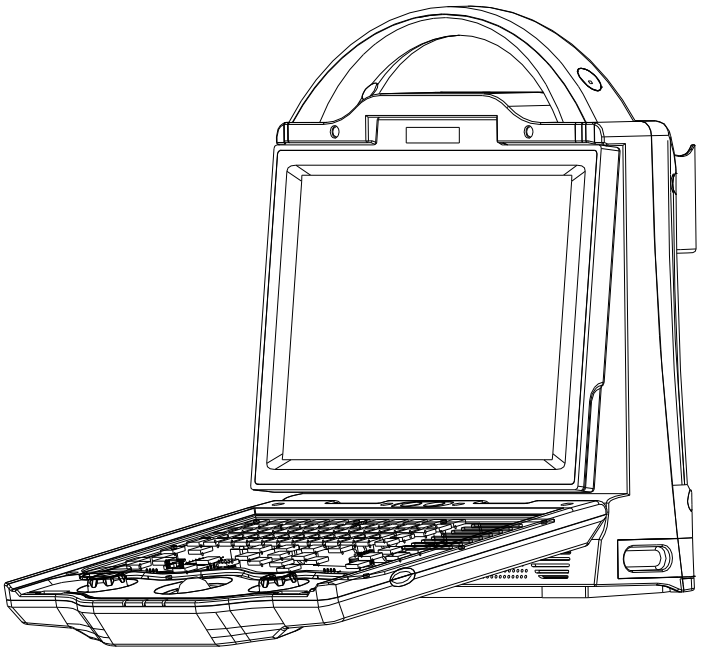
Ophthalmological A/B mode ultrasound scanner

User’s Manual



Introduction

Thank you for purchasing ophthalmological A/B mode ultrasound scanner.

Users shall carefully read through this manual and fully understand the text before operating the equipment.

Please keep this manual after reading so that you can access at any time when needed.

The user's manual issue date: June 25, 2019, Version: V1.08

For the changes of appearance, this manual is subject to change without further notice!

Statement

We have the final explanation right of this user's manual.

We were considered responsible for the safety, reliability and performance in case of meeting all the following requirements:

1. Assembly, expansion, readjustment, improve and repair are all performed by professionals recognized by us;
2. All replacement parts and accessories, consumables involved repairs are original or approved by us;
3. Related electrical equipment complies with national standards and the requirements of the user's manual;
4. Operate the product in accordance with the user's manual.

Warranty and repair service

Purchased the product warranty, sees the company's service policies.

The qualified service personnel can repair the instrument out of warranty by themselves. But this should be agreed by us. We will provide circuit diagrams, component part lists or other information to assist service personnel to repair those parts of our equipment that are designated by our company.

Important Statement

1. User shall be fully responsible for the maintenance and management of this product after purchasing this product.
2. Even in the warranty period, warranty does not include the following:
   a) Damage or loss caused by error or rough using.
   b) Damage or loss caused by force majeure (such as fires, earthquakes, floods, or lightning etc.).
   c) Damage or loss caused by not meeting the conditions of use specified by the system, such as inadequate power supply, incorrect installation or environmental conditions do not meeting the requirements.
   d) Damage or loss caused by not used the system in the initial buy region.
   e) Damage or loss caused by the system purchased not by us or its authorized dealer or agents.
3. Medical personnel qualified with professional qualifications only to use this system.
4. Do not modify the software or hardware of the equipment without authorization of the manufacturer.
5. In any case, we shall not be liable for the problems, damages or losses due to re-installation, alteration or repair the system by non-us designated personnel.
6. This product is intended to provide clinical diagnostic data for the doctor.
   The doctor shall be responsible for the diagnostic process. We shall not be liable for any problems arising out of the process.
7. Be sure to back up important data to external storage media, such as notebooks.
8. Due to operator's error or abnormal condition causing the data stored in the internal system is lost, we are not responsible.
9. This user's manual contains warnings for predictable dangers. Users shall also exercise care at any time to be aware of the dangers unforeseen in this manual. We shall not be liable for the damages and losses arising out of neglecting to follow the operation instructions herein described.
10. This user's manual shall be furnished with the machine so that managerial and operating personnel can refer to it any time as necessary. Once the managerial personnel of the system changes, it shall hand over this user's manual.
11. Deal with the exhausted product according to the local statute.
12. The maintenance and servicing of product shall be performed by professional engineer or by us.
13. Professional engineer mentioned in the user's manual is the person who has been trained and authorized by us.

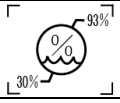
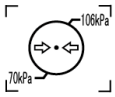
Safety Cautions

1. Warning Symbols and Definitions

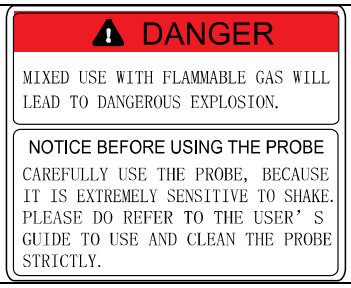
The following warning symbols are used in this manual to indicate safety level and other important items. Please remember these symbols and understand the meaning as you read this user's manual. These symbols convey specific meanings as detailed in the table below:

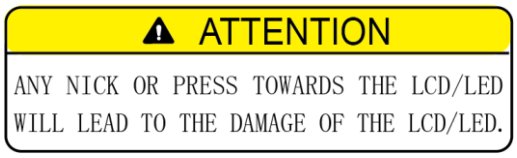
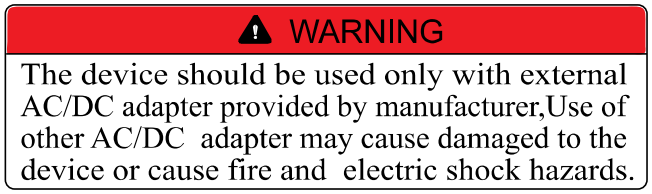
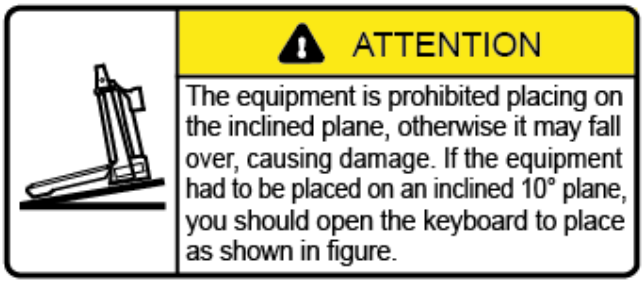
Symbols & Words	Connotation
⚠**Danger**	Indicates an imminent danger that may result in personal death or serious injury if not avoided.
⚠**Warning**	Indicates a potential danger that may result in personal injury if not avoided.
⚠**Attention**	Indicates a potential danger or unexpected use condition that may result in light injury or property loss or affecting the use if not avoided.

2. Safety Symbols

Symbols	Meaning	Symbols	Meaning
	Type B applied part		Up
	Stand-by		Keep dry
	Power supply indication		Fragile
	Adapter connection indication		Stacking limit by number
	Battery charge indicator		Temperature limits (Storage and transport)
	Follow instructions for use		Humidity limitation (Storage and transport)
	Marking for the separate collection of electrical and electronic equipment		Atmospheric pressure limitation (Storage and transport)

3. Labels

Label	Description
	**Danger:** 1. It may have explosion hazard if used with flammable gas. 2. Operate the probe with care. Read the probe information in the relevant manual for proper probe use.

	**Attention:** Do not place object on the machine. Do not apply external force on the machine. Close the keyboard before moving the machine.
	**Attention:** It is prohibited to scratch or squeeze the LCD/LED.
	**Warning:** The device should be used only with external AC/DC adapter provided by manufacturer. Use of other AC/DC adapter may cause damaged to the device or cause fire and electric shock hazards.
	**Attention:** The equipment is prohibited placing on the inclined plane; otherwise it may fall over, causing damage. If the equipment had to be placed on an inclined 10 °plane, you should open the keyboard to place as shown in figure.

	**Symbol for the marking of electrical and electronics devices according to Directive 2012/19/EU. The device, accessories and the packaging have to be disposed of waste correctly at the end of the usage. Please follow Local Ordinances or Regulations for disposal.**

Contents

Chapter One Overview

1.1 Introduction

Ophthalmological A/B mode ultrasound scanner is a portable ultrasound scanner, which is composed of main unit, probe and so on. A-mode scan is suitable for measuring the anterior chamber depth, lens thickness, vitreous body length, axial length and calculating the IOL power for an implanted lens; B-mode scan is suitable for ultrasonic diagnosis.

The expected service life of Ophthalmological A/B mode ultrasound scanner is 10 years; applied part of Ophthalmological A/B mode ultrasound scanner is ultrasonic probe. The essential performance of A-mode scan meets the requirements of YY 0107-2005 "A mode ultrasonic biometer for ophthalmology"; B-mode scan meets the requirements of YY 0773-2010 "General technical requirements for ophthalmic ultrasound B-mode Scan".

1.2 Intended Use

Ophthalmological A/B mode ultrasound scanner is used to clinical ophthalmic ultrasonic diagnosis for medical institutions and the measurement of axial biological parameters.

It is suitable for over one age population, weight has no limit. Instrument can not be used in the examination of organ with gas, pathological change with gas and bone.

Contraindications: It is forbidden using B-mode ultrasound examination for eyelid trauma, severe ocular infection personnel; forbidden using A-mode axial biological parameter measurement for corneal inflammation, trauma personnel.

> ⚠**Warning: This equipment shall not be used for fetal.**

> ⚠**Warning: Part of population is allergic to isopropyl alcohol.**

Chapter Two Technical Specifications

2.1 Technical Parameter

1. Gray scale: 256
2. Monitor: 10.4" LED
3. Adapter rating: 100-240V~, 1.2-0.6A, 50-60Hz
4. Output of Adapter: DC12.8V 3.0A
5. Main device rating: DC12V 3.0A
6. Main Unit Size: approx. 256 * 150 * 326 (L * M * H, mm)
7. Weight of main unit: approx. 4.6 kg (excluding accessories)

2.2 Primary Functions

1. Automatically switching of probe.
2. Mode conversion.
3. Adjustment of total gain, dynamic range and TGC.
4. Frame correlation.
5. Edge enhancement.
6. Image post-process.
7. Image up/down, left/right reversal.
8. Depth range selection.
9. Delay depth adjustment.
10. Images freeze/unfreeze.
11. Display basic information: hospital name, patient name, patient ID, OS/OD, sex, age, date and time.
12. Cine loop.
13. Storage of image, measurement information.
14. System preset function.
15. Has DICOM3.0 function.
16. Transfer image to Network Printer by one-key;
17. Network print function;
18. LED brightness adjustment function;
19. Energy-saving function;
20. Patient information input function.
21. Measurement functions (distance, circumference, area, volume, angle, histogram, profile, anterior chamber depth, lens thickness, vitreous body length, axial length, intraocular lens degrees, etc.).
22. Can automatic/manual switching when A-ultrasound calculates axial length.
23. Have reports (screen copy, IOL calculation data report, and ophthalmic ultrasound examination report).

Chapter Three System Outline

3.1 System structure components

Ophthalmological A/B mode ultrasound scanner is composed of main unit and probe, etc.

3.2 Components name

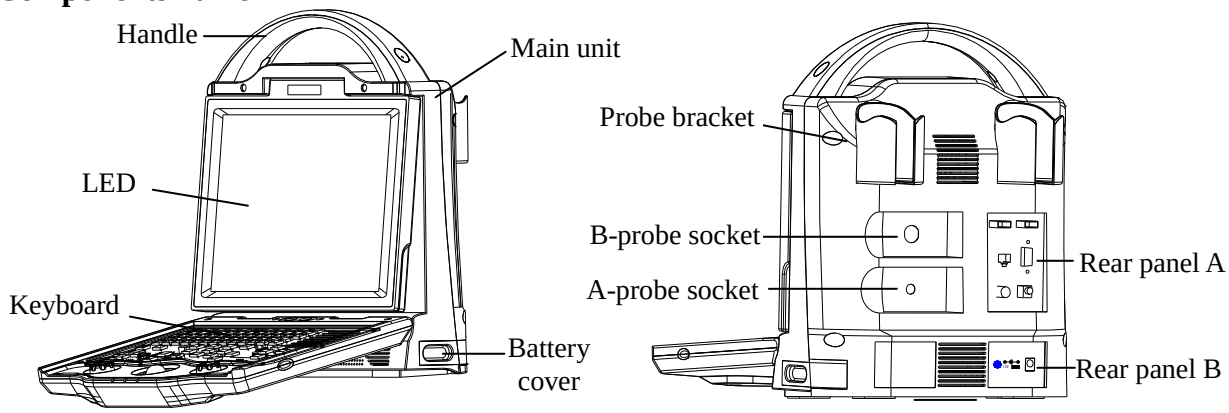


Fig. sketch map

3.3 Parts of the probe

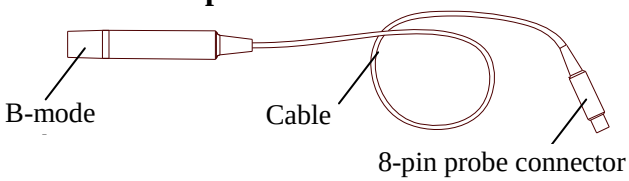


Fig. B-mode probe

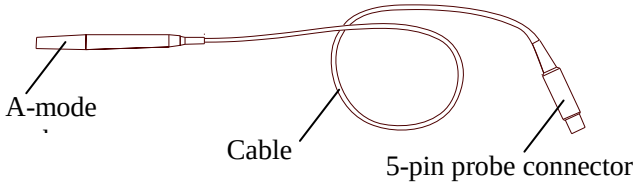


Fig. A-mode probe

3.4 Rear panel instruction

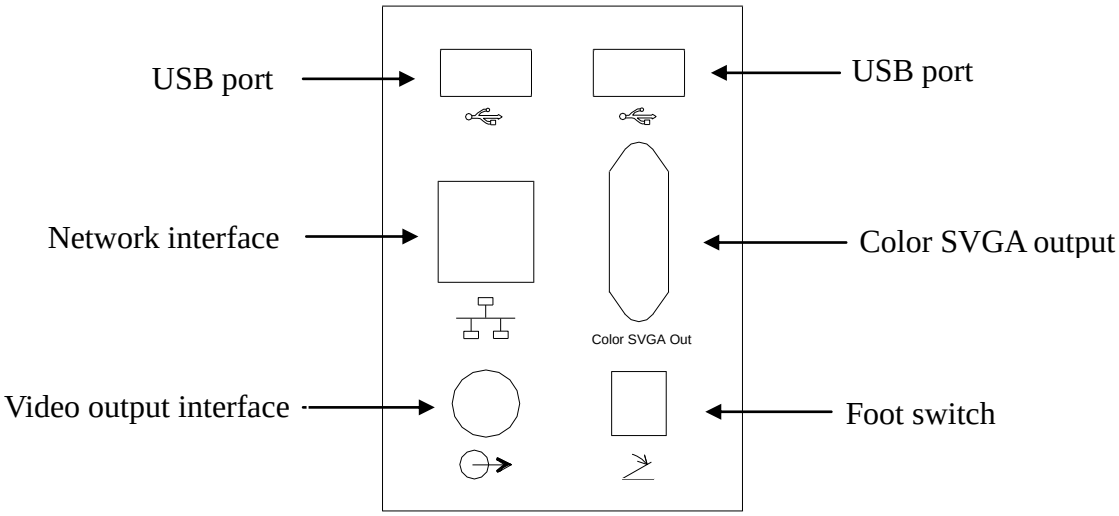


Fig. Real panel A sketch map

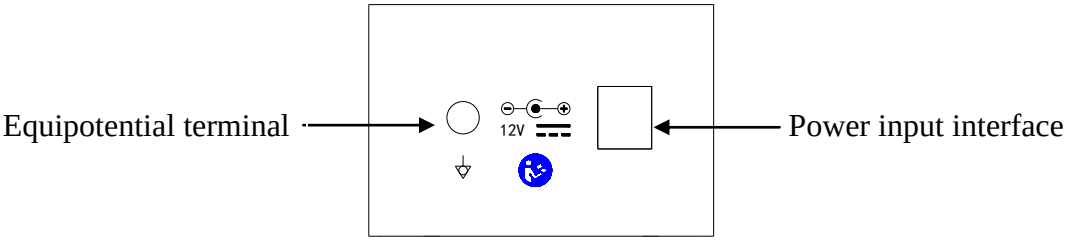


Fig. Real panel B sketch map

3.5 Function keys instruction

SN	Key symbol	Key name	Key function
1	Setup	System Preset	Enter/exit system preset interface;
2	☀▼ ☀▲	LED Settings	Adjust the brightness of LED;
3	F1 F2	User-defined keys	Reserved;
4	Print	Print report	Press the key to print out the report;
5	ABC Comment	Text input	In B, B/B, 4B, B/A mode and in frozen status, enter/exit text input status;
6	CHS	Chinese/English conversion	To complete Chinese/English conversion when input text (The function is only used in Chinese version);
7	Arrow	Arrow	In B, B/B, 4B, B/A mode and in frozen status, press key to enter/exit arrow mark status;
8	Esc	Exit	To exit ultrasonic application program;
9	Reset	Reset	Keyboard reset;
10	Patient	New patient	·Access to new patient module; ·Input the information and data for a new patient;
11	CAPS	Case conversion	Switch the input between capital letters and small letters;
12	Shift	Shift	Shift key with the standard keyboard;
13	Back	Backspace	Delete the character before the cursor while the cursor move left;
14	↵	Enter	Accept the input data
15	Space	Space	Input space character;
16	Dot	Decimal point	Input decimal point;
17	iStation	One-key transfer image	Press the key to transfer images or data to the software NetworkPrinter.exe, the specific use of Network Printer sees its instructions for use;
18	Prt sc	Print screen	Print or copy the current screen;
19	⇧ ⇦ ⇨ ⇩	Direction keys	Direction keys can be used to change the position of cursor.
20	Omit	Numbers, letters, symbols	Can be used to input the text;
21	B	B mode	Press key to enter B mode;
22	B/B	B/B mode	Press key to enter B/B mode;
23	4B	4B mode	Press key to enter 4B mode;
24	B/A	B/A mode	Press key to enter B/A mode;

25		A mode	Press key to enter A mode;
26		OS/OD mark	Press key to realize the switching of left eye(OS) and right eye (OD);
27		Auto/Manual measurement	Press key to realize the measurement switching between automatically and manual;
28		IOL calculation	Press key to enter IOL calculation;
29		A-ultrasound record selection key	Move arrow to select A-ultrasound measurement record;
30		Exchange starting point and end point	In the measurement, press key to exchange starting point and end point;
31		A general measurement	In A mode, press key to conversion between A general measurement and A five-point measurement;
32		B general measurement	In B, B/B, 4B, B/A mode, press key to enter/exit B general measurement;
33		Set	·Select or confirm ·Press the key to increase the values of parameters;
34		Back	·Press the key, in reverse order revoked the measured results and measured reference lines; ·Press the key to decrease the values of parameters;
35		Depth range selection	In real time, press key to select depth range, 12 segments; In real time, press number keys 1~8, can quickly select the corresponding depth range.
36		Frame average	In real time mode, press the key to adjust the frame average;
37		Store image	Press key to enter/exit the image storage;
38		Cine loop	In frozen status, press the key to enter the cine playback status;
39		Freeze	Press the key to freeze or unfreeze the image;
40	『TGC』	TGC	Through the segments to adjust the gain at different depths;
41		Gain	Rotate【Gain】knob to adjust the image's gain;
42		Function knob	·In B, B/B, 4B, B/A, A mode and in scanning status, adjust the dynamic range value; ·In arrow annotation, adjust the direction of arrow mark; ·In ellipse measurement, adjust the elliptical minor axis.
43		Power switch	Open/close the main unit;
44		Keyboard light	Open/close the keyboard light.

Chapter Four System Configuration

4.1 Typical configuration

1	Main unit	1 unit
2	Power adapter	1 PC
3	10MHz mechanical sector B-mode probe	1 PC
4	10MHz A-mode probe	1 PC
5	A-mode probe calibration cup	1 PC
6	Foot switch	1 PC

4.2 Optional parts

1	Video recorder
2	Battery
3	Charger

Chapter Five Operation Condition

5.1 Power supply

Adapter rating: 100-240V~, 1.2-0.6A, 50-60Hz
Adapter model: BJE01-40-001M
Output of Adapter: DC12.8V 3.0A
Main device rating: DC12V 3.0A

5.2 Operation Environment

Ambient temperature: 10℃-40℃
Relative humidity: 30%-75% (without condensation)
Atmospheric pressure: 800hPa-1060hPa
Altitude: < 2000 m
Overvoltage: Overvoltage Category Ⅱ
Pollution degree: 2

5.3 Storage and Transport

Ambient temperature: -20℃-55℃
Relative humidity: 30%-93% (without condensation)
Atmospheric pressure: 700hPa-1060hPa

⚠**Danger: Do not use this equipment where flammable gas (such as anesthetic gas, oxygen or hydrogen) or flammable liquid (such as alcohol) are present. Failure to do so may result in explosion.**

⚠**Warning: Avoid using this equipment with high-frequency electric knife, high-frequency therapy equipment or defibrillators and other electronic devices, or may an electric shock occur to the patient.**

⚠**Attention: The main voltage is varies with different countries or regions.**

⚠**Attention: Using radio transmitting equipment nearby the system may interfere with the normal operation of the system. Prohibited carry or use of devices that can generate radio waves within the room installed this system, such as cell phones, radio transceivers and wireless remote control toys.**

⚠**Attention: System should be avoided using in following environments:**

1. Splash	**2. Moist**	**3. Rain**
4. Thunderstorm weather	**5. No ventilation**	**6. Dust**
7. Close to heat source	**8. Direct sunlight**	**9. Dramatic temperature change**
10. Chemical medicines	**11.Poisonous gas**	**12. Corrosive gas**
13. Strong shock	**14. Strong electromagnetic field (e.g. MRI)**	
15. Radiation (e.g. X-ray, CT)	**16. Defibrillators or short wave therapy equipment**	

Chapter Six System Installation and Check

⚠Warning: To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

⚠Warning:

1. **All plugs of instruments of this system shall be connected into the power socket with protectively earth on the wall and the socket must meet the requirement of power rating of instrument. Use of multiple portable socket-outlets may affect protective earth to make leakage currents exceed the safety requirements.**
2. **Please follow the correct electrical connections method to connect the power supply and earth, otherwise there will be danger of electric shock. Do not connect the grounding wire to any gas pipe or water pipe, or it may cause bad grounding and danger of explosion.**
3. **This equipment is not waterproof, not use this equipment in place where liquid may into the interior of the equipment. Never pour any liquid on the equipment; otherwise there will be danger of electric shock or cause equipment damage. If accidentally spill liquid on the equipment, turn off the power immediately and contact your local representative.**
4. **Prohibit the live parts of the equipment or other devices (such as various signal input and output ports, etc.) contact with the patient, if this equipment or other equipment has failure, the patient will have danger of electric shock.**
5. **Additional equipment connected to the medical electrical equipment must comply with the respective IEC or ISO standards (e.g. IEC60950 for data processing equipment). Furthermore all configurations shall comply with the requirements for medical electrical systems (see IEC 60601-1-1 or clause 16 of IEC60601-1 3rd, respectively). Anybody connecting additional equipment to medical electrical equipment configures a medical system and is therefore responsible that the system complies with the requirements for medical electrical systems. Attention is drawn to the fact that local laws take priority over the above mentioned requirements. When more than one device is connected to use, the accumulation of leakage current may cause the danger of security. If in doubt, consult your local representative or the technical service department.**
6. **If the integrity of the external protective conductor in the installation or its arrangement is in doubt, equipment shall be operated from its internal electrical power source.**

⚠Warning:

1. **When instrument works abnormally, do stop working, turn off the power and check the reason, then contacts us about it.**
2. **Turn off power and pull out of the plug from socket after each ultrasonic diagnostic operation.**
3. **It is forbidden to drag and press the power and probe cables emphatically; regularly inspect whether there is pull-apart and bareness, if there is the phenomena like this, turn off power supply immediately and change it for new one.**
4. **It is forbidden to load and unload the probe or move the instrument in galvanic to avoid danger of safety.**
5. **Pull out of the plug from socket after operation in thunderstorm weather to avoid the instrument being damaged by lightening.**
6. **If the temperature changes greatly in short time will cause vapor recovery inside of instrument, the case may damage the instrument.**
7. **The instrument is turned off completely only by disconnecting the power supply from the wall socket.**

⚠Warning: The power adapter, probes, foot switch and battery as described in this section may be replaced by operator. To replace according to the method of this section, does not result in an unacceptable risk.

6.1 System placement

Please carefully read through and fully understand the safety cautions before moving and placing the system.

1. Unpack the instrument case and check the goods for its completeness according to the packing list.
2. Place the instrument on a stable and leveled position.
3. Leave adequate space of 20 centimeters as minimum from rear, left and right side of the instrument.

⚠Attention: Adequate space from rear, left and right side of the machine shall be reserved, or the machine may malfunction under excessive heat inside the enclosure.

6.2 Probe bracket installation

The probe bracket should be mounted behind the main unit.

6.3 Ultrasonic probe installation

⚠Warning:

1. **Do not use the probe not provided by our company, otherwise the equipment and the probe will cause damage, and may cause fire in extreme cases.**
2. **Check the ultrasonic probe and connecting cable after diagnostic operation. Use of defective probe may cause electric shock.**
3. **Do not strike the probe; using the damaged probe may cause electric shock to the patient.**
4. **Unauthorized disassembly of the probe shall be prohibited as it may cause electric shock.**

⚠Attention:

1. **Usually the probe should be placed within the probe bracket, not on the desktop or other support to avoid the drop. The sound window of probe is thin, please be careful not to scratch the surface of probe and protect it.**
2. **Turn off the ultrasonic system before disconnecting the ultrasonic probe. Disconnecting the probe with system power on may damage the system or probe.**
3. **Before disconnecting the ultrasonic probe, place the probe on the probe bracket so that the probe may not be damaged by unexpected fall.**
4. **Freeze the instrument when instrument is start-up without operation to increase of service life of probe.**
5. **Repeat available machine time should be more than 5 minutes to avoid turn on/off power supply in short time.**

6.3.1 Ultrasonic probe connection

⚠Warning: Before connecting or using the probe, make sure that the probe, connecting cable and connector are in normal condition (free of cracks or drop). Use of defective probe may cause electric shock.

⚠Attention: The red mark of connector should be aligned with the red mark on the socket when inserting the probe.

The B-mode probe inserts the 8-pin B-probe socket; A-mode probe inserts the 5-pin A-probe socket.

6.3.2 Ultrasonic probe disconnection

⚠Attention: Disconnecting the probe, do not pull the probe cable to prevent cable damage.

Make sure the system is turned off, hold the red marked part near the probe connector, and pull out the ultrasound probe connector vertically.

6.4 Install/Remove the battery

1. Install the battery

Shutdown the system; remove the battery cover on the right side of main unit. According to the direction of battery indication to install the battery and then install the battery cover.

2. Remove the battery

Shutdown the system; remove the battery cover on the right side of main unit, push forward the battery putter at the bottom of main unit and the battery is launched, remove the battery.

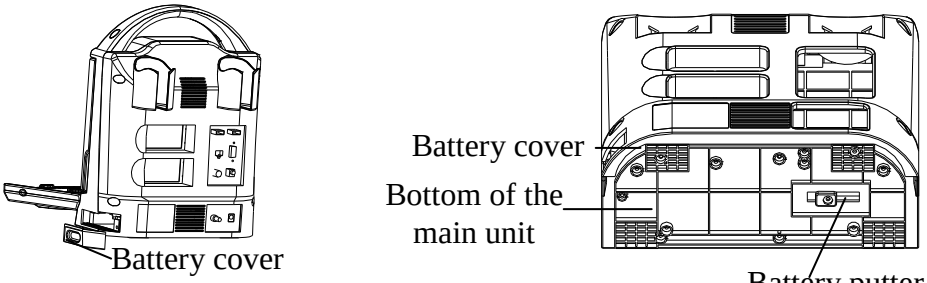


Fig. Install, Remove the battery

6.5 Install foot switch

Shutdown the system; insert the plug of foot-switch into the "⇗" socket at the back of the main unit.

⚠Attention: The waterproof grade of foot switch is IPX1.

6.6 Connection to video recorder

1. Shutdown the system; connect the equipotential terminal (⏚) of the video recorder to the earthing;
2. Connect one end of the video cable to the video recorder and the other end to the video output interface on the rear panel of the main unit;
3. Insert one end of power plug (jack) of the video recorder to its power input socket, the other end to the power supply socket.

6.7 Connection to power

1. Connect to the power adapter

Insert the output plug of adapter into DC power input port, which is at the back of main unit.

2. Connect to the main power supply

Insert the power plug (jack) furnished with the machine into power input socket of the power adapter, the other end to the mains socket-outlet. The instrument uses three-core power supply. It connects with the protective earth line when power plug inserts into its socket.

⚠Warning:

1. **Adapter has no switch. APPLIANCE COUPLER or MAINS PLUG is used as the isolation means from the SUPPLY MAINS. Not to position the EQUIPMENT so that it is difficult to operate the disconnection device.**
2. **The equipment should be used only with adapter provided by us.**
3. **To avoid damaging power adapter or harming people by unexpected fallen, make sure the power adapter is placed on the leveled desk.**
4. **The operator must not touch signal input/ signal output and patient simultaneously.**

6.8 Ultrasonic probe check before and after operation

Before and after ultrasonic diagnosis to check if there are any exceptionally on the surface of the probe or cable jacket, such as peeling, cracks, bulge, or if the acoustic lens is reliable, cleaned or disinfected.

6.9 Main unit check before and after operation

6.9.1 Inspection before start-up

Check the following items before starting the machine:

1. The temperature, humidity and atmospheric pressure shall meet the requirement of operation conditions.
2. No condensation occurs.
3. No distortion, damage or contamination on system and peripheral. Clean the parts as specified in relevant sections, if the contaminant is present.
4. Check the control panel, LED screen and enclosure to ensure they are in good working condition and free of abnormity (such as cracks and loosened screws).
5. No damage on cable (such as power cable, etc.), and not loose the connection.
6. Check probe and its cable to ensure they are free of abnormity (such as scuffing, drop-off or contamination). If the contaminant is present, clean the contaminated objects as specified in relevant sections.
7. See to it that there are no foreign objects on the control panel (Remove the object if any).
8. No barriers around the intake of equipment.
9. See to it that whether probe has been cleaned, disinfected; else dispose it as specified in relevant sections.
10. Check all the ports of the machine for possible damage or blockage.
11. Clean the field and environment.

6.9.2 Inspection after start-up

Check the following items after starting the machine:

1. No abnormal voice, strange smell and overheating appear.
2. Check the machine to ensure a normal start-up: The power indication light is on; startup picture is shown on the screen, and then the machine will automatically enter B mode.
3. Check the acoustic lens for abnormal heat when the probe is in use. This can be done by hand touching the probe to feel the temperature of the lens.
4. Check the image to ensure trouble-free display (e.g. no excessive noise or flicker).
5. Check the control panel to ensure normal operation condition.
6. Check the instrument to ensure that the phenomenon of too high local temperature will not appear.

⚠Attention: If the overheat acoustic lens is placed on the patient's skin, heat injury may occur.

⚠Attention: Thoroughly clean the coupling gel on the probe surface each time after ultrasonic operation, or the coupling gel may become hardened on the acoustic lens of the probe, deteriorating quality of image.

6.10 Reset

System reset: In case of abnormal screen display or no-working for system operation, turn off the power and try to restart the system.

Keyboard reset: When the keys or trackball failure, press key "Reset" on the panel to reset.

Chapter Seven System Preset

Press Setup key on the keyboard, "System Preset" dialog box will be displayed on the screen.

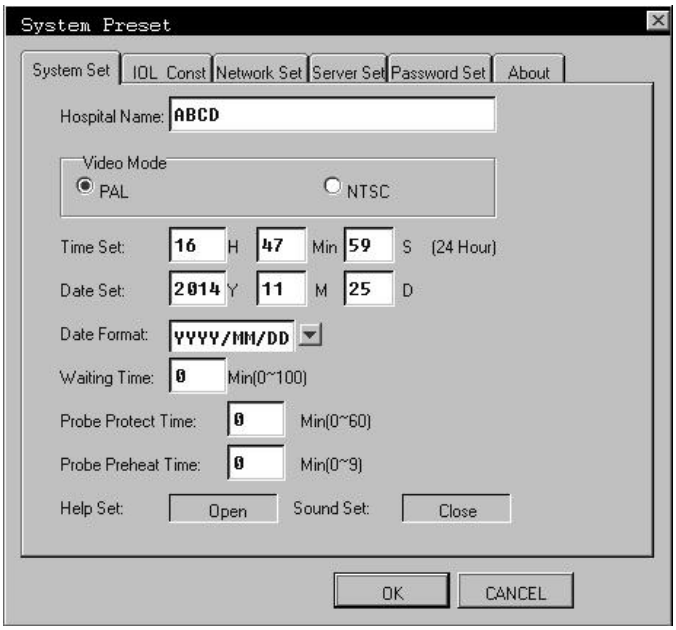


Fig. System preset menu

7.1 System set

- **Hospital Name set**

1. Move the cursor to the "Hospital Name" input box, press『Set』key to confirm the cursor position.
2. Press CHS key to input Chinese, press up/down direction keys to turn page, press digital key to select the desired Chinese character, press CHS key to exit Chinese input status (The function is only used in Chinese version);
3. If need to revise, press ⇦⇨ direction keys, or operate trackball and press『Set』key, move the cursor to the back of revised position, press Back key to delete the previous character and retype.

- **Video Mode selection**

Move the cursor to the dot of "PAL" or "NTSC", press『Set』key to confirm.

- **Time, Date and the Format of date**

1. Move the cursor to the "Time Set" input box and press『Set』key to confirm the cursor position then input "hour, minute, second";
2. Move the cursor to the "Date Set" input box and press『Set』key to confirm the cursor position then input "year, month, day";
3. Move the cursor to drop-down box of the "Date Format" and choose the right format.

Note: Because of the system software, the effective range of "Date Set" is from 1970 to 2037.

- **Waiting Time setting**

1. Move the cursor to the "Waiting Time" input box, press『Set』key to confirm the cursor position;
2. Input the screensaver time, number "0-100", in minute; "0" stands for turn off the screensaver time.

Note: Go beyond the system setting energy-saving time without pressing any key, the system will automatically enter the energy saving status. Press any key, system will return to normal operation status.

- **Probe Protect Time**

1. Move the cursor to the "Probe Protect Time" input box and press『Set』key to confirm the cursor position.
2. Input the probe protect time, number "0-60", in minute; "0" stands for turn off the probe protection time.

- **Probe Preheat Time**

1. Move the cursor to the "Probe Preheat Time" input box and press『Set』key to confirm the cursor position.
2. Input the probe preheat time, number "0-9", in minute; "0" stands for turn off the probe proheat time.

Note: At low temperature, the probe may turn abnormally, you can set the probe preheat time, the probe enters into the normal state after preheat.

- **Help set**

Move the cursor to the "Help Set" select box and press『Set』key repeatedly, choose "Open" and "Close" which showed alternately in the select box.

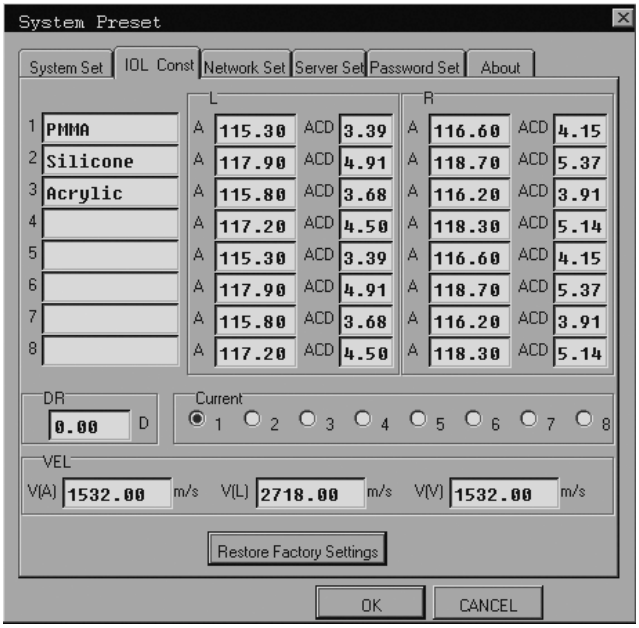
- **Sound set**

Move the cursor to the "Sound Set" select box and press『Set』key repeatedly, choose "Open" and "Close" which showed alternately in the select box.

After presetting the system parameters "Hospital Name", "Video Mode", "Time Set", "Date Set", "Date Format", "Waiting Time", "Probe Protect Time", "Probe Preheat Time", "Help Set" and "Sound Set", move the cursor to「OK」then press『Set』key, the system will preserve the data of preset and exit the dialog box; If choose「CANCEL」, press『Set』key, the system will give up the data of preset and exit the dialog box. You also can press Setup or Esc key to give up and exit the preset.

7.2 IOL set

Move the cursor to the "IOL Const", press『Set』key. Display the IOL set dialog box, as shown.



IOL setting items include: IOL material name, constant A, constant ACD, diopter, current selection, sound velocity for special eye.

Setting method: Use the number keys and [Dot] key to complete the input, use the [Back] key to delete or modify, press『Set』key to confirm.

- **Set IOL constants (A and ACD in IOL calculation)**

Two constants A and ACD are set to 1~8 eight groups, the data of left and right are respectively used to the left formula and right formula in IOL calculation.

- **Set the current selection**

Select "1" button, the constants in the current 1 group become effective, or select one of the digital buttons, the constants in the selected group become effective.

The constants of the machine factory are set to:

Left	1 (group 1)	A = 115.30	ACD = 3.39	Right	1 (group 1)	A = 116.60	ACD = 4.15
	2 (group 2)	A = 117.90	ACD = 4.91		2 (group 2)	A = 118.70	ACD = 5.37
	3 (group 3)	A = 115.80	ACD = 3.68		3 (group 3)	A = 116.20	ACD = 3.91
	4 (group 4)	A = 117.20	ACD =4.50		4 (group 4)	A = 118.30	ACD = 5.14
	5 (group 5)	A = 115.30	ACD = 3.39		5 (group 5)	A = 116.60	ACD = 4.15
	6 (group 6)	A = 117.90	ACD = 4.91		6 (group 6)	A = 118.70	ACD = 5.37
	7 (group 7)	A = 115.80	ACD = 3.68		7 (group 7)	A = 116.20	ACD = 3.91
	8 (group 8)	A = 117.20	ACD =4.50		8 (group 8)	A = 118.30	ACD = 5.14
Current Selection = 1							

- **Set sound velocity**

When select intraocular lens (IOL) or special eye (SPEC) model to measure automatically, you can set the sound velocity of anterior chamber, lens and vitreous body by manual. The sound velocity of IOL can consult from IOL manufacturer. V(A), V(L), V(V) respectively stand for the sound velocities of anterior chamber, lens and vitreous body, units are all meter/second (m/s).

After setting, move the cursor to「OK」, press『Set』key, the system will preserve the data of preset and exit the dialog box, the setting will take effect at next boot time; If choose「CANCEL」, press『Set』key, the system will give up the data of preset and exit the dialog box. You also can press [Setup] or [Esc] key to give up and exit the preset.

7.3 Network set and Server set

1. Respectively move the cursor to the "Network Set" or "Server Set", press『Set』key to show the "Network Set" or "Server Set" dialog box.
   The details refer to **Chapter Twelve "Print and Transfer files"**.
2. Choose「CANCEL」press『Set』key or directly press [Esc] key to exit the network set or server set.

7.4 Password set

Move the cursor to "Password Set", press『Set』key. Display password set dialog box.

- **Password set**

1. Move the cursor to "Demo date" input box, press『Set』key to confirm the cursor position then enter the trail "Day" number;
2. Move the cursor to "Enter Password" input box, press『Set』key to confirm the cursor position then enter the "Password";
3. Move the cursor to "Confirm Password" input box, press『Set』key to confirm the cursor position then re-enter the "Password";

4. Move the cursor to「Affirm Password」in the dialog box, press『Set』key, the system will pop up "Password Set Success!" prompt box;
5. Move the cursor to「OK」in the prompt box, press『Set』key and close the prompt box, then choose「OK」in the dialog box, press『Set』key to exit the password set interface.

Explanation:

1. Trial days setting range: 0 to 999 days.

2. Password setting range: up to 12-bit numbers, characters or combination of numbers and characters.

3. When the trial days are up to the setting date, the system will automatically freeze and stop working, the freeze icon will turn up.

- **Cancel password set**

1. Enter the system preset interface;
2. Move the cursor to the "Password Set" , press『Set』key. Display the password cancel dialog box;
3. In the "Enter Password" box, enter the password has been set;
4. Move the cursor to「OK」in the password cancel dialog box, press『Set』key, system will pop up "Password is cancel" prompt box;
5. Move the cursor to the「OK」 in the prompt box, press『Set』key and close the prompt box, then choose「OK」in the dialog box, press『Set』key to exit the password set interface.

> ⚠**Warning: Business personnel or service personnel setting the password, be sure to remember the set password, make notes! If you forget password, consult us.**

7.5 About

Move the cursor to "About", press『Set』key. Display "About" dialog box. In the dialog box, display the product information, such as device name, probe model, software information, software full version and release version, etc.

- **Software upgrade**

1. Insert U disk with upgrade program into the USB port of main unit;
2. Move the cursor to「Software Upgrade」, press『Set』key, the system prompts being upgraded;
3. Choose「OK」button in the dialog box, press『Set』key.

> ⚠**Warning:**
>
> **1. Turn on the machine and then insert U disk.**
>
> **2. Don't disconnect the power or unplug U disk when software is upgrading, otherwise system will occur serious failure, only to return us to maintenance.**

Chapter Eight Functional Operation

8.1 Startup and Shutdown

Press the button ⏻ on the bottom of screen, turn on the machine. If you want to turn off the machine, please press the button ⏻ again, then pull out mains plug from the supply mains.

8.2 Keyboard light

Press the button on the bottom of screen, open the keyboard light. If you want to close the light, press the button again.

8.3 Patient basic information

1. Press Patient key, "Patient Data Input" dialog box will be showed;
2. Move the cursor to "Name", "Age" and "ID" , press『Set』key, input the data individually;
3. Choose the sex;
4. Move the cursor to「OK」of the dialog box after inputting, press『Set』key to confirm saving and exit;
5. Press「CANCEL」of the dialog box it will give up inputting information and exiting the dialog box.

Note: If need to input Chinese, please refer to Chapter 7.1 "Hospital Name set".

8.4 Mode selection

8.4.1 Amode

1. Starting the machine or press A key to enter A mode;
2. Press freeze key to freeze or unfreeze the current image;
3. In real-time, press B or B/B or 4B or B/A key to exit A mode.

8.4.2 B mode

Press B key, a single-framed image in B mode is displayed. Press freeze key to freeze or unfreeze the current image. In real-time mode, press B/B or 4B or B/A or A key to exit B mode.

8.4.3 B/B mode

1. Press B/B key to enter B/B mode;
2. Switch the B/B image. In real-time mode, press B/B key to switch the display for left image or right image. The switched image is activated and the other image is frozen;
3. Press freeze key to freeze or unfreeze the current image;
4. In real-time mode, press B or 4B or B/A or A key to exit B/B mode.

8.4.4 4B mode

Press 4B key to enter 4B mode and display the first real-time image, press 4B key again to display the second real-time image while the first image is frozen. There are all together 4 images to be displayed in sequence by pressing the 4B mode key, one image being activated and the other three images frozen. Press this key repeatedly to switch images between "frozen" and "real-time".

In real-time mode, press B or B/B or B/A or A key to exit 4B mode.

8.4.5 B/Amode

1. Press B/A key to enter B/A mode;
2. Press freeze key to freeze or unfreeze the current image;
3. In real-time mode, press ⇧ ⇩ keys to move the sample line, the following A-mode waveform will be changed and shown in the direction of the sample line;
4. In real-time mode, press B or B/B or 4B or A key to exit B/A mode.

8.5 Probe scanning position marker

1. Move the trackball to the probe scanning position marker↑(located on the top of the fan-shaped image), Press『Set』key, the marker will rotate clockwise; every time press the "↑" , rotate 45° .
2. Probe scanning position markers are divided into 9 kinds of position, respectively are ⊙ (Probe is placed perpendicular to the eyeball),↑,↗,→,↘,↓,↙,←,↖(Probe is placed in according with the direction of the eight position markers).

8.6 Image quality adjustment

8.6.1 Image brightness adjustment

Proper brightness of the LED is essential for a quality image. The brightness adjustment should be done in relation to the ambient brightness. Therefore the actual brightness shall be adjusted according to the specific environmental condition.

Method of operation:

1. Press☀▾ ☀▴keys, the "LED Settings" adjustment box appear on the screen;
2. Press☼▾ ☼▴keys to change the brightness of LED backlight;
3. Finish the settings, press⇦Esckey to exit the "LED Settings" adjustment box.

Tip: In general, the brightness adjustment is performed according to the gray scale. It should be adjusted in such that the background appears dark while all the gray scale strips can be seen.

8.6.2 TGC adjustment

In real-time B, B/B, 4B, B/A mode, adjust TGC slide potentiometer, TGC curve will automatically displayed at the top right of the screen, the image can be adjusted. After stop the adjustment, TGC curve will automatically disappear.

8.6.3 Total gain adjustment

Clockwise rotate the Gain knob on the panel to increase the total gain value, counterclockwise to decrease the value. Adjust the total gain knob can control the total gain of the image until the image quality is satisfied. The total gain value is shown on "GN" position of above the image area.

Note: If the total gain is adjusted to the biggest but still can't be satisfied, you can adjust TGC to compensate.

8.6.4 Dynamic range adjustment

Clockwise rotate the Function knob on the the panel to increase the dynamic range value, or counterclockwise to decrease the value. The dynamic range value is shown on "Dyn" position of above the image area.

8.6.5 Frame correlation adjustment

A. Shortcut key adjust the frame correlation

In real-time mode, press⧉key to realize four levels of the frame correlation. The frame correlation is displayed in the〖Frame Avg〗of the right menu.

B. Adjust the frame correlation by the menu

1. In real-time mode, move the cursor to the submenu〖Frame Avg〗of【B MODE MENU】;
2. Press『Set』or『Back』key to realize four levels of the frame correlation. Four kinds of frame correlation are 0, 1, 2, 3 and displayed in the〖Frame Avg〗of the right menu.

8.6.6 Edge enhancement adjustment

1. In real-time mode, move the cursor to the submenu〖Edge〗of【B MODE MENU】;

2. Press『Set』or 『Back』key to realize image sharpening. A sharpened picture can better highlight the organ outline for convenient observation. Four kinds of edge enhancement are 0, 1, 2, 3 and displayed in the〖Edge〗of the right menu.

8.6. 7 Compression curve adjustment

1. In real-time mode, move the cursor to the submenu〖Compress Curve〗of【B MODE MENU】;
2. Press『Set』or『Back』key to realize compression curve processing. The compression curve falls into four levels, which are 1-4 and displayed in the〖Compress Curve〗of the right menu.

8.6.8 Image post-process adjustment

1. In real-time or frozen mode, move the cursor to the submenu〖IP〗of【B MODE MENU】;
2. Press『Set』or『Back』key to realize image post-process. Image post-process falls into eight levels, which are 0-7 and displayed in the〖IP〗of the right menu. NO.2 is recommended when normal use.

8.7 Image control

8.7.1 Depth range selection

In real-time B, B/B, 4B, B/A mode, press key to get images in different depth. 12 kinds of depth range to select and the selected depth range is shown on the left side of the image. Users also can fast select depth range with 1-8 number keys.

8.7.2 Image up/down reverse

1. In real-time mode, move the cursor to the submenu〖V Rev〗of【B MODE MENU】;
2. Press『Set』or『Back』key to realize image vertical reversal. Reversal is marked with "U" logo.

8.7.3 Image left/right reverse

1. In real-time or froze mode, move the cursor to the submenu〖H Rev〗of【B MODE MENU】;
2. Press『Set』or『Back』key to realize image horizontal reversal that change the probe scanning direction. Reversal is marked with "U" logo.

8.7.4 Color selection

1. In real-time or frozen mode, move the cursor to the submenu〖B Color〗of【B MODE MENU】.
2. Press『Set』or『Back』key to realize the conversion of eight kinds of colors (including one kind of black and white).

8.7.5 Image freeze/unfreeze

In real-time mode, press key to freeze the image; in frozen status, press key to unfreeze the image.

8.8 Image file storage and recall

8.8.1 Save image file

1. Freeze the image which needs to be saved;
2. Press Store Recall key and enter【File Menu】;
3. Move the cursor to『Store BMP』, press『Set』key, the corresponding dialog box will be showed;
4. Move the cursor to "Select Driver " and make it turn to "▼", press『Set』key to choose the driver and press『Set』key again to confirm;
5. Move the cursor to the "File name" edit column of the dialog box, press『Set』key, the annotation cursor"|" will be showed in the edit column then input the file name which need to be saved;
6. Move the cursor to「OK」in the dialog box, press『Set』key and save the image, the Success prompt box will be showed, choose「OK」, press『Set』key, it will exit the saving dialog box, image file is saved in the corresponding root directory of driver; if want to save in the existing folder, move the cursor to the folder, first press『Set』key to select this folder and then press『Set』key to open this folder, repeat the above-mentioned step "5";

7. Choose「CANCEL」in the dialog box, press『Set』key, it will give up saving and exit the saving file dialog box;
8. Move the cursor to「Dicom Archive」button, press『Set』key, the frozen image can be transferred to server.

8.8.2 Open image file

1. Press Store Recall key to enter【File Menu】;
2. Move the cursor to『Recall BMP』, press『Set』key, the corresponding dialog box will be showed;
3. Move the cursor to "Select Driver" and make it turn to "▼", press『Set』key to choose the driver and press『Set』key again to confirm;
4. Move the cursor to the "File" area of the dialog box and select the image file need to be opened in the root directory then press『Set』key; if want to open the file in the folder, move the cursor to the folder, first press『Set』key to select this folder, and then press『Set』key to open this folder and then select the file in this folder;
5. Move the cursor to「OK」in the dialog box and press『Set』key, the opened image will be showed on the screen, the operation strip of the opened image will be showed in the lower right corner of the screen, the file name is displayed at the top of the operation strip. Press the close button can close the image which is being showed now and return to the file menu status. If open images in C disk, press the left/right button of the operation strip to preview the images have been saved; Press the disk button can save the image being showed to U disk or D disk;
6. Move the cursor to the "File" area of the dialog box and select the image file need to be opened in the root directory then press『Set』key, move the cursor to「Dicom Archive」button, press『Set』key, the stored image can be transferred to Dicom server.
7. Move the cursor to the "File" area of the dialog box and select the image file need to be opened in the root directory then press『Set』key, move the cursor to「OK」in the dialog box and press『Set』key, the opened image will be showed on the screen, press iStation key or long press foot switch for 3 to 5 seconds, the stored image can be transferred to Network Printer.
8. Choose「CANCEL」in the dialog box, press『Set』key, it will give up recalling image and exit the opening image file dialog box;

Explanation: The setting of Dicom and Network Pritnter sees the Chapter Twelve "Print and Transfer files".

8.8.3 Cinema file storage and recall

This product does not support the function.

8.8.4 Disk manager

- **New folder (folders only be created in U disk and D disk)**

1. Press Store Recall key to enter【File Menu】;
2. Move the cursor to〖File Manager〗, press『Set』key, the corresponding dialog box will be showed;
3. Move the cursor to "Select Driver" and make it point to "▼", press『Set』key to choose U disk or D disk and press『Set』key again;
4. Move the cursor to select the "New Folder" button, press『Set』key to confirm, the dialog box will be showed;
5. Input the folder name and move the cursor to「OK」, press『Set』key, the folder name will be saved to the "Folder" column;
6. If choose「CANCEL」button press『Set』key, it will give up the new folder.

Note: The folder name can not contain any of the following characters: space, ( ) \ / : * ?

" < >

- **Copy and paste folder**

1. Press Store Recall key to enter【File Menu】;
2. Move the cursor to〖File Manager〗, press『Set』key, the corresponding dialog box will be showed;
3. Move the cursor to "Select Driver" and make it point to "▼", press『Set』key to choose U disk or D disk and press 『Set』 key again;
4. Move the cursor to "Folder" column and choose the folder which need to be copied, press 『Set』 key to confirm, and then move the cursor to "Copy Folder" button, press 『Set』 key;
5. Choose the folder in U disk or D disk, press 『Set』 key twice, move the cursor to "Paste Folder" button and press『Set』key, "Disk Background process is workout" will be popped up; choose 「OK」of the prompt box, press『Set』key to close the prompt box, the copied folder will be showed in the folder area.

Note: This function is only limited to copy and paste between the folders in the root directory of U disk and D disk.

- **Delete folder**

1. Press Store Recall key to enter【File Menu】;
2. Move the cursor to〖File Manager〗, press『Set』key the corresponding dialog box will be showed;
3. Move the cursor to "Select Driver" and make it point to "▼" , press『Set』key to choose U disk or D disk and press 『Set』 key again;
4. Move the cursor to "Folder" column and choose the folder which need to be deleted, press『Set』 key to confirm, and then move the cursor to "Del Folder" button, press 『Set』 key, a corresponding warning box appears, move the cursor to 「OK」 button, press『Set』key, "Disk Background process is workout" will be popped up; Choose「OK」of the prompt box, press『Set』 key to close the prompt box, the folder is be deleted; If choose 「CANCEL」 button, press『Set』 key, it will give up deleting the folder.

- **Rename folder**

1. Press Store Recall key to enter【File Menu】;
2. Move the cursor to〖File Manager〗, press『Set』key the corresponding dialog box will be showed;
3. Move the cursor to "Select Driver" and make it point to "▼", press『Set』key to choose U disk or D disk and press 『Set』 key again;
4. Move the cursor to "Folder" column and choose the folder which need to be renamed, press 『Set』 key to confirm, and then move the cursor to "Rename Folder" button, press『Set』key, a corresponding dialog box appears, input the folder name, move the cursor to 「OK」, press『Set』 key, the Success prompt box will be popped up, choose「OK」, press『Set』key to close the prompt box.

- **Copy and paste file**

1. Press Store Recall key to enter【File Menu】;
2. Move the cursor to〖File Manager〗, press『Set』key the corresponding dialog box will be showed;
3. Move the cursor to "Select Driver" and make it point to "▼", press 『Set』 key to choose driver and press 『Set』 key again;
4. Move the cursor to "File" column and choose the file which need to be copied, press『Set』key to confirm, and then move the cursor to "Copy File" button and press 『Set』 key;
5. Choose the driver saved the file or the folder within the driver, move the cursor to "Paste File" button and press『Set』key, the "Copy File" progress strip will be popped up, after finishing copy

the file, the successful prompt box appears, choose「OK」, press 『Set』key to close the prompt box, the copied file will be shown in the file area.

Note: This function only can copy files in C disk to U disk/D disk; or can copy and paste the files between the various folders in U disk or D disk.

- **Rename File**

1. Press Store Recall key to enter【File Menu】;
2. Move the cursor to〖File Manager〗, press『Set』key the corresponding dialog box will be showed;
3. Move the cursor to "Select Driver" and make it point to "▼", press『Set』key to choose driver and press『Set』key again;
4. Move the cursor to the file which need to be renamed and press『Set』key;
5. Move the cursor to "Rename File" button, press『Set』key the input name dialog box will be showed;
6. Input new file name and move the cursor to「OK」, press『Set』key, file name is changed, the Success prompt box appears, choose「OK」of the prompt box, press『Set』key to close the prompt box.

- **Delete File**

1. Press Store Recall key to enter【File Menu】;
2. Move the cursor to〖File Manager〗, press『Set』key, the corresponding dialog box will be showed;
3. Move the cursor to "Select Driver" and make it point to "▼", press『Set』key to choose driver and press『Set』key again;
4. Move the cursor to the file which need to be deleted and press『Set』key;
5. Move the cursor to "Del file" button, press『Set』key, the warning dialog box will be popped up;
6. Press「OK」in the warning dialog box, the file will be deleted; The Success prompt box appears then choose「OK」, press『Set』key to close it; If choose「CANCEL」in the warning dialog box, press『Set』key, it will give up deleting the file.

- **Format**

1. Press Store Recall key to enter【File Menu】;
2. Move the cursor to〖File Manager〗, press『Set』key the corresponding dialog box will be showed;
3. Move the cursor to the "Format" button, press『Set』key, the warning dialog box will be popped up;
4. Press「OK」in the warning dialog box, C disk will be formatted; The Success prompt box appears then choose「OK」, press『Set』key to close it; If choose「CANCEL」in the warning dialog box, press『Set』key, it will give up formatting.

Note: This function is only suitable to C disk; please do U disk formatting in your computer; delete files in D disk by manual after saved fully.

8.9 Play back and Measurement

- Play back

In real-time status, in B, B/B, 4B, B/A mode, the system is always saving the scanned image. The playback images are for a period time images before freeze.

Freeze image, press Cine key to enter the automatic playback; press Cine key again to enter single image playback status, press ⇦⇨ keys or operate the trackball to choose the image needed playback. Press Cine key again to return to automatic playback status. Press Esc key to exit playback status. Press ❄ key unfreeze and exit playback status.

- Playback measurement

In automatic playback status, press Cine key to enter single image playback status and choose measured image, press Esc key to exit playback status and perform measurement. The detail

measurement method refers to corresponding chapters. Press(Cine)key again to return to automatic playback status.

Note: If the displayed images appear abnormal, that is without enough storage time and the images have not been stored full. Store fully need about 30 second.

8.10 Print report

1. Press(Print)key to enter ultrasound report interface;
2. Move the cursor to OS/OD image area, press『Set』key to enter "Open Image File" interface, select the desired picture, press『Set』key to open the image, press「OK」button to recall the image;
3. Fill in the ultrasonic findings and information;
4. Move the cursor to「Save Report」button in the dialog box, press『Set』key, pop up dialog box, select the driver, click「SAVE PIC」button, pop up "Disk Background process is workout" prompt box, choose「OK」of the prompt box, press『Set』key to close the prompt box, the desired image file is saved;
5. Move the cursor to「Print Report」button in the dialog box, press『Set』key, the desired image file is printed out;
6. Choose「Close」button in the dialog box, press『Set』key, it will give up printing.

Explanation: The print setting sees the Chapter Twelve "Print and Transfer files".

8.11 Screen copy

The screen content is directly printed out by printer, or saved into U disk or D disk. It is suitable for the output of images and reports. Operation as follows:

1. Screen print: Press(Prt sc)key to pop up dialog box, move the cursor to select「PRINT PIC」button in the dialog box, press『Set』key to print the current screen content.

   Explanation: The print setting sees the Chapter Twelve "Print and Transfer files".
2. Save picture: Press(Prt sc)key to pop up dialog box, move the cursor to select D disk or U disk (if insert U disk), press『Set』key; select「SAVE PIC」button in the dialog box, press『Set』key, pop up "Copy File" condition strip. After the condition strip vanishing, the screen content will be saved to the folder in the U disk or D disk. If you do not enter ID, it will automatically generate the name for folder and file; the folder name is "yy**##" and the file name is generated according to the current date and time. If have entered ID, the folder name is ID and the file name is also generated according to the current date and time;
3. Move the cursor to choose「CANCEL」button, press『Set』key, it will give up this operation;
4. Choose the close button in upper right corner of the dialog box, press『Set』key, exit the screen copy status.

Explanation:

- **Folder (do not enter ID): "yy" two bits represent the last two digits of year; "**" two bits represent the check month; "##" two bits represent the check date.**
- **Such as:**

  D:\123\20141125095359.bmp (has entered ID)

  It indicates the picture that is saved under the "123" (patient ID) folder in D disk, which is diagnosed at 09:53:59 on November 25, 2014.

  U:\141125\20141125094830.bmp (not enter ID)

  It indicates the picture that is saved under the "141125" folder in U disk when not entered ID, which is diagnosed at 09:48:30 on November 25, 2014.

⚠Attention: In A mode, first freeze and then copy screen.

⚠Attention:

1. **Turn on the machine and then insert U disk.**
2. **Operating U disk or D disk should allow sufficient storage time to prevent the files are missing.**
3. **U disk or D disk storage especial screen copy, it should be concerned about the free space to prevent the invalid storage.**
4. **Two USB ports at the rear panel of main unit can not be used simultaneously; if use only uses one of them.**

8.12 Annotation

1. In B, B/B, 4B, B/A mode and in frozen status, press [ABC Comment] key, the cursor "I" will be showed on the screen;
2. Move the cursor to the needed position, press 『Set』 key;
3. Input annotation and press 『Set』 key to confirm. It can annotate many times by moving the cursor;

   Press [CAPS] key to switch between capital letters and small letters. When capital, the "Caps" mark is shown in the upper right corner of the screen.

   Press [Shift] key to switch between upper function and lower function of a key. When annotating the special characters, the "Shift" mark is shown in the upper right corner of the screen.

   Press [↵] key to end the text input.
4. If need to be modified during annotation, press [Back] key to delete the previous character and input again;
5. Press [ABC Comment] key to exit annotation after finish inputting;
6. Press [Arrow] key to mark arrow, rotate Function knob to change the arrow direction, press 『Set』 key to confirm, press [Arrow] key again to exit arrow status;
7. Press [Store Recall] key to clear the annotation; then press [Store Recall] key again to turn back the current status;
8. Press [❄] key to unfreeze and clear the screen.

Chapter Nine B General Measurement

> ⚠**Attention: The accuracy of software measurement: distance measurement ≤0.1mm; area measurement ≤ 0.1mm^2; volume measurement ≤ 0.1mm^3. Due to differences in images obtained by each user in different times, the actual object for the accuracy of the measurement may be greater than the above-mentioned values.**

In B, B/B, 4B, B/A mode, press『B_meas』key to enter【B MEAS】menu. B general measurement menu is shown as follows:

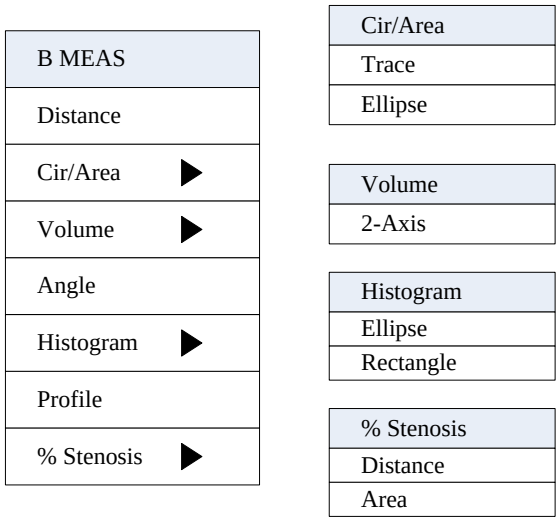


Fig. B general measurement menu and secondary menu

9.1 Distance measurement

Function: Measure the distance between two dots.

Operation steps:

1. In B, B/B, 4B, B/A mode, chooses a valuable image;
2. Press『B_meas』key, the cursor will show "+";
3. Operate the trackball or the direction keys to move the "+" mark to the desired position, press 『Set』key, make the "+" position as the starting point to be measured;
4. Operate the trackball or the direction keys to move the "+" mark to the end point of the measurement, at the same time a lighted dotted line appears between two measurement marks as the locus of the measurement, the measured value will be automatically shown at the right hand of the screen;
5. Press『D+』key to exchange the starting point and the end point;
6. Press『Set』key to finish the first time measurement;
7. Repeat the steps from 3 to 6 to complete multi-group data measurement;
8. Press『B_meas』key to exit the measurement.

9.2 Circumference/area measurement

Two kinds of operation methods

A. Trace measurement

Function: Measure the circumference/area of a confined area with the trace method.

1. In B, B/B, 4B, B/A mode, choose a valuable image;
2. Press『B_meas』key, the cursor will show "+", move the cursor to the〖Trace〗of〖Cir/Area〗submenu of【B MEAS】, press『Set』key;
3. Operate the trackball or the direction keys to move the "+" mark to the desired position, press 『Set』key, make the "+"position as the starting point to be measured;

4. Operate the trackball or the direction keys to move the "+" mark to the end point of the measurement, at the same time it appears a trace between two measurement marks along the direction of operation. The measured circumference value is automatically displayed at the built-in mark "C1: ----mm" on the right part of the screen. Press『Set』key to automatically display the measured value of the area formed by measurement line enclosure;
5. Repeat the steps 3~4 to complete multi-group data measurement;
6. Press『B_meas』key to exit the measurement.

B. Ellipse measurement

Function: Measure the circumference/area of a confined area with the ellipse approximations.

1. In B, B/B, 4B, B/A mode, choose a valuable image;
2. Press『B_meas』key, the cursor will show "+", move the cursor to the〖Ellipse〗of〖Cir/Area〗submenu of【B MEAS】, press『Set』key;
3. Operate the trackball or the direction keys to move the "+" mark to the desired position, press『Set』key, make the "+"position as the starting point to be measured;
4. Operate the trackball or the direction keys to move the "+" mark to end point of the measurement, at the same time the elliptic curve appears, rotate『Function』knob to change the minor axis of the ellipse to make it satisfy the area need to be measured;
5. Press『D+』key to exchange the starting point and the end point;
6. Press『Set』key to finish the first measurement;
7. Repeat the steps 3~6 to complete multi-group data measurement;
8. Press『B_meas』key to exit the measurement.

9.3 Volume measurement with 2-Axis method

Function: Measure the target volume. It only needs to measure the vertical section.

Formula of 2-Axis method: $(\pi/6) * A * B^2$

Where, A is the major axis of the ellipse; B is the minor axis of the ellipse.

1. In B, B/B, 4B, B/A mode, chooses a valuable image;
2. Press『B_meas』key, the cursor will show "+", move the cursor to the〖2-Axis〗of〖Volume〗submenu of【B MEAS】, press『Set』key;
3. Operate the trackball or the direction keys to move the "+" mark to the desired position, press『Set』key, make the "+"position as the starting point to be measured;
4. Operate the trackball or the direction keys to move the "+" mark to end point of the measurement, at the same time it appears elliptical curve, rotate『Function』knob to change the minor axis of the ellipse to make it satisfy the area need to be measured, the measured values of area and volume are automatically displayed on the right part of the screen;
5. Press『D+』key to exchange the starting point and the end point;
6. Press『Set』key to finish the first measurement;
7. Repeat the steps 3~6 to complete multi-group data measurement;
8. Press『B_meas』key to exit the measurement.

9.4 Angle measurement

Function: measure the included angle of the two straight lines. (0°-180°)

Operation steps:

1. In B, B/B, 4B, B/A mode, chooses a valuable image;
2. Press『B_meas』key, the cursor will show "+", move the cursor to the submenu『Angle』of【B MEAS】, press『Set』key;
3. At first draw line along one hand of the measurement angle referring to the "Distance" measurement;

4. Then draw line again along the other hand of the measurement angle referring to the "Distance" measurement. At last the included angle of two lines and their length will show on the right of the shown area;
5. Press『B_meas』key to exit the measurement.

9.5 Histogram measurement

Function: Measures the grey distribution of ultrasonic echo signals within a closed region, and indicates with histogram. The target region needs enclosed with ellipse or rectangle. Histogram is only measured on the frozen image.

A. Ellipse method measurement

1. In B, B/B, 4B, B/A mode, freeze a valuable image;
2. Press『B_meas』key, the cursor will show "+", move the cursor to the〖Ellipse〗of〖Histogram〗submenu of【B MEAS】, press『Set』key;
3. Operate the trackball or the direction keys to move the "+" mark to the desired position, press『Set』key, make the "+"position as the starting point to be measured;
4. Operate the trackball or direction keys to move the "+" mark to end point of the measurement, at the same time the elliptical curve appears, rotate『Function』knob to change the minor axis of the ellipse to make it satisfy the area need to be measured, press『D+』key to exchange the starting point and the end point; press『Set』key, the peak of histogram is automatically displayed on the right part of the screen, while the histogram is also displayed in the lower right of screen;
5. Repeat the steps 3, 4 can measure for several times;
6. Press『B_meas』key to exit the measurement.

B. Rectangle method measurement

1. In B, B/B, 4B, B/A mode, freeze a valuable image;
2. Press『B_meas』key, the cursor will show "+", move the cursor to the〖Rectangle〗of〖Histogram〗submenu of【B MEAS】, press『Set』key;
3. Operate the trackball or direction keys to move the "+" mark to the desired position, press『Set』key, make the "+"position as the starting point to be measured;
4. Operate the trackball or direction keys to move the "+" mark to end point of the measurement, at the same time the rectangular area appears, operate the trackball or direction keys to change the size of rectangle to make it satisfy the area need to be measured, press『D+』key to exchange the starting point and the end point; press『Set』key, the peak of histogram is automatically displayed on the right part of the screen, while the histogram is also displayed in the lower right of screen;
5. Repeat the steps 3, 4 can measure for several times;
6. Press『B_meas』key to exit the measurement.

9.6 Profile measurement

Function: Measures the grey distribution of ultrasonic echo signals on a cross-section in a horizontal or vertical direction, and indicates with profile. Profile is only measured on the frozen image.

1. In B, B/B, 4B, B/A mode, freeze a valuable image;
2. Press『B_meas』key, the cursor will show "+", move the cursor to the submenu『Profile』of【B MEAS】, press『Set』key;
3. Operate the trackball or direction keys to move the "+" mark to the desired position, press『Set』key, make the "+"position as the starting point to be measured;

4. Operate the trackball or direction keys to move the "+" mark to end point of the measurement, at the same time a dashed line appears between the two measurement marks, press『D+』key to exchange the starting point and the end point; press『Set』key, the peak, valley and mean values are automatically displayed on the right part of the screen, while profile is also displayed in the image area;
5. Repeat the steps 3, 4 can measure for several times;
6. Press『B_meas』key to exit the measurement.

9.7 Stenosis ratio measurement

Function: measure and calculate the stenosis degree of the blood vessel. There are two kinds of stenosis ratio, one is distance stenosis ratio the other is area stenosis ratio. Both are calculated according to the distance and area.

Stenosis ratio formulas:

Distance stenosis ratio: %D = [(D1-D2)/D1] * 100%

Area stenosis ratio: %A = [(A1-A2)/A1] * 100%

Where, D1 is the distance at the non-stenosis position; A1 is the area at the non-stenosis position either. D2 and A2 are separately the distance and area at the stenosis position.

9.7.1 Distance Stenosis Ratio measurement

1. In B, B/B, 4B, B/A mode, chooses a valuable image;
2. Press『B_meas』key, the cursor will show "+", move the cursor to the submenu〖Distance〗of 〖% Stenosis〗of【B MEAS】, press『Set』key;
3. Measure the distance D1 at the non-stenosis position, the method is the same as "Distance" measurement;
4. Measure the distance D2 at the stenosis position, the method is the same as "Distance" measurement. After measurement, DSR and distance value will be showed on the right of the shown area;
5. Repeat the steps 1, 2, 3, 4 to measure the next distance stenosis ratio;
6. Press『B_meas』key to exit the measurement.

9.7.2 Area Stenosis Ratio measurement

1. In B, B/B, 4B, B/A mode, chooses a valuable image;
2. Press『B_meas』key, the cursor will show "+", move the cursor to the submenu〖Area〗of〖% Stenosis〗of【B MEAS】, press『Set』key;
3. Measure the area A1 at the non-stenosis position, the method is the same as "Circumference/area" of the "Ellipse";
4. Measure the area A2 at the stenosis position and the method is the same as "Circumference/area" of the "Ellipse". After measurement, ASR and area value will be showed on the right of the shown area;
5. Repeat the steps 1, 2, 3, 4 to measure the next area stenosis ratio;
6. Press『B_meas』key to exit the measurement.

Chapter Ten A-ultrasound Biological Measurement

A-ultrasound biological measurement can measures the anterior chamber depth, lens thickness and vitreous body length with ultrasound method, and calculates the axial length. To ensure accuracy, it should be as far as possible from corneal vertex into ultrasonic wave, and coincides with the optic axis.

It can choose manual mode and automatic mode in system measurement; manual mode is divided into A measurement method, A mode five-point measurement method and B/A mode five-point measurement method. Automatic mode is only used in A mode five-point measurement method.

The correct settings of sound velocity significantly affect the measurement accuracy and the results, so it should be correctly set the sound velocity for normal eye, aphakia, special eye, and cataract eye.

Default and user-defined sound velocity description table

Sound velocity / Eye model	Anterior chamber depth Va(m/s)	Lens thickness Vl(m/s)	Vitreous body length Vv(m/s)
Normal eye	1532	1641	1532
Cataract eye	1532	1629	1532
Aphakia	----	----	1532(*)
Special eye	1532(*)	2718(*)	1532(*)
Referable velocity for lens material: PMMA:2718, Acrylic:1946, Silicone:1050			

Note: (*) The system provides defaults but user can change the sound velocity in the system preset; the sound velocity of lens thickness for special eye can be set in the system preset after user consult from the IOL manufacturer; aphakia can be used as a special eye when need to set sound velocity.

According to the contact between A-mode probe and cornea, the measurement can be divided into contact and immersion measurement.

Contact measurement that is A-mode probe directly contact with corneal vertex. This measurement method is sample and easy to master. However, probe contacts cornea, which may cause corneal injury, also affect the measurement results due to a slight deformation of cornea. So the operator's skill should be light, try not to oppress the cornea. The contact method is available for auto/manual measurement.

Immersion measurement that is A-mode probe acts on the eye through acoustic coupling medium, not directly contact with the cornea. Gently place the eye cup within the eyelid, fix the eye cup with eyelid, the eye cup is injected into the saline as coupling medium, A-mode probe is immersed into the saline, not contact with the cornea. The probe is perpendicular to cornea and close to it; it starts automatic measurement when distance is 3mm – 8mm between the current terminal and corneal vertex.

10.1 A-mode calibration

Before A-mode measurement, you can use A-mode probe calibration cup equipped with the machine to test the A-mode measurement function is properly.

1. Measure at room temperature (25℃), the A-mode probe calibration cup is filled with degassed distilled water, pay special attention to not have bubbles in water. Gently and vertically place A-mode probe on the highest ladder in the A-mode probe calibration cup (as shown below);
2. Press Setup key on the keyboard, open "System Preset" dialog box, set the sound velocity for special eye as 1497m/s (sees the "VEL" in the IOL Constant dialog box);
3. Press A key to enter A mode;

4. Move the cursor to〖AUTO/MANL〗of【Five Point MEAS】, press『Set』key; or press AUTO MANL key to select measurement status "AUTO", the selected result is shown in the status line;
5. Move the cursor to〖CONT/IMME〗of【Five Point MEAS】, press『Set』key, select measurement method "Contact", the selected result is shown in the status line;
6. Move the cursor to〖OP MODE〗of【Five Point MEAS】, press『Set』key, select the appropriate eye mode "Special eye", the selected result is shown in the status line;
7. To make the machine in scanning status, properly adjust gain to obtain a good waveform, press up/down direction keys to adjust A-ultrasound measurement threshold;
8. When you hear a bunch of "tick" song, it indicates the result has been measured and shown on the screen. If not hear the "tick" song, you can slightly move the probe until the "tick" song appears and the result be measured. If the error between measured simulation axial length (AL) and nominal equivalent length marked on the A-mode probe calibration cup is not more than 0.1mm, indicating that the machine is working properly (due to user conditions, almost the same measured AL value is generally normal).

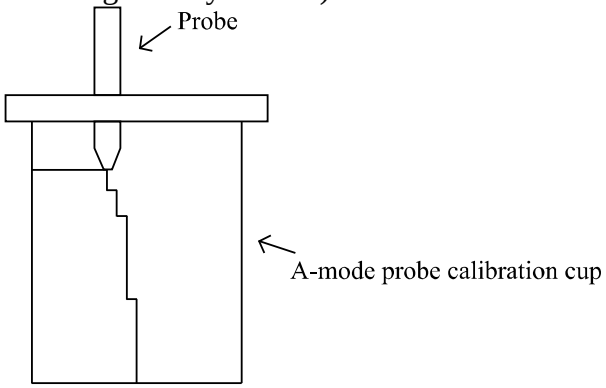


Fig. Accuracy calibration diagram

Note: (1) The nominal equivalent length that simulated axial length (AL) is marked on the A-mode probe calibration cup.

(2) If you observe the measured simulation axial length AL has large deviation, you need to move the A-mode probe repeatedly and the A-mode probe is perpendicular to the cylinder, observe that the measured data is whether within the range (if measured data not within the range, please contact us).

A measurement, A mode five-point measurement, five-point measurement in B/A mode will be introduced separately in the following.

10.2 A measurement

Press A key to enter A mode, press『A_meas』key, enter "A MEAS" menu, as figures:

A MEAS
OP MODE
ACD
LENS
VITR
DELAY

Fig. A measurement menu

10.2.1 Anterior chamber depth measurement

Operation steps:

1. Press『A_meas』key, enter "A MEAS" menu;
2. Freeze a valuable image;
3. Move the cursor to〖OP MODE〗of【A MEAS】, press『Set』key, select eye mode;

4. Move the cursor to〖ACD〗of【A MEAS】, press『Set』key, enter the measurement;
5. Operate the trackball or left/right direction keys to move the cursor to the starting point of the measurement, press『Set』key to confirm the starting point of measurement;
6. Operate the trackball or left/right direction keys to move the cursor to the end point of the measurement, press『Set』key, complete this measurement, the measured value is displayed on the anterior chamber depth;
7. Repeat the steps from 4 to 6 to start measurement for next time;
8. Press key to freeze and clear the screen.

10.2.2 Measure lens thickness, vitreous body length

The measurement methods for lens thickness and vitreous body length are the same as "Anterior chamber depth measurement".

10.2.3 Function operation in A measurement

- In real time "A MEAS" mode, press key to change the image magnification (it has 1, 2, 4 magnification), the prompt information "ZOOM DISP: x1" shown in the lower right of A-ultrasound waveform;
- Move the cursor to〖DELAY〗of【A MEAS】, press『Set』key, "⟷" mark appears in the upper right of A-ultrasound waveform, operate the trackball to choose delay depth, press『Set』key to lock the delay depth, press Esc key to exit the delay depth.

10.3 Five-point measurement in A mode

Five-point mark method that when a beam of ultrasound through the visual axis, we can get ultrasonic reflection of five interfaces, they are: 1 – corneal previous vertex, 2 – posterior cornea, 3 – anterior lens, 4 – posterior lens, 5 – retina.

Due to the eye's special structure, the sound velocity in different tissues is different, the velocities for each segment are:

Cornea: Vcor = 1620 m/s (1) - (2)
Anterior chamber: Vac = 1532 m/s (2) - (3)
Lens: Vlen = 1641 m/s (3) - (4)
Vitreous body: Vvitr = 1532 m/s (4) - (5)

Axial length (AL) = Vcor* (t2-t1) + Vac* (t3-t2) + Vlen * (t4-t3) + Vvitr * (t5-t4)

As long as we mark the five feature points accurately, according to above formula we can accurately calculate the axial length. This is five-point mark method for measuring axial length.

Press A key to enter A mode.

Status information in A mode interface are divided into three types: 1. Auto/Manual, 2. Contact/Immersion, 3. Normal eye/aphakia/cataract eye/special eye.

AC – Anterior chamber depth, LENS – Lens thickness, VITR – Vitreous body length, AL – Axial length, the following are the corresponding sound velocity (except AL – Axial length) and 10 groups of measurements, as well as (S.D.) standard difference and (AVG) measurement average value.

The five-point measurement menu is in the upper right corner of A mode interface.

10.3.1 Auto measurement

Operation steps:

1. Press A key to enter A mode;
2. Move the cursor to〖AUTO/MANL〗of【Five Point MEAS】, press『Set』key; or press AUTO MANL key to select measurement status "AUTO", the selected result is shown in the status line;
3. Move the cursor to〖CONT/IMME〗of【Five Point MEAS】, press『Set』key, select measurement method "Contact" or "Immersion", the selected result is shown in the status line;
4. Move the cursor to〖OP MODE〗of【Five Point MEAS】, press『Set』key, select the appropriate eye mode "normal eye" or "aphakia" or "special eye" or "cataract eye", the selected result is shown in the status line;
5. To make patient supine and eyes open, the test eye surface for anesthesia;

6. Pick up A-mode probe; wash the front of probe with chloramphenicol eye drops;
7. To make the machine in scanning status; If choose contact measurement, tell patient to look into the probe, gently place the probe on the corneal vertex of tested eye; or if choose immersion measurement, place the eye cup into the eyelid, inject the saline into the cup, vertically immerse the probe into the eye cup, tell patient to look into the probe, carefully move the probe close to cornea gradually (the front of probe is away from cornea 2mm–6mm), properly adjust gain to obtain a good waveform, press up/down direction keys to adjust A-ultrasound measurement threshold;
8. When you hear a bunch of "tick" song, it indicates the result has been measured and shown on the screen. If not hear the "tick" song, you can slightly move the probe until the "tick" song appears and the result be measured. After finishing a measurement, it will automatically the next measurement until press freeze key or foot switch to freeze and stop measurement, or it will automatically freeze and stop measurement after finishing ten groups. Each patient can be measured up to ten groups of results, operator can decide the number of groups according to need;

> ⚠**Attention**: **Automatic measured results need be sample average for several times, so it requires the doctor practice to light, to stable. Until the measured result is displayed on the screen, you can remove the probe.**

Observe the measured results, delete the unreliable data: press [+] [-] key can move the ➞ mark to the line to be deleted, move the cursor to〖DEL〗of【Five Point MEAS】, press『Set』key, this line will be deleted, record will automatically move up. After deletion, average value will be recalculated.

Need to delete the following results:

1) The position of mark is not corresponding with the front of waveform;
2) The retina peak is not steep;
3) It has larger difference between measured result and average value;

9. Mark the eye position: press [OS/OD] key to mark left eye (OS) and right eye (OD);
10. Clear the current result, re-measurement: move the cursor to〖NEW〗of【Five Point MEAS】, press『Set』key, the current all records will be cleared, can re-measurement;
11. After finishing the measurement, the system will automatically save ten groups of measured results and the corresponding waveforms for correction, system will automatically clear the last saved results if re-measurement.

Explanation: After measure ten groups of results and automatically freeze, press ❄ key not to freeze; only choose any item in〖AUTO/MANL〗,〖CONT/IMME〗,〖OP MODE〗,〖NEW〗in the【Five Point MEAS】menu, press『Set』key can unfreeze and clear the records.

10.3.2 Manual measurement

When auto measurement is difficult to measure the results, or difficult to meet patient's body conditions, can use manual measurement, otherwise not recommend using manual measurement.

Operation steps:

1. Press [A] key to enter A mode;
2. Move the cursor to〖AUTO/MANL〗of【Five Point MEAS】, press『Set』key; or press [AUTO MANL] key to select measurement status "MANL", the selected result is shown in the status line;
3. Move the cursor to〖CONT/IMME〗of【Five Point MEAS】, press『Set』key, select measurement method "Contact" or "Immersion", the selected result is shown in the status line;
4. Move the cursor to〖OP MODE〗of【Five Point MEAS】, press『Set』key, select the appropriate eye mode "normal eye" or "aphakia" or "special eye" or "cataract eye", the selected result is shown in the status line;

5. To make patient supine and eyes open, the test eye surface for anesthesia;
6. Pick up A-mode probe, wash the front of probe with chloramphenicol eye drops;
7. To make the machine in scanning status;

- If choose contact measurement, tell patient to look into the probe, gently place the probe on the corneal vertex of tested eye.
- If choose immersion measurement, place the eye cup into the eyelid, inject the saline into the cup, vertically immerse the probe into the eye cup, tell patient to look into the probe, carefully move the probe close to cornea gradually, when the front of probe is away from cornea 2mm–6mm;

8. Move the cursor to〖START〗of【Five Point MEAS】, press『Set』key to start measurement;
9. Properly adjust gain to obtain a good waveform, press up/down direction keys to adjust A-ultrasound measurement threshold;
10. Press key to freeze the waveform, move the trackball to A-ultrasound waveform, press 『Set』key in turn to mark five feature points (if not distinguish the front and back of cornea, point 1 and point 2 can be marked in the position of point 1 at the same time); when completed the mark of the fifth point, the measured result of axial length will be automatically displayed on the screen;
11. Mark the eye position: press key to mark left eye (OS) and right eye (OD);
12. Clear the current result, re-measurement: move the cursor to〖NEW〗of【Five Point MEAS】, press『Set』key, the current all records will be cleared, can re-measurement;
13. After finishing the measurement, the system will automatically save ten groups of measured results and the corresponding waveforms, system will automatically clear the last saved results if re-measurement.

10.3.3 Measured results correction

When completed auto measurement and the standard deviation S.D. can not meet the clinical requirements, can use manual mark to correction:

1. Press key to observe the measured A-ultrasound waveform, re-mark the inaccurate results of automatic measurement mark;
2. Move the cursor to〖CORRECTION〗of【Five Point MEAS】, press『Set』key to enter mark status;
3. Move the trackball to A-ultrasound waveform, press『Set』key in turn to mark four feature points;
4. When completed the mark of the fourth point, this measured result will be re-calculation according to mark, axial average value and the standard deviation (S.D.) will be all re-calculation.

10.4 Measure axial with five-point mark method in B/A mode

1. Press key to enter B/A mode;
2. Use immersion method to scan eyeball, obtain the desirable image and freeze it;
3. Move the trackball, move the cursor to〖Five Point MEAS〗of【B/A MODE MENU】, pop up the submenu of eye mode, move the cursor to choose eye mode. press『Set』key to enter five-point mark status;
4. Move the trackball to A-ultrasound waveform at the bottom of screen, press『Set』key in turn to mark five feature points (if not distinguish the front and back of cornea, point 1 and point 2 can be marked in the position of point 1 at the same time);
5. When completed the mark of the fifth point, the measured result of axial length will be automatically displayed on the screen.

Chapter Eleven IOL calculation

11.1 Constants in the formula

The machine provides six groups of IOL formulas, SRK-Ⅱ, SRK-T, BINKHORST, HOLLADAY, HOFFER-Q and HAIGIS. Different formulas use different constants, respectively be marked to A or ACD or SF. These constants are provided by the IOL manufacturers. They can be modified, saved in System Preset; the operation method sees System Preset.

In BINKHORST, HOFFER-Q formula use ACD constant, that is anterior chamber depth, this constant can also be calculated out by A constant:

ACD = {[(A*0.5663)-65.60]+3.595}/0.9704, or

ACD = (SF+3.595)/0.9704

SF constant is used in HOLLADAY formula, which also is calculated out by A constant:

SF = (A*0.5663) - 65.60, or

SF = (ACD*0.9704) - 3.595

After enter A constant, this machine will automatically complete SF calculation.

A constant is used in SRK-Ⅱ, SRK-T formula, which is calculated out by the following formulas:

A = (SF+65.60)/0.5663, or

A = 109.49 + (1.71358*ACD)

Use three constants a0/a1/a2 in SRK-Ⅱ, SRK-T formulas, the three constants can also be calculated out by A constant:

a0 = (0.62467*A) - 72.434

a1 = 0.40

a2 = 0.10

11.2 IOL calculation steps

1. Before each calculation, first input patient information (including name, age, ID, sex) and choose OS/OD;
2. Press IOL key to enter calculation status;
3. Move the trackball to choose the appropriate formula;
4. Input parameters:

   AL = Axial Length

   K1, K2 = Corneal curvature

   After enter the calculation status, the average value of axial length automatically measured is filled into AL. If need to input by manual, move the trackball to "AL", press 『Set』 key, with number keys and decimal key Dot to input.
5. A or ACD constant in the following formula is modified or saved in the System Preset, the operation sees the System Preset.

Note: For HAIGIS, need to input the AC. Enter the calculation status, the average value of anterior chamber depth automatically measured is filled into AC. If need to input by manual, move the trackball to "AC", press 『Set』 key, use the number keys and decimal point Dot to complete the input.

6. Move the trackball to "Cal" button in the interface, press『Set』key, automatically calculate. The calculated results as follows:

   DEM Emmetropization IOL degree, unit (D)

   DAM Post-operation keep degree, need to implant IOL degree, unit (D)

   IOL Intraocular lens degree, unit (D)

   REFR Post-operation residual vision degree, unit (D)

   Each group of axial length, corneal curvature and post-operation keep degree can be calculated with two formulas simultaneously in order to control.

7. Save data: The parameters and results displayed on the screen are as a record, move the trackball to "Save" button in the interface, press『Set』key, the records will be saved.
8. Read data: Move the trackball to "Cur Rec" in the interface to click the drop-down control, find the record need to be read.
9. Transfer data: Move the trackball to "Transfer" button in the interface and press『Set』key, or press iStation key, or long press foot switch for 3 to 5 seconds, IOL calculation data will be transferred to Network Printer software.
10. Exit the interface: Move the trackball to "CLOSE" button in the interface, press『Set』key to close it.

Chapter Twelve Print and Transfer files

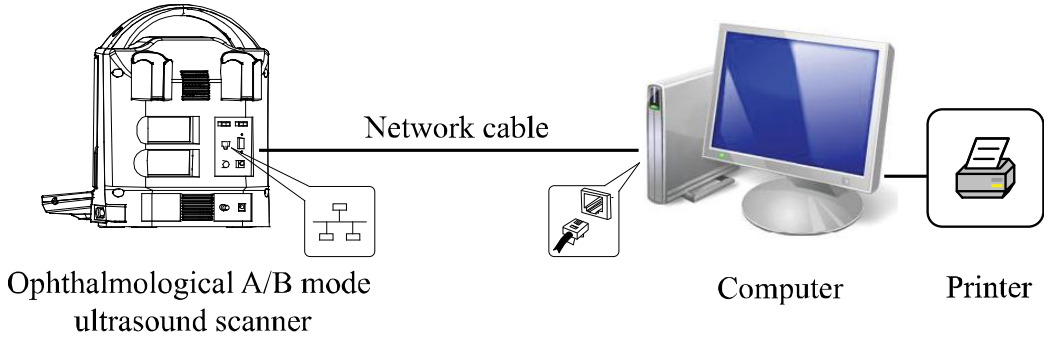
12.1 Print

The system supports network print and USB print.

12.1.1 Network print

Before using the network print, you must install the PC application software "Network Printer". Network setting has two ways: "Direct Line to the Ultrasound", "Line to the network". By the "Direct Line to the Ultrasound" or "Line to the network" way, it can achieve the network printing function.

- **Direct Line to the Ultrasound**



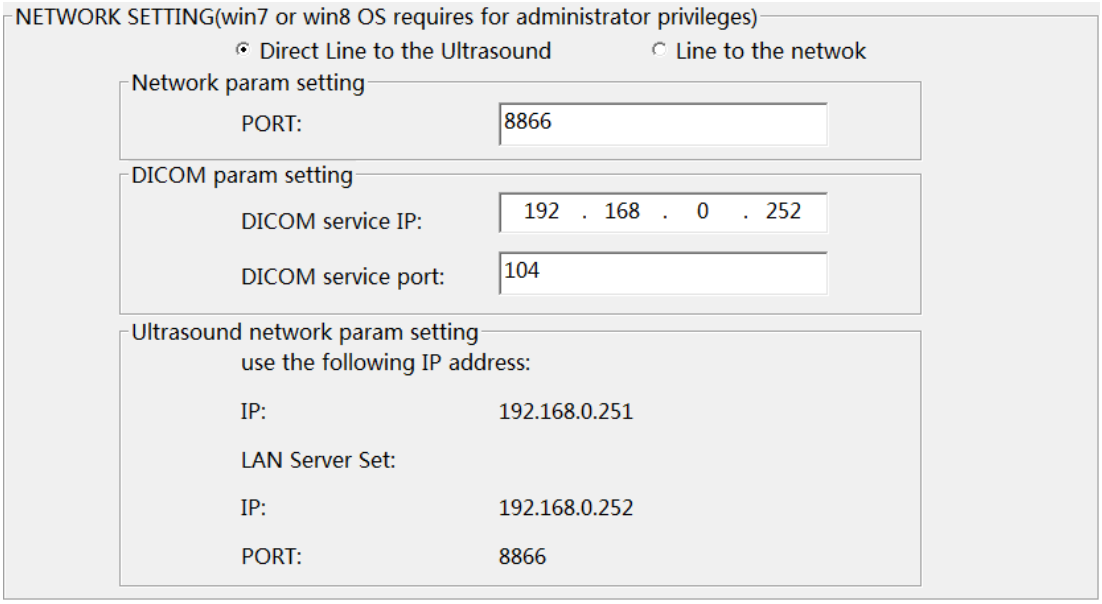
Schematic: Direct Line to the Ultrasound

1. Open the Opthalmological A/B mode ultrasound scanner.
2. Use a network cable to connect the network port of the instrument and the computer's network port, and then installs the printer on your computer.
3. Unzip the "Network Printer_V3.1" compressed package to PC side, open the folder of Network Printer, and right click the icon NetworkPrinter.exe to select "Run as administrator" to open the software.

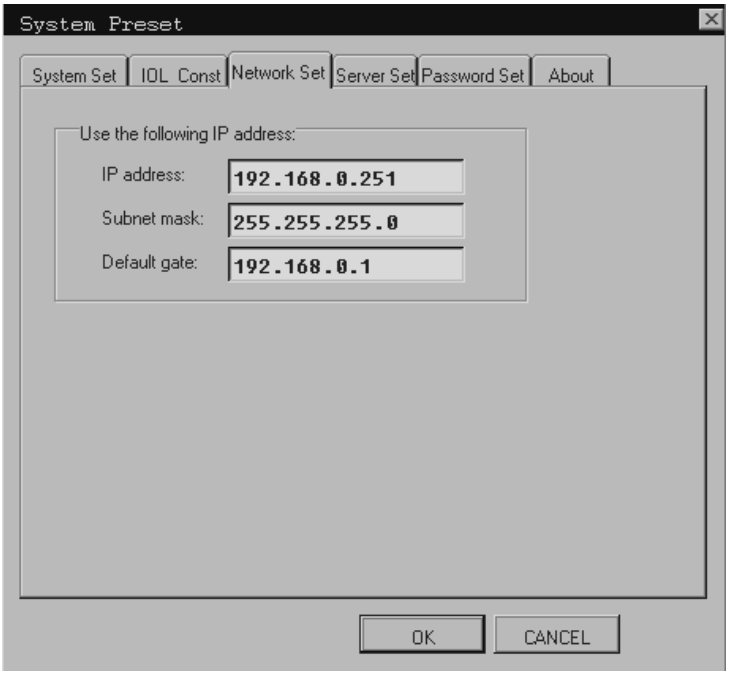
⚠Attention:

1. **In Windows XP operating system, directly double click the icon NetworkPrinter.exe to open the software; In Win 7, Win 8 operating system, you need to right click and choose "Run as administrator" to run the software.**
2. **When you run the Network Printer.exe first time, please close the Windows Firewall or Anti-virus software, if pop-up the Windows Security Alert or appears unknown program, choose the all access or unblock, the software can run normally.**

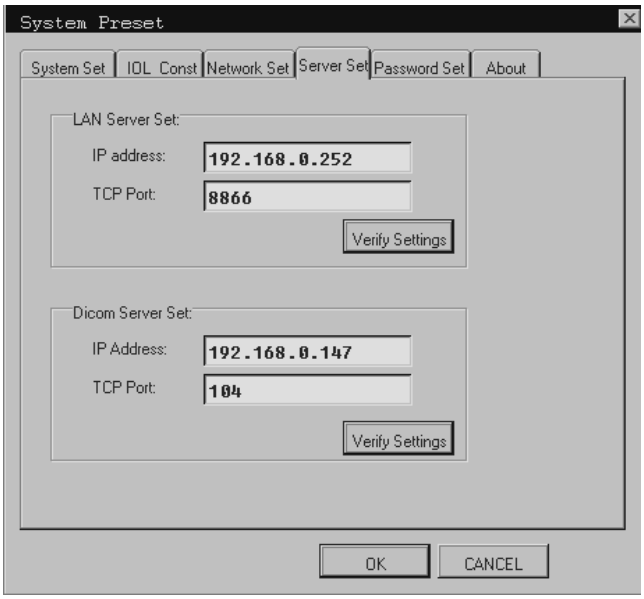
4. In the Network Printer software, the default way "Direct Line to the Ultrasound". Without requiring the user to set network parameters of ultrasonic diagnostic instrument, the default value is displayed as shown below:



5. Press Setup key on the keyboard to open "System Preset" dialog box, select『Network Set』, press 『Set』key to show the "Network Set" dialog box, ensure that the default setting as shown on the Figure:

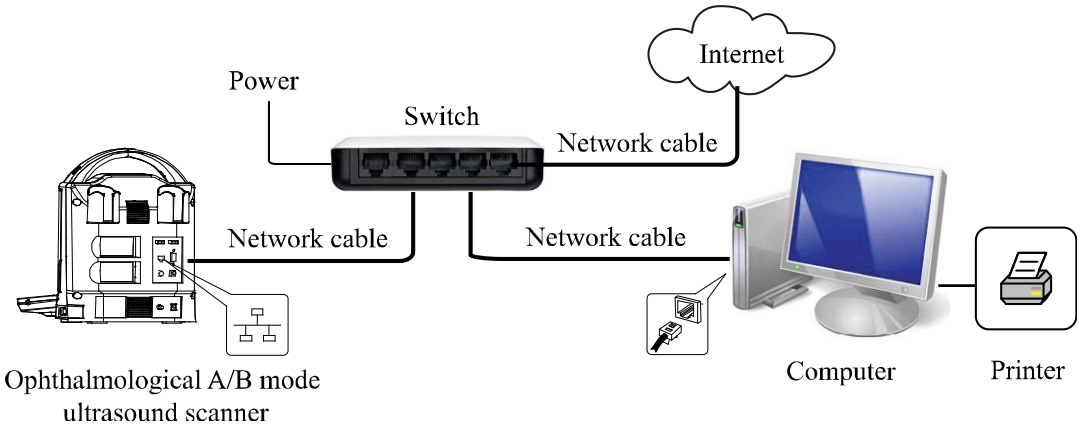


6. Press Setup key on the keyboard to open "System Preset" dialog box, select『Server Set』, press 『Set』key to show the "Server Set" dialog box. View the "LAN Server Set" in the "Server Set" dialog box; ensure that the IP address is the same as the IP address of LAN Server Set in the Network Printer software.



7. After setting is correct, you can directly print report or image.
   Note: In the "Direct Line to the Ultrasound" way, the computer cannot connect to the Internet network.

- **Line to the network**



Schematic: Line to the network

1. Open the Opthalmological A/B mode ultrasound scanner.
2. Using a network cable to connect the network port of the instrument to the switch, the network port of computer also connects to the switch, and then installs the printer on your computer, the printer sets for sharing; Make sure the PC can connect to Internet.
3. Unzip the "Network Printer_V3.1" compressed package to PC side, open the folder of Network Printer, and right click the icon NetworkPrinter.exe to select "Run as administrator" to open the software.

⚠Attention:

1. **In Windows XP operating system, directly double click the icon NetworkPrinter.exe to open the software; In Win 7, Win 8 operating system, you need to right click and choose "Run as administrator" to run the software.**
2. **When you run the Network Printer.exe first time, please close the Windows Firewall or Anti-virus software, if pop-up the Windows Security Alert or appears unknown program, choose the all access or unblock, the software can run normally.**

4. In the Network Printer software, click the system setting icon, in the "Network param setting", the default value of PORT is 8866, usually it doesn't need to re-set. Select the way "Line to the network", click APPLY button, the ultrasound network parameter automatically appears, as shown on the Figure 1:

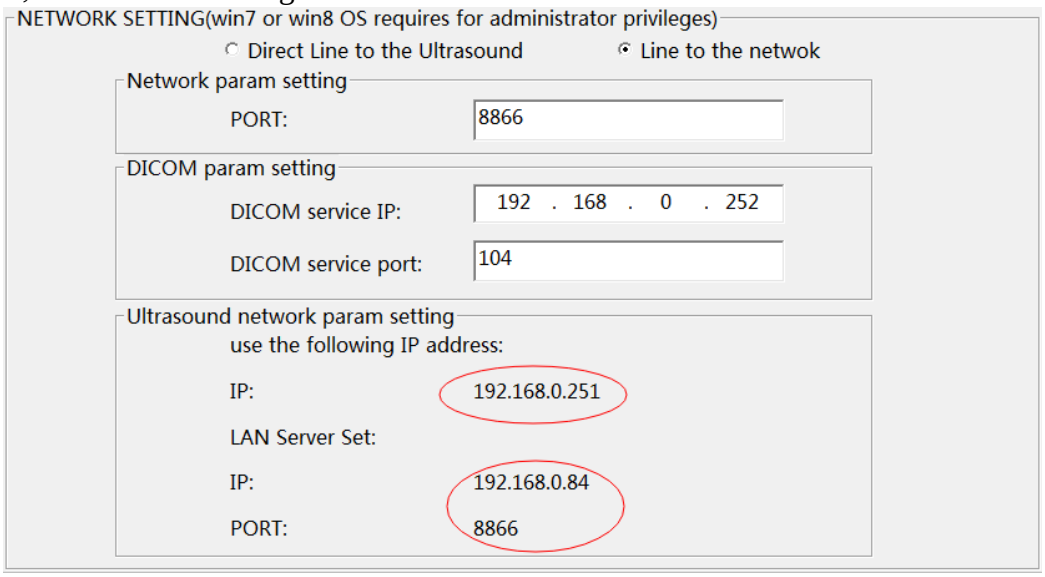


Fig 1. Network Setting on the way "Line to the network"

Note: In the interface "Ultrasound network param setting", if not display the local IP, please wait for a while to display.

5. Press Setup key on the keyboard to open "System Preset" dialog box, select『Network Set』, press 『Set』 key to show the "Network Set" dialog box, the IP address of the instrument in the "Ultrasound network parameter setting" appeared on Fig 1 directly are entered into the "Network Set" dialog box, as shown on the Fig 2:

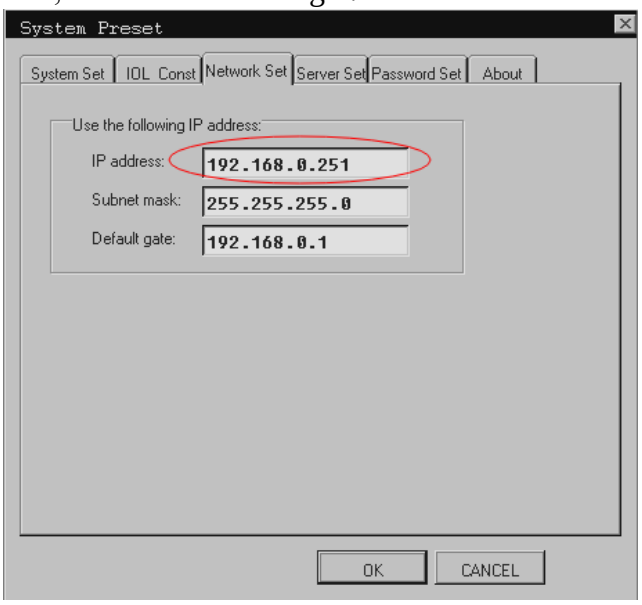


Fig 2. Network Set in the way "Line to the network"

Description1: Set the network properties of the Opthalmological A/B mode ultrasound scanner, including IP address, subnet mask, and default gate. For example:

IP address: 192.168.0.251
Subnet mask: 255.255.255.0
Default gate: 192.168.0.1

Description2: The IP address of the instrument and LAN Server should be on the same subnet. Do not clash with other hosts of the LAN when setting IP address.

6. Press Setup key on the keyboard to open "System Preset" dialog box, select『Server Set』, press 『Set』key to show the "Server Set" dialog box, the "LAN Server Set" in the "Ultrasound network parameter setting" appeared on Fig 1 directly are entered into the "Server Set" dialog box, as shown on the Fig 3:

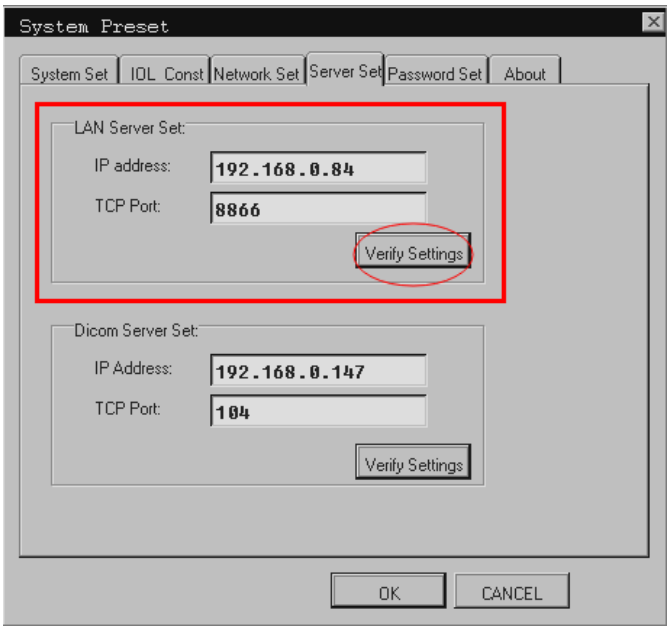


Fig 3. Server Set in the way "Line to the network"

Description: In the LAN Server Set, IP address is the LAN Server; TCP port is 8866.

7. After the setting is complete, choose『Verify Settings』 button marked on the dialog box, "Success!" prompt box will pop up, press「OK」of the prompt box, press『Set』key, and then press 「OK」of dialog box, press『Set』key, that is finishing the correct LAN Server Set, you can directly print report or image; If pop the warning box, please check IP address and TCP port, as well as the network cable is properly connected.
8. After setting is correct, you can directly print report or image.

Note: In the "Line to the network" way, the computer connects to the Internet network.

Description: the specific use of Network Printer sees its instructions for use.

⚠Warning:

1. **It is forbidden to unplug the printer data cable in the case of without shutting down the system's power switch and printer's power switch; or it may cause the system or printer damage or electrical shock.**
2. **It is forbidden to unplug the printer's power plug in the case of without shutting down the printer's power switch; or it may cause the printer damage or electrical shock.**

⚠Attention:

1. **Some network anomalies cause a timeout for a long time, especially unplug the network cable in the phase of connecting and printing, need to wait several minutes to tens of minutes, so recommend the user not to do network anomalies operation.**
2. **During the network printing, do not close the NetworkPrinter.exe software.**
3. **Make sure the printer connected to the system normally, the printer has papers and the printer's work status is normal.**

12.1.2 USB Print

1. Insert U disk into the USB port at the back of main unit;
2. Save the images or reports within the system to U disk, unplug the U disk after completed saving;
3. Connect U disk to PC, you can print out the images or reports by the default printer in the PC.

12.2 Transfer files

After successfully set the network, you can press iStation key on the keyboard or long press foot switch for 3 to 5 seconds to transfer the images or data to PC application software "Network Printer".

12.2.1 Transfer real-time or frozen images to Network Printer

1. Complete the correct settings of network;
2. In real-time or frozen status of B, 2B, 4B, B/A, A mode, press iStation key on the keyboard or long press foot switch for 3 to 5 seconds to transfer the current image to Network Printer.

12.2.2 Transfer A-scan measurement results and waveform to Network Printer

1. Complete the correct settings of network;
2. In frozen A mode, press iStation key on the keyboard or long press foot switch for 3 to 5 seconds to transfer the measurement results and waveform to Network Printer.

12.2.3 Transfer stored images to Network Printer

1. Complete the correct settings of network;
2. In the B, 2B, 4B, B/A mode, press 『Store/Recall』 key to enter【File Menu】;
3. Move the cursor to〖Recall BMP〗button, press 『Set』 key, the corresponding dialog box will be showed;
4. Move the cursor to "Select Driver" and make it point to "▼" then press 『Set』 key to choose driver and press 『Set』 key again to confirm;
5. Move the cursor to "File" column and choose the file which need to be opened, press『Set』key to confirm, move the cursor to「OK」in the dialog box and press 『Set』 key, the opened image will be showed on the screen, press iStation key or long press foot switch for 3 to 5 seconds, the stored image will be transferred to Network Printer.

Note: Open the image file in the B, 2B, 4B, B/A mode, transfer the stored image file to the Network Printer. In A mode transfer the stored image file, the image file received by the Network Printer will be shown abnormally.

12.2.4 Transfer IOL calculation data to Network Printer

1. Complete the correct settings of network;
2. Press IOL key to enter "IOL Cal" interface;
3. Move the trackball to "Transfer" button in the interface and press 『Set』 key, or press iStation key, or long press foot switch for 3 to 5 seconds, IOL calculation data will be transferred to Network Printer software.

12.3 DICOM parameter setting

After the success of the network settings, set the DICOM parameters of Network Printer software, ultrasound images can be transferred to the DICOM server.

1. set the DICOM parameters in the Network Printer software, as shown on the figure A:
   (1) DICOM service IP: the default IP is 192.168.0.252. Whichever way you choose "Direct Line

to the Ultrasound" or "Line to the network"; the entered IP should be the same as DICOM service IP.

(2) DICOM service port: is fixed value "104".

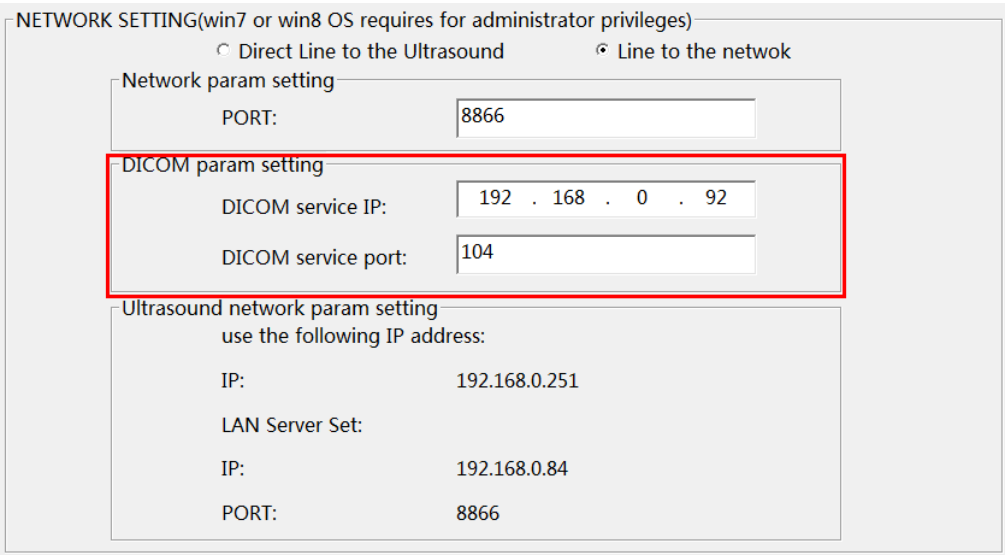
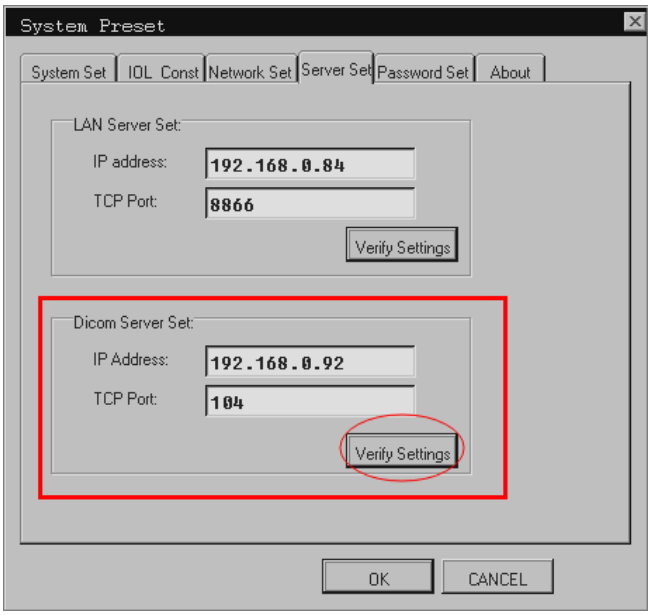


Figure A: DICOM parameter setting in the Network Printer software

2. Press Setup key on the keyboard to open "System Preset" dialog box, select『Server Set』, press 『Set』key to show the "Server Set" dialog box. In the Server Set interface, the "DICOM param setting" appeared on Figure A directly are entered into the "Server Set" dialog box, as shown on the Figure B:



3. After the setting is complete, choose『Verify Settings』button marked on the dialog box, "Echo success!" prompt box will pop up, press「OK」of the prompt box, press『Set』key, and then press 「OK」of dialog box, press『Set』key, that is finishing the correct Dicom Server Set, you can transfer DICOM files; If pop the warning box, please check IP address and TCP port, as well as the network cable is properly connected.

12.4 Transfer DICOM files

After successfully set the network, the images or reports can be transferred to DICOM server.

12.4.1 Transfer frozen images to Dicom server

1. Complete the correct settings of network and Dicom server;
2. Freeze the image which needs to be saved;
3. Press Store Recall key to enter【File Menu】;
4. Move the cursor to〖Store BMP〗button, press『Set』key, the corresponding dialog box will be showed;
5. Directly press「Dicom Archive」button, "Archiving success!" prompt box will be popped up, press「OK」of the dialog box, press『Set』key, it can realize the current frozen image archive to Dicom server;
6. Choose「CANCEL」button in the dialog box, press『Set』key, it will give up Dicom archive.

12.4.2 Transfer stored images to Dicom server

1. Complete the correct settings of network and Dicom server;
2. Press Store Recall key to enter【File Menu】;
3. Move the cursor to〖Recall BMP〗button, press『Set』key, the corresponding dialog box will be showed;
4. Move the cursor to "Select Driver" and make it point to "▼" then press『Set』key to choose driver and press『Set』key again to confirm;
5. Move the cursor to "File" column and choose the file which need to be opened, press『Set』key to confirm, press「Dicom Archive」button, "Archiving success!" prompt box will be popped up, and then choose「OK」;
6. Choose「CANCEL」button in the dialog box, press『Set』key, it will give up Dicom archive.

Chapter Thirteen Principle of Sound Power

13.1 Biological effect

It is generally recognized that ultrasonic diagnosis is safe for human's health. So far, there has been no report on bodily harm done by ultrasound.

Nevertheless it is also believed that not all types of ultrasound are absolutely safe. Relevant researches have already indicated that high-intensity ultrasound is harmful for human body.

With the development of ultrasonic diagnosis technology in recent years, people are more aware of the potential risk in biological effect caused by use of ultrasound and application of ultrasonic diagnostic technology.

13.2 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 heat index TI can explain two types of effects influencing level, the smaller value of MI/TI is, the less bio effect produce.

13.3 Prudent-use statement

Whereas it is not proved that ultrasonic diagnostic instrument may result in biological effect in human body, there is possibility that such biological effect is proved to be true in the future. Therefore we shall exercise prudence in applying the diagnostic ultrasound to clinical practice. We shall obtain clinical information necessary for the diagnosis with reasonable ultrasound and avoid using high-intensity ultrasound for long period of time.

13.4 LARA (as low as reasonably achievable) principle

Application of ultrasound shall be based on the ALARA principle that requires a minimized, biological effect-free energy output to obtain necessary diagnostic information. The ultrasonic energy intensity is related to output power and exposure time. Different patients and cases require different ultrasonic intensity.

Not all diagnosis can be done with extra-low ultrasonic energy output. The extra-low ultrasound power produces poor-quality image or weaker Doppler signal that may reduce the diagnostic reliability. On the other hand, use of sound power larger than diagnostically required makes no more contribution to improvement of the diagnostic information quality and increase the risk of biological effect possibility.

Therefore, user of the diagnostic ultrasound shall be fully aware of the patient's safety and choose a proper output level for a specific purpose based on ALARA principle.

13.5 The limits of acoustic output

When using any probe match in each mode, the acoustic output parameters for thermal index and mechanical index are below 1.0. Acoustic output data sees to appendix A.

13.6 Factors impacting sound power

Because the settings (transmission voltage, transmission frequency, etc.) are fixed in this system, there are no factors impacting sound power.

13.7 Image control impact on sound power output

Change of image control and adjustment may have influence on sound power output. See table below:

Operation	Influence on sound power output
Change image mode, automatically replace probe	This system provides two ultrasonic probes. B-mode probe is used in B, B/B, 4B, B/A mode; A-mode probe is used in A mode. The sound power for different probes is different.
Freeze	If freeze function makes the power transmission part of system stop operation, the system will not be able to transmit the ultrasound.
Restart or turn off/on power	Turn off/on the power will set the system in default status and change the sound power output.

Chapter Fourteen System Maintenance

The system maintenance should be performed by the user and service engineer. Users shall be in full charge of maintenance and operation of the system after purchasing the product.

⚠Warning: The following parts of the equipment are not serviced or maintained while in use with the patient.

14.1 Maintenance by users

14.1.1 System cleaning and disinfection

⚠Warning: Turn off the instrument and pull out the power supply wire before cleaning every instrument of the system. It may cause electric shock if clean the system under power is on.

⚠Warning: There is no any waterproof device in the system. Do not splash any water or liquor into the system when cleaning or maintaining; otherwise it will cause malfunction or electric shock.

⚠Warning: Part of population is allergic to isopropyl alcohol.

⚠Attention:

1. **Probe without cleaning, disinfection may become the source of contamination, so cleaning or disinfection to the probe is very necessary after every ultrasonic diagnosis.**
2. **To prevent possible infection, it is advisable to wear sterilized gloves when cleaning, disinfecting the ultrasonic probe.**
3. **In the process of cleaning and disinfection, avoid probe overheat (exceeding 60℃) as it may be deformed or damaged under excessive heat.**
4. **Do not use the probe packing box to store the probe as the box may become the source of contamination.**
5. **The waterproof grade of probe is IPX7, immersion depth is from probe's acoustic head to the part of probe shell; the immersion depth of B-mode probe is as shown below  , the immersion depth of A-mode probe is as shown below  .**

A. Clean the probe

1. Wear sterilized gloves to prevent possible infection;
2. Clean the probe with sterile water to remove all contaminants. Not use brush as it may damage the probe;
3. Dry the probe with sterilized cloth or gauze after cleaning. Do not dry the probe by heating it.

B. Pre-disinfected and disinfect the probe

1. It should use routine cleaning procedure to ensure good cleaning, pre-disinfection and disinfection after probe be used.
2. Usually use high infection risk cleaning methods to ensure good cleaning, pre-disinfection and disinfection after probe used for patients with Creutzfeld-Jacob disease.

⚠Attention:
Measurement unit: - %a.c. = active chlorine percentage
- ° chl = Gay-Lussac chlorometric grade
1. Pre-disinfected: * 0.5% a.c. (~1.5° chl) Sodium hypochlorite
2. Disinfection: * 2% a.c. (~6° chl) Sodium hypochlorite

Tip:
a. Before disconnecting the probe, it must be mandatory to turn off the equipment.
b. To avoid splashing the liquid on the probe connector (connect to the end of cable in the equipment)

Reagent Preparation

1). Disinfection: 2% A.C. Sodium hypochlorite preparation
(1) Pour 1L warm water (20~30℃) into 2L pot
(2) Pour 250 ml 9.6% a.c. (~36° chl) concentrated bleach
(3) Fill the pot with warm water (750 ml) and stir

⚠Attention: Place 2% sodium hypochlorite in a pot to store under 20℃ at room temperature for 6 months and without exposure to sunlight.

2). Pre-disinfected: 0.5% A.C. Sodium hypochlorite preparation
(1) Pour 1L warm water (20~30℃) into 4L pot
(2) Pour 1L 2% sodium hypochlorite solution prepared according to above procedure
(3) Fill the pot with warm water (2L) and stir

⚠Attention: Place 0.5% sodium hypochlorite in a pot to store under 20℃ at room temperature for 6 months and without exposure to sunlight.

3). Renew the contents in the immersed plate

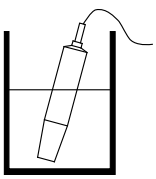
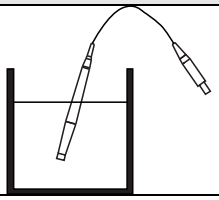
⚠Warning: Before emptying the contents in the immersed plate and after final disinfection, wait 10 minutes.

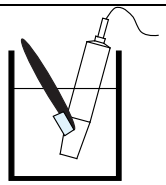
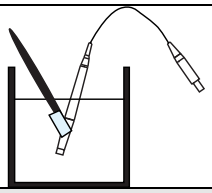
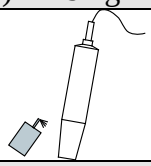
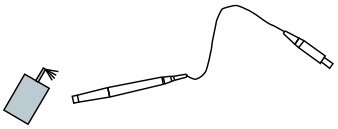
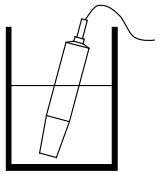
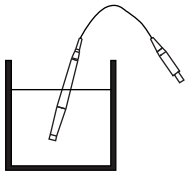
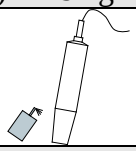
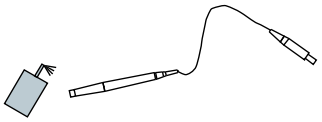
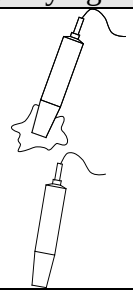
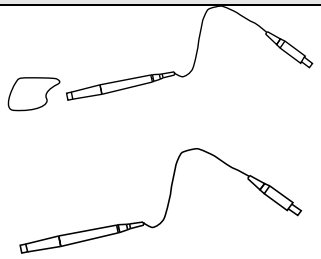
We should replace the contents in the immersed plate once a day.

⚠Attention: If it is regularly used, it should replace the contents in the immersed plate at the start of the morning and afternoon.

Standard draft

Tip:
a. Before disconnecting the probe, it must be mandatory to turn off the equipment.
b. To avoid splashing the liquid on the probe connector (connect to the end of cable in the equipment)

B-mode probe		A-mode probe	
A) Pre-disinfected			
	1. Place the probe into 0.5% sodium hypochlorite solution for 15 minutes	1. Place the probe into 0.5% sodium hypochlorite solution for 15 minutes	

	2. Use brush to wash the end of probe in the 0.5% sodium hypochlorite solution for one minute. - Wash the rest part of probe body with wipes moistened for a solution	
B) Rinsing		
	3. Rinse the probe and cable with soften water or distilled water. Do not wet the connector.	
C) Disinfection		
	4. Place the probe into 2% sodium hypochlorite solution for 15 minutes - Wash the rest part of probe body with wipes moistened for a solution	4. Place the probe into 2% sodium hypochlorite solution for 15 minutes 
D) Rinsing		
	5. Rinse the probe and cable with soften water or distilled water. Do not wet the connector.	
E) Drying		
	6. Use a sterile non-woven hemp brush to dry or if the wash water is sterile, to dry for once. 7. Probe to be used.	

⚠**Warning: Before emptying the contents in the immersed plate and after final disinfection, wait 10 minutes.**

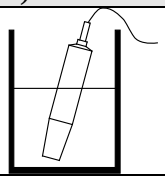
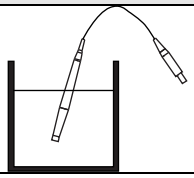
⚠**Attention: Pay attention to the preparation time and use time that declared by the manufacturer.**

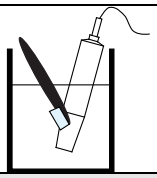
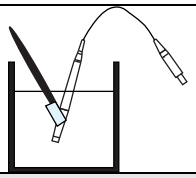
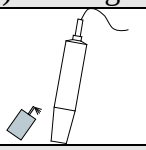
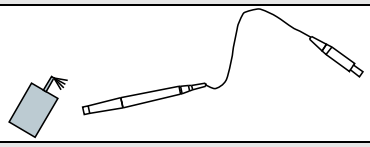
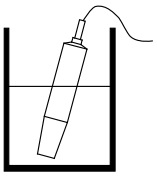
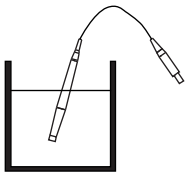
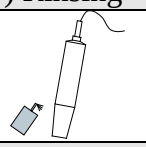
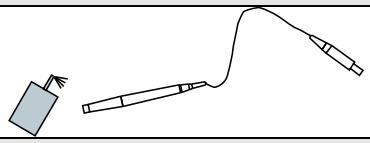
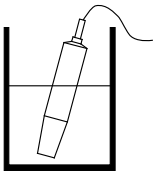
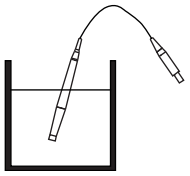
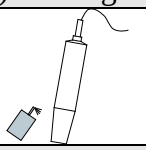
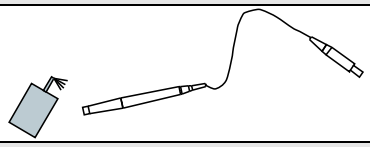
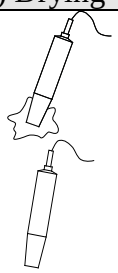
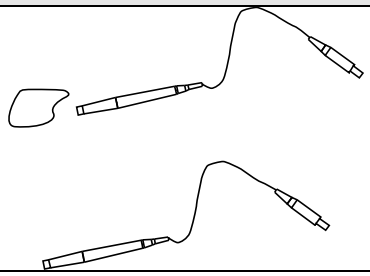
Risk patients protocol

Tip:

a. Before disconnecting the probe, it must be mandatory to turn off the equipment.

b. To avoid splashing the liquid on the probe connector (connect to the end of cable in the equipment)

B-mode probe		A-mode probe	
A) Pre-disinfected			
	1. Place the probe into 0.5% sodium hypochlorite solution for 15 minutes	1. Place the probe into 0.5% sodium hypochlorite solution for 15 minutes	

	2. Use brush to wash the probe in the 0.5% sodium hypochlorite solution for one minute. - Wash the rest part of probe body with wipes moistened for a solution		
B) Rinsing			
	3. Rinse the probe and cable with soften water or distilled water. Do not wet the connector.		
C) Inactivation			
	4. Place the probe into 20℃ 2% sodium hypochlorite solution for 60 minutes - Wash the rest part of probe body with wipes moistened for a solution	4. Place the probe into 20℃ 2% sodium hypochlorite solution for 60 minutes	
D) Rinsing			
	5. Rinse the probe and cable with soften water or distilled water. Do not wet the connector.		
E) Disinfection			
	6. Place the probe into 2% sodium hypochlorite solution for 15 minutes - Wash the rest part of probe body with wipes moistened for a solution	6. Place the probe into 2% sodium hypochlorite solution for 15 minutes	
F) Rinsing			
	7. Rinse the probe and cable with soften water or distilled water. Do not wet the connector.		
G) Drying			
	8. Use a sterile non-woven hemp brush to dry or if the wash water is sterile, to dry for once. 9. Probe to be used.		

⚠**Warning: Before emptying the contents in the immersed plate and after final disinfection, wait 10 minutes.**

⚠**Attention: Pay attention to the preparation time and use time that declared by the manufacturer.**

⚠Attention:

1. It is a normal phenomenon that color of the acoustic lens may change and color of the probe label may fade away.

2. The disinfection times should be minimized as it may lead to degrade of the probe safety and performance.

C. Check probe after cleaning and disinfection

1. Check the probe enclosure and its cable to ensure they are free of abnormity (such as scuffing, cracks or drop-off);
2. The sound window of probe is thin; ensure that there are no any abnormity on the sound window, such as scuffing, cracks, peeling, bulge or drop-off.

14.1.2 Clean the probe cable and its connector

1. Clean the probe cable and its connector with soft, dry cloth;
2. In case of die-hard blots, clean with soft cloth dipped in moderate detergent and then air-dry it.

14.1.3 Clean the LED screen

Use a soft cloth dipped in glass cleaner to clean the LED screen, and then air-dried.

⚠Attention: Do not clean the screen with hydrocarbon detergent such as alcohol or OA equipment cleaning media. These kinds of liquid may degrade the internal function of the screen.

⚠Attention: Prohibit using sharp objects to touch the LED screen, and prohibit pressing or squeezing against the LED screen.

14.1.4 Clean the trackball

⚠Attention: Trackball should be cleaned regularly, or because of dust, stains, etc. resulting in the non-flexible use of trackball.

1. Dismantle the trackball

Respectively hold down the both sides of sealing cover with middle fingers of left hand and right hand or hold down the two small holes of the cover with two small screwdriver, and then forced rotate it counterclockwise, remove the cover and take out the trackball. As follows:

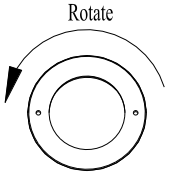


Fig.1

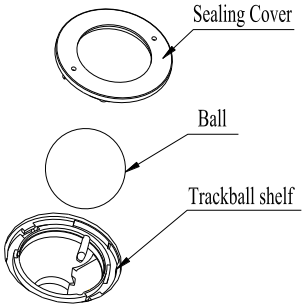


Fig.2

2. Clean the trackball

① Clean the trackball lightly with dry, soft flax or anti-static LCD clean cloth generally.

② In case of die-hard blots, clean with soft cloth dipped in moderate detergent and then air-dry it.

3. Clean the trackball shelf

Clean the trackball shelf lightly with dry, soft flax or anti-static LCD clean cloth.

4. Install the trackball

Place the sealing cover into the trackball shelf, respectively hold down the both sides of sealing cover with middle fingers of left hand and right hand or hold down the two small holes of the cover with two small screwdriver, and then forced rotate it clockwise to lock the cover (When locking, the two small holes of the sealing cover are in the horizontal line).

14.1.5 Clean the video recorder and foot switch

1. Use the soft dry cloth to wipe the video recorder and foot switch;
2. If it is difficult to wipe away the blemish, clean with soft cloth dipped in moderate detergent and then air-dry it.

14.1.6 Clean the control panel, shell and probe bracket

Clean the instrument surface with soft, dry cloth or with soft cloth dipped in moderate water cleaning media to remove the blots, and then dry the instrument with soft, dry cloth or with air.

14.2 Replace the parts and consumables

14.2.1 Replace the probe, foot switch, power adapter, power supply cord and fuse

During the service life of the product, if the probe, foot switch, power adapter, power supply cord or fuse are damaged, please contact us for support.

Replacement method:

1. Replacement of the probe see section 6.3;
2. Replacement of foot switch see section 6.5;
3. Replaement of power adapter and power supply cord seee section 6.7;
4. Replace the fuse is to replace the power adapter.

⚠Attention:

1. **The fuse is inside the power adapter. Fuse shall be replaced by professional engineer.**
2. **Before replacing the fuse, you must disconnect the mains supply. External fuse need to put insulation heat shrink tubing.**
3. **Fuse Type: T3.15AH250VAC.**

14.2.2 Replacement of battery

Battery is consumable; the battery cycle-life is based on the times of charge and discharge as unit. When the use time reduced significantly compared with normal conditions, the battery should be promptly replaced.

Replacement of the battery see section 6.4.

14.3 Use and maintenance for the rechargeable battery

- **The battery use for main unit**

1. Only use charger and battery pack (model HYLB-1614) provided by our company.
2. The output port of adapter plugs into the input port of "Charger" to charge (see the charge sketch map for main unit battery). The charge indicator is green and blinking state when charging; the charge indicator is green and no blinking when fully charged.
3. The charging time is about 3 hours, over-charging or discharging will shorten the battery life; the full charged battery can be used about 3.5 hours.

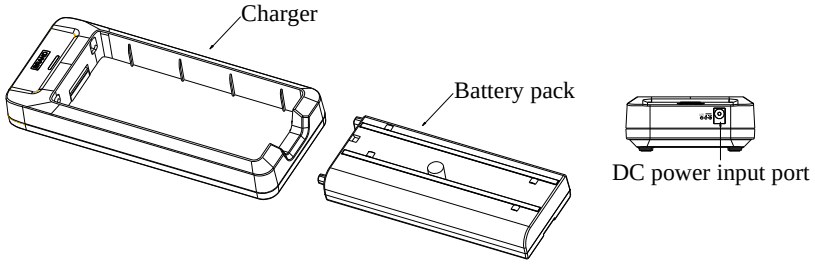


Fig. the charge sketch map for main unit battery

⚠Attention: Main unit will power off automatically when the electric quantity is too low. Connect the main unit to external power supply and recharge the battery, or turn off the machine to recharge.

- **The maintenance for the rechargeable battery pack**

1. Battery is consumable; the battery cycle-life is based on the times of charge and discharge as unit. When the use time reduced significantly compared with normal conditions, the battery should be promptly replaced.
2. The excess high or low temperature will affect the charging and discharging performance, and short the battery life and capacity.

⚠Attention:

1. **Do not throw the battery into water or be wet, which will lead to the battery leakage, explosion or fire;**
2. **Do not use or store the battery near the heat source, such as fire or heater, which will lead to the battery leakage, explosion or fire;**
3. **Do not connect the anode and cathode reversely, which will lead to the battery leakage, explosion or fire;**
4. **Do not heat up or throw the battery into fire, which will lead to the leakage, explosion or fire;**
5. **Do not connect the anode and cathode with any metal or conductor; do not transport or store the battery together with necklaces, hairpins or other metal objects, which will lead to the leakage, explosion or fire;**
6. **Do not hammerblow, throw or mechanically shake the battery, which will lead to the leakage, explosion or fire;**
7. **Do not insert the battery with nail or other spiculate objects; do not hammerblow or trample the battery, which will lead to the leakage, explosion or fire;**
8. **Do not weld the battery terminal directly, which will lead to the leakage, explosion or fire;**
9. **Do not disassemble the battery in any way, which will lead to the leakage, explosion or fire;**
10. **Do not charge the battery near the heat source or extra-hot environment, which will lead to the leakage, explosion or fire;**
11. **Do not put the battery into the microwave oven or pressure vessel, which will lead to the leakage, explosion or fire;**
12. **Do not mixed use the battery together with one-off battery (such as dry battery), or different capability or different model or different brand battery, which will lead to the leakage, explosion or fire;**
13. **Do not use the abnormal battery with particular smell or abnormal heat or distortion or turn colors or abnormal phenomena, which will lead to the leakage, explosion or fire;**
14. **Do stop the charge and pull out the battery from the charger at once if any abnormal phenomenon happens to the battery, such as particular smell or abnormal heat or distortion or turn colors. Otherwise, each of above will lead to the leakage, explosion or fire;**
15. **Do remove the battery from the near fire if any leakage or particular smell happens, which will lead to the leakage, explosion or fire;**
16. **If any leakage splash into eye, do not wipe the eye, instead of washing it and get help from the doctor as soon as possible. Otherwise, the eye will be injured;**
17. **Do not use the battery in the extremely hot environment, such as hot sunshine or in the car when it is too hot, because these will catch fire, even worsen its performance and shorten its life;**
18. **If use the battery beyond the listed environment on the manual, it will worsen its performance or shorten its life, even lead to extreme heat or explosion or fire.**

⚠Attention: Battery charger shall meet the requirements of the IEC60601-1 standard.

⚠Attention: Battery is consumable; the battery cycle-life is based on the times of charge and discharge as unit. When the use time reduced significantly compared with normal conditions, the battery should be promptly replaced.

⚠Attention: If long-term use external power or do not intend to use the equipment within such a period of time, please remove the battery, to avoid over-charging or discharging the battery which will curtail battery life, or to reduce other risk.

⚠Attention: Don't throw away the exhausted battery anywhere; especially throw it in the fire. Please deal with it according to local statutes. Use pollution degree II to deal with.

14.4 Troubleshooting

To ensure normal operation, users are recommended to prepare a proper maintenance and regular examination plan to regularly check on product safety performance. If any abnormity occur, timely contact us for support.

If the following problems occur on starting up the machine, try to make corrections following the method in the table. If the problem remains unsolved, contact us for support.

Trouble	Correction
Power light is off and no screen display is present when starting the machine.	1. Check power supply. 2. Check power cable and plug.
Character and gray scale are displayed, but no ultrasonic image on the screen.	Probe is not properly connected. Turn off the power and reconnect the probe.
Intermittent stripe, snow, or far-field interference appears on screen.	1. Check power supply.(spark interference present) 2. Check environment.(source of interference around the machine, such as electric motor, ultrasonic atomizer, automobile, computer or other interference) 3. Check power plug/socket of the instrument or probe connectors. They shall be properly contacted.
Image display is not clear.	1. Adjust the total gain, TGC. 2. Adjust the brightness and contrast level.
Control panel malfunction	Press reset key to reset or restart the system after shutdown.

14.5 Periodic Safety Checks

To ensure the system performance and safety, it must be checked after using 1 year. When check the instrument, please consult us or its dealers, as they need to have professional technology engineers.

1. The following safety checks should be performed at least every 12 months by a qualified person who has adequate training, knowledge, and practical experience to perform these tests.
   - Inspect the equipment and accessories for mechanical and functional damage.
   - Inspect the safety relevant labels for legibility.
   - Inspect the fuse to verify compliance with rated current and breaking characteristics.
   - Verify that the device functions properly as described in the instructions for use.
   - Test the protection earth resistance according to IEC 60601-1: Limit: 0.1Ω.
   - Test the earth leakage current according to IEC 60601-1: Limit: Normal Condition 500μA, Single Fault Condition: 1000μA.
   - Test the touch current according to IEC 60601-1: Limit: Normal Condition 100μA, Single Fault Condition: 500μA.
   - Test the patient leakage current according to IEC 60601-1: Limit: for a.c.: 100μA (B), for d.c.: 10μA (B).
   - Test the patient leakage current under single fault condition with mains voltage on the applied part according to IEC 60601-1: Limit: for a.c.: 500μA (B), for d.c.: 50μA (B).

   The leakage current should never exceed the limit. The data should be recorded in an equipment log. If the device is not functioning properly or fails any of the above tests, the device has to be repaired.
2. Please clean the plug of power cord at least once a year. Too much dust on plug may cause the fire.

Chapter Fifteen Storage and Transportation

Storage and Transportation

1. If the instrument is stored over 3 months, take out the instrument from the packing case, connect it to power supply for 4 hours, and then disconnect the power and place it in the case again following the direction indicated by arrows on the package. Store the case in the warehouse. Do not pile the case. The instrument case should have adequate space from ground, walls and ceiling of the warehouse.
2. Environment requirement:
   Ambient temperature: -20℃－55℃; Relative humidity: 30%－93% (without condensation); Atmospheric pressure: 700hPa-1060hPa. The warehouse should be well ventilated and free of direct sunlight and corrosive gas.
3. Shockproof measures have been taken inside the packing case to allow for transport by air, railway, land and sea. The goods shall not be exposed to poor weather conditions like rain and snow, nor shall the goods be placed upside down, bumped, knocked or over-stacked.

Chapter Sixteen Standard Compliance

The compliant standards are listed below:

93/42/EEC
EN ISO 14971:2012
IEC 60601-1:2012
IEC 60601-2-37:2015
IEC 60601-1-2:2014
EN ISO 15223-1:2012
EN 1041/A1:2013
YY 0107-2005
YY 0773-2010
ISO 10993-1:2018
ISO 10993-5:2009
ISO 10993-10:2010

Chapter Seventeen Safety Classification

1. Classified according to electric shock protection type:
   Class I, internally powered equipment
2. Classified according to electric shock protection degree:
   Type B applied part
3. Classified according to the degree of protection against ingress of liquid:
   Main unit belong to IPX0 equipment
4. Classified according to operation safety in condition of existence of flammable anesthetic mixture with air or oxygen or nitrous oxide:
   It is neither of category AP equipment nor of category APG equipment
5. Classified according to mode of operation:
   Continuous operation equipment
6. Classified according to the protection of radio services:
   Group I Class A equipment

Chapter Eighteen Guidance and manufacturer's declaration

This product complies with EMC test standard IEC 60601-1-2

⚠Warning: The use of inappropriate accessory will reduce the performance of the product.

⚠Attention:

1. **Use of the accessories, transducers or cables other than those specified could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.**
2. **Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.**
3. **The system needs to be specifically for EMC protection, and need to be installed and maintenance in the environment meeting the following provided EMC information.**
4. **The system may be interfered with by other equipment, even if that other equipment complies with CISPR emission requirements.**
5. **Prevent electromagnetic interference (Conducted Immunity). Conducted immunity level higher than 3 Vrms may cause the performance degradation of the system. We recommend the system away from the conduction noise source.**
6. **Portable and mobile communications equipment can affect the performance of the system. See the following tables 1, 2, 3, 4.**

1. Equipment Under Test cables

No.	Name	Cable lengths (m)	Cable Shielded
1	AC Mains cable	≤2m	unshielded
2	A-mode probe cable	≤1.6m	shielded
3	B-mode probe cable	≤1.6m	shielded
4	Foot switch cable	≤1.5m	shielded

Electromagnetic interference may appear on the system in a variety of ways, depending on the system's cables, transducers and accessories. Use the cables, transducers and other accessories specified by the manufacturer of this equipment, so that the possibility of degradation of the performance of this equipment should be minimized.

Table 1:

Guidance and manufacturer's declaration — electromagnetic emissions		
The instrument is intended for use in the electromagnetic environment specified below. The customer or the user of the instrument should assure that it is used in such and environment.		
Emission test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The instrument uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class A	The instrument is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies building used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Complies	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Table 2 :

Guidance and manufacturer's declaration — electromagnetic immunity			
The instrument is intended for use in the electromagnetic environment specified below. The customer or the user of instrument should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0%U_T (>95%dip in U_T) for 0.5 cycle 0%U_T (95%dip in U_T) for 1 cycles 70%U_T (30%dip in U_T) for 25 (50Hz) cycles 0%U_T (>95%dip in U_T) for 250 (50Hz) cycles	0%U_T (>95%dip in U_T) for 0.5 cycle 0%U_T (95%dip in U_T) for 1 cycles 70%U_T (30%dip in U_T) for 25 (50Hz) cycles 0%U_T (>95%dip in U_T) for 250 (50Hz) cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the instrument requires continued operation during power mains interruptions, it is recommended that the instrument be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30(A/m)	30(A/m)	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Table 3:

Guidance and manufacturer's declaration — electromagnetic immunity			
The instrument is intended for use in the electromagnetic environment specified below. The customer or the user of instrument should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 V_{rms} 150 kHz to 80 MHz 3 V/m 80 MHz to 2.7 GHz	3 V 3V/m	Portable and mobile RF communications equipment should be used no closer to any part of the instrument, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = \frac{6}{E}\sqrt{P}$ $d = 2\sqrt{P}$ 80 MHz to 2.7 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the instrument is used exceeds the applicable RF compliance level above, the instrument should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the instrument. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Table 4:

Recommended separation distances between portable and mobile RF communications equipment and the instrument			
The instrument is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the instrument can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the instrument as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz $d=2\sqrt{P}$	**80 MHz to 800 MHz** $d=2\sqrt{P}$	**800 MHz to 2.7 GHz** $d=2\sqrt{P}$
0.01	0.2	0.2	0.2
0.1	0.63	0.63	0.63
1	2	2	2
10	6.3	6.3	6.3
100	20	20	20
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Appendix A: Acoustic Output Data Disclosure

Pursuant to the provisions of IEC 60601-2-37:2015 "Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment", acoustic output data disclosure as follows:
In the acoustic output measurement data, the MI uncertainty is 12%, TI uncertainty is 23%.

Manufacturer: Xuzhou Kaixin Electronic Instrument Co., Ltd.
Product Name: Ophthalmological A/B mode ultrasound scanner
Test frequency: 10.0MHz

A.1 10A07L1

Test Mode: A **Transducer Type: 10A07L1**

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.21	0.048		0.002		(a)
Index component value				0.048	0.003	0.002	0.002	
Associated acoustic parameters	$p_{r.a}$ at z_{MI}	(MPa)	0.68					
	P	(mW)		0.1		0.1		(a)
	$P_{1\times1}$	(mW)		0.1		0.1		
	z_s	(cm)			0.84			
	z_b	(cm)					0.96	
	z_{MI}	(cm)	0.98					
	$z_{PII.\alpha}$	(cm)	0.98					
	f_{awf}	(MHz)	10.05	10.05		10.05		(a)
Other Information	prr	(Hz)	49.825					
	srr	(Hz)	#					
	n_{pps}		1					
	$I_{pa.\alpha}$ at $z_{PII.\alpha}$	(W/cm2)	14.48					
	$I_{spta.\alpha}$ at $z_{PII.\alpha}$ or $z_{SII.\alpha}$	(mW/cm2)	0.19					
	I_{spta} at z_{PII} or z_{SII}	(mW/cm2)	0.37					
	$p_{r.}$ at z_{PII}	(MPa)	0.95					
Operating control conditions	*Freq*	(MHZ)	/					
	Focus Position	(cm)	/					
	Depth	(cm)	/					
	Others							

(a) Intended use does not include cephalic so TIC is not computed
No data reported

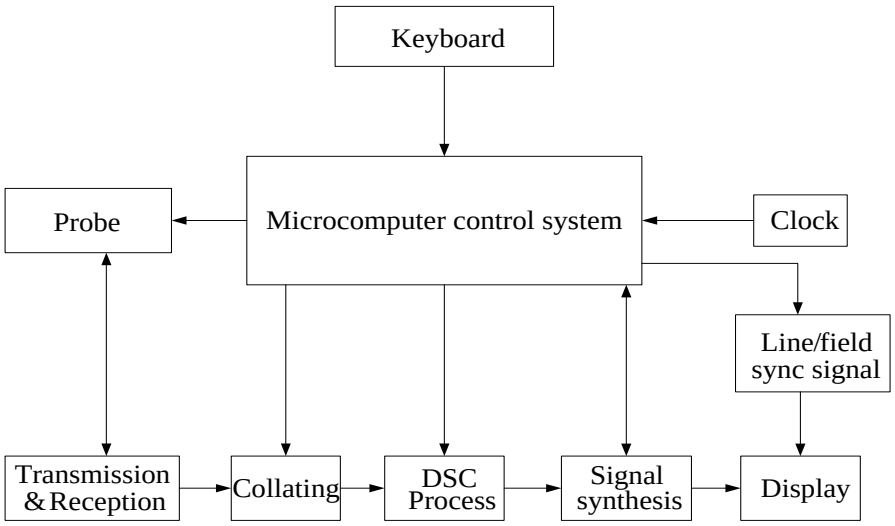
A.2 10S53K1

Test Mode: B Transducer Type: 10S53K1

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.55	0.04		0.06		(a)
Index component value				0.04	0.04	0.06	0.04	
Associated acoustic parameters	$p_{r.a}$ at z_{MI}	(MPa)	1.50					
	P	(mW)		1.7		1.7		(a)
	$P_{1\times1}$	(mW)		1.1		1.1		
	z_s	(cm)			#			
	z_b	(cm)					#	
	z_{MI}	(cm)	1.68					
	$z_{PII.\alpha}$	(cm)	1.68					
	f_{awf}	(MHz)	7.55	7.55		7.55		(a)
Other Information	*prr*	(Hz)	4882.8					
	srr	(Hz)	9.5367					
	n_{pps}		1					
	$I_{pa.\alpha}$ at $z_{PII.\alpha}$	(W/cm2)	142.61					
	$I_{spta.\alpha}$ at $z_{PII.\alpha}$ or $z_{SII.\alpha}$	(mW/cm2)	0.58					
	I_{spta} at z_{PII} or z_{SII}	(mW/cm2)	1.35					
	p_r at z_{PII}	(MPa)	2.33					
Operating control conditions	*Freq*	(MHZ)	/					
	Focus Position	(cm)	/					
	Depth	(cm)	/					
	Others							

(b) Intended use does not include cephalic so TIC is not computed
No data reported

Appendix B: System Block Diagram



Information contained in this manual is subject to change without further notice.