co., Ltd. (Tel: +86 23-68102805).

Do not use high pressure method to sterilize probe.

7.4 Maintenance During Long-term Non-use

Before long-term shutdown, the instrument should be cleaned and wiped, then covered with clean sheets or polyethylene film, wrapped, or dismantled.
In order to protect the housing, do not use friction cleaning tools. If possible, remove stains before drying.

7.5 How to Prevent Cross Infection of 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. When cleaning, follow the label instructions. Other FDA-licensed disinfectants can also be used.

The probe cannot be completely immersed - only the tip of the probe can be disinfected in a disinfectant solution. The maximum immersion depth of the probe is 5 cm.

 Connectors cannot be immersed. It is not possible to sterilize probe or wire under high pressure.
After cleaning, the end of the probe is thoroughly cleaned with normal saline, and all remaining liquids are washed away.

Follow the instructions on the disinfectant label.

Dry the surface with a non-cotton lint cloth.

7.6 Common Faulty Troubleshooting

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

For ordinary malfunction users can remove it by themselves. If there are other malfunctions, please contact our company to solve them.

7.7 Parts Replacement

Customerte can repair or replace the parts information by itself (must use the specified model of our company)

1. Safety Pipe Type and Rating: F1AH250V (Fuse must meet the requirements of GB 9364)

Note: When replacing the fuse, first disconnect the power supply and open the fuse box for replacement.

2. A-scan probe (10MHz), Pachymetry probe (20MHz) and B-scan probe (10MHz);

3. Foot switch (model: TFS-1);

4. Thermal Printing Paper: Thermal Printing Paper with 110 mm Width

5. Relevant technical drawings and circuit diagrams for maintenance can be provided if users need them.

7.8 Waste Disposal

During the normal operation and maintenance of the equipment, the replaced components or other wastes should be properly handled according to the requirements of local laws and regulations, and can 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. In order to avoid causing environmental pollution.

7.9 Manufacturer Responsibility

The manufacturer is responsible for the safety and reliability of the equipment only in the following circumstances:

—— Assemblies, additions, commissioning, modifications or maintenance are carried out by approved personnel.

—— The electrical facilities in the rooms concerned meet the relevant requirements.

—— The equipment is used according to the instructions.

CHAPTER 8 ANNOUNCMENT OF PROBE SOUND WAVE OUTPUT

Mechanical Effect and Thermal Effect

Research indicates that two different ultrasonic properties influence human body:one is when ultrasonic negative pressure exceeds some limited number,air pocket forms mechanical effect;another is when tissues absorb ultrasonic,appearance of heat energy of ultrasonic may cause thermal effect.two parameters which are mechanical index MI and thermal index TI can explain two types of effects influencing level,the smaller value of MI/TI is,the less bio effect produce.

 **Attention:**

1. The nature of the transducers within the probes is such that degradation can occur over extended lengths of time.The sensitivity test can determine the sensitivity of probes,and should be performed before each use.
2. The results of the sensitivity tst can not meet the requirements ,indicating it may not be sensitive enough to perform accurate scans.Is general this is due to a loss of sensitivity in the probe .If this is the case the probe should be replaced . However,in order to confirm that it is the probe which is the case of the problem,it is necessary for evaluation by SunKingdom Company.

Tissues Exposed to Ultrasound Energy

SK-3000A equipment can only be used in ophthalmology, with A-scan and B-scan probes.

 Warning: This device cannot be used for infants.

Warning section (as low as possible):

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

Except for the length of irradiation time, the user can not control the ultrasonic energy. However, in order to reduce exposure, the measurement time can be as short as possible.

Sound wave output announcement:

B-scan Sound wave output announcement	**A-scan Sound wave output announcement**
1、maximum power（mW） 1.2Mw	1、maximum power（mW） 0.091
2、p_(Mpa) 2.33Mpa	2、P_(Mpa) 2.08
3、Iob(mW/ cm^2) 2.38	3、Iob(mW/ cm^2) 0.94
4、Ispta (mW/ cm^2) 4.79	4、Ispta (mW/ cm^2) 1.12
5、System setup	5、System setup
6、Lp (㎜) 30	6、Lp (㎜) 5
7、Wpb6(㎜) (Ⅱ)： 5.2 （⊥）： 2.8	7、Wpb6(㎜) (Ⅱ)： 1.59 （⊥）： 3.05
8、prr(kHz) not applicable	8、prr(kHz) 0.6
9、srr(Hz) 14.28	9、srr(Hz) not applicable
10、Output wave beam size（cm^2）0.5024	10、Output wave beam size（cm^2）0.0962
11、fawf(MHz) 9.36	11、fawf(MHz) 8.5
12、APF not applicable	12、APF not applicable
13、Boot mode not applicable	13、Boot mode not applicable
14、AIF not applicable	14、AIF not applicable
15、Initial mode not applicable	15、Initial mode not applicable
16、Sound wave output freeze Yes	16、Sound wave output freeze Yes

CHAPTER 9 EMC INFORMATION REQUIREMENTS

For this equipment, special precautions concerning electromagnetic compatibility (EMC) should be taken, and the equipment must be installed and used according to the EMC information specified in this specification.
Portable and mobile radio frequency communication equipment may have an impact on the equipment.

In addition to the cables (transducers) sold as spare parts of internal components, the use of accessories and cables (transducers) other than those specified may lead to an increase in equipment or system emission or a decrease in immunity.

Devices or systems should not be used close to or overlay other devices. If they must be used close to or overlay, they should be observed and verified to operate normally under the configuration they are using.

<table>
<tr><td colspan="3">Guidelines and Manufacturers'Statements - Electromagnetic Launch
The equipment is expected to be used in the electromagnetic environment specified below, and the purchaser or user shall ensure that it is used in such an electromagnetic environment:</td></tr>
<tr><th>Launching test</th><th>Conformity</th><th>Electromagnetic Environment - Guide</th></tr>
<tr><td>radio-frequency emission
CISPR 11</td><td>1group</td><td>The AB-type ophthalmic ultrasound diagnostic instrument (SK-3000A) uses radio frequency energy only for its internal functions, so its radio frequency emission is very low and the possibility of interference to nearby electronic equipment is very small</td></tr>
<tr><td>radio-frequency emission
CISPR 11</td><td>A type</td><td rowspan="3">Ophthalmological AB-type ultrasound diagnostic instrument (SK-3000A) is suitable for use in all facilities which are not directly connected with the public low-voltage power supply network of household and non-household houses.</td></tr>
<tr><td>Harmonic radiation
IEC 61000-3-2</td><td>applicable</td></tr>
<tr><td>Voltage fluctuation/scintillation emission
IEC 61000-3-3</td><td>applicable</td></tr>
</table>

Guidelines and Manufacturers'Statements - Electromagnetic Immunity

The Ophthalmological AB-type Ultrasound Diagnostic Instrument (SK-3000A) is expected to be used in the following specified electromagnetic environment, and the purchaser or user shall ensure that it is used in such an electromagnetic environment:

Immunity Test	**IEC60601 Test Electrical level**	**Conformity Electrical level**	**Electromagnetic Environment - Guide**
electrostatic discharge（ESD） IEC61000-4-2	±8kV Contact discharge ±15kV Air discharge	±8kV Contact discharge ±15kV Air discharge	The floor shall be of wood, concrete or ceramic tiles. If the floor is covered with synthetic materials, the relative humidity shall be at least 30%.
electrical fast transient IEC61000-4-4	±2kVTo power cable ±1kV To input/output cable	±2kV To power cable	Network power supply should have the quality to be used in typical commercial or hospital environments
Surge IEC61000-4-5	±1kV cable to cable ±2kV cable to ground	±1kV Difference Patterns	Network power supply should have the quality to be used in typical commercial or hospital environments
Voltage sags, short interruptions and voltage variations on power input lines IEC61000-4-11	< 5% U_T，last 0.5 cycle(on U_T ， > 95% sag) 40% U_T，last 5cycle(on U_T ， 60% sag) 70% U_T，last 25 cycles(on U_T ， 30% sag) < 5% U_T，last 5s (on U_T ， > 95% sag)	< 5% U_T，last0.5 cycle(on U_T ， > 95% sag) 40% U_T，last 5 cycle(on U_T ， 60% sag) 70% U_T，last 25 cycle(on U_T ， 30% sag) < 5% U_T，last 5s On U_T ， > 95% sag)	Network power supply should have the quality to be used in typical commercial or hospital environments. If the users of the ophthalmic AB-type ultrasound diagnostic instrument (SK-3000A) need to run continuously during power interruption, it is recommended that the ophthalmic AB-type ultrasound diagnostic instrument (SK-3000A) be powered by uninterrupted power supply or battery.
Power frequency magnetic field （50/60Hz）	3 A/m	3 A/m	The power frequency magnetic field should have the horizontal

IEC 61000-4-8			characteristics of the power frequency magnetic field in typical commercial or hospital environments.
Note：U_TRefers to the AC network voltage before the test voltage is applied.			

Guidelines and Manufacturers'Statements - Electromagnetic Immunity

The Ophthalmological AB-type Ultrasound Diagnostic Instrument (SK-3000A) is expected to be used in the following specified electromagnetic environment, and the purchaser or user shall ensure that it is used in such an electromagnetic environment:

Immunity Test	**IEC60601 Test Electrical level**	**Conformity Electrical level**	**Electromagnetic Environment - Guide**
Radiofrequency conduction IEC61000-4-6	3 V（Effective value） 150kHz - 80MHz	3 V（Effective value）	Portable and mobile radio frequency communication devices should not be used closer to any part of the device, including cables, than recommended isolation distances. The distance is calculated by a formula corresponding to the transmitter frequency. Recommended isolation distance $d = 1.2\sqrt{P}$ 150kHz-80MHz $d = 1.2\sqrt{P}$ 80MHz-800MHz $d = 2.3\sqrt{P}$ 800MHz-2.5GHz
Radiofrequency radiation IEC61000-4-3	3 V/m 80MHZ - 2.5GHZ	3 V/m	In formula： P——According to the maximum rated output power of the transmitter provided by the transmitter manufacturer, in Watt (W)； d——The recommended isolation distance is in meters (m). Fixed RF transmitter field strength is determined by electromagnetic field

			survey [a], which should be one [b] lower than the corresponding level in each frequency range. Disturbance may occur near equipment marked with the following symbols. 

Note 1： The formula of higher frequency band is used at 80MHz and 800MHz frequencies.

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.

[a] Fixed transmitters, such as base stations of wireless (cellular/cordless) telephones and ground mobile radios, amateur radios, AM and FM radio broadcasting and television broadcasting, can not accurately predict their field strength in theory. In order to evaluate the electromagnetic environment of fixed radio frequency transmitter, the survey of electromagnetic field should be considered. If the field intensity of SK-3000A is higher than that of RF, the equipment should be observed to verify its normal operation. If abnormal performance is observed, supplementary measures may be necessary, such as reorientation of the direction or position of the ophthalmic AB ultrasound diagnostic instrument (SK-3000A).

[b] In the whole frequency range of 150 kHz-80 MHz, the field intensity should be less than 3V/M

Recommended Isolation Distance between Portable and Mobile Radio Frequency Communication Equipment and Ophthalmic AB Ultrasound Diagnostic Instrument (SK-3000A)

Ophthalmological AB-type ultrasound diagnostic instrument (SK-3000A) is expected to be used in radio frequency radiation disturbance controlled electromagnetic environment. According to the maximum rated output power of communication equipment, the buyer or user can prevent electromagnetic interference by maintaining the minimum distance between portable and mobile radio frequency communication equipment (transmitter) and ophthalmic AB ultrasonic diagnostic instrument (SK-3000A) recommended below.

Maximum rated output power of transmitter W	Isolation distance corresponding to different frequencies of transmitter /m		
	150kHz - 80MHz $d = 1.2\sqrt{P}$	80MHz - 800MHz $d = 1.2\sqrt{P}$	800MHz - 2.5GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73

1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

Note 1： At 80MHz and 800MHz frequencies, higher frequency band formulas are used.

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 emission and anti-interference requirements:

Cable name	Length
Cable（10A）	＜3m
Other	/

CHAPTER 10 WARRANTY STATEMENT

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

1. Our company will provide equipment maintenance and free consultation for life. Before contacting our company by telephone, we suggest that you confirm the following work:

●The name and model of the equipment you are using

●The factory number of the equipment you are using

●Accurate description of information displayed on screen

●What happened? What were you doing when it happened?

●What measures have you taken to solve this problem?

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

3. In accordance with the instructions and the operating precautions in the normal operation state, once the machine breaks down, please contact our company immediately.

4. The following items are not included in the warranty:

●Damage caused by failure to follow the instructions for use, maintenance and storage.

●Personnel unauthorized by Chongqing Sunkingdom Medical instrument Co., Ltd., who demolished or refitted the equipment without authorization, caused damage to the equipment.

●Damage to equipment caused by accident, misuse or irresistible natural factors.

Note: 1. The company does not bear medical liability for medical malpractice caused by non-standard operation or non-standard operation.

2. The right of final interpretation of this instruction is vested in Chongqing Sunkingdom Medical Instrument Co., Ltd. Without further notice, if any amendment is made.

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