

### **WED-380**

### Full Digital Ultrasound Diagnostic System

## **User Manual**

SHENZHEN WELL.D MEDICAL ELECTRONICS CO. LTD.

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### CE mark



### **Preface**

### Copyright

This publication, including pictures and illustrations, is property of Shenzhen Well. D Medical Electronics Co., Ltd. and under protection of international copyright law.

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### **Statement**

Information in this document are not annotated to change. The manufacture shall not state nor observe any warranty basing on this point, and definitely give up any implied warranty basing on any special purpose of selling or making benefit.

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### Manufacturer's warranty

Shenzhen Well. D Medical Electronics Co., Ltd. assumes the responsibility for device security, reliability and performance only under the preconditions that the disassembly, assembly and maintenance of the device are all performed by its assigned professional and the device is used strictly in compliance with the operation manual.

Shenzhen Well. D Medical Electronics Co., Ltd. ensures a guarantee period within a year and a half since the delivery day and promises there is no problem with the new device in material and technology. Within the warranty period, Shenzhen Well. D Medical Electronics Co., Ltd. will maintain the device and replace the parts of non-man-made damages free of charge. But will not repair or replace the device surface if it is damaged.

This guarantee is only available for failures occurred when the device is operated in compliance with the operation manual. And the guaranteed device can only be used in the prescribed range given in manual.

This guarantee excludes losses or damages caused by external reasons such as thunder struck, earthquake, theft, unsuitable use or abuse and refitting the device.

Shenzhen Well. D Medical Electronics Co., Ltd. shall not be responsible for damages caused by other devices or arbitrary connection to other devices.

Shenzhen Well. D Medical Electronics Co., Ltd. shall not be responsible for losses, damages or injuries caused by delayed service request.

When there is problem with the products, please contact Shenzhen Well. D Medical Electronics Co., Ltd. and explain the device model, serial number, date of purchase and the problem.

### **Matters need Attention**

To ensure operational safety and long-term stable equipment performance, please read this operation manual closely and understand the device functions, operation and maintenance at all points before operating the device, especially contents of "Warning", "Caution" and "Note".

Misoperation or inobservance of the instructions given by manufacturer or its agents may result in device damage or personal injury.

The following convention works through this manual to lay special emphasis on some information.

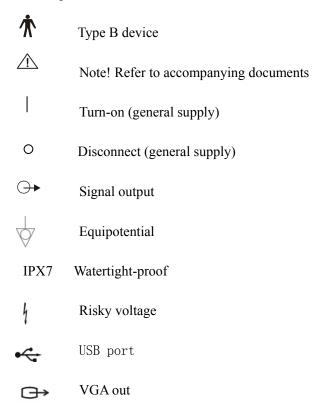
"Warning": Stands for neglect of it will cause severe personal injury, death or realized property loss.

"Caution": Stands for neglect of it will cause slight personal injury or property damage.

"Note": to remind user of installation, operation or maintenance information. These information is very significant but with no risk.. Any warning against dangers shall not be contained in NOTE.

### Safety labels

Device labels explanation:



Packing and transportation labels explanation:

Ţ	Handle carefully	
*c *c	Temperature limit	
<u>11</u>	Upward	
5	Piling limit	
Ť	Keep dry	
*	Protect against heat	

### System labels diagram

Refer to Appendix A for device labels.

### General tips for device operation

### ♦ In operation

- 1. Heat radiation holes are strictly prohibited to be covered.
- 2. After closedown, do not switch on the device within 2 3 minutes.
- 3. On scanning, if any abnormal case is found, stop scanning immediately and shut down the device.
- 4. Patient is not allowed to touch any non-application parts.
- 5. Do not press the keyboard too much in case the equipment be damaged.

### ◆ After operation

- 1. Power off the device.
- 2. Pull out the plug from power supply socket instead of pulling the cable.
- 3. Clean off the coupling gel on the probe with soft medical sterilized tampon.
- 4. put the probe into its box.

### **General Safety Message**

Safety of the operator and patients and reliability of the device are taken into consideration during designing and producing, the following safety precaution must be implemented:

- 1. The device shall be operated by qualified operating staff or under their instructions.
- 2. Do not open the device and change the parameters without permission. If necessary, please turn to for Shenzhen Well.D Medical Electronics Co., Ltd. or its authorized agent for service.
- 3. The device has already been regulated into its optimal performance. Do not adjust any preset control or switch unless operate as per instructions in the manual.
- 4. If there is device failure, please shut down the device at once and contact for Shenzhen Well.D Medical Electronics Co., Ltd. or their authorized agent.
- 5. If it is needed to connect the device with other company's' electronic or mechanical devices, please contact Shenzhen Well. D Medical Electronics Co., Ltd. before connection.
- 6. Device operation, storage and transportation environment

Environmental requirements on normal operation:

- a) Environment temperature range: +5°C ~+40°C
- b) Relative humidity range: ≤80%
- c) Atmosphere pressure range: 86KPa~106KPa

Environment requirements on device storage and transportation:

- a) Environment temperature range: 40 °C ~+55 °C
- b) Relative humidity range: 10%~100%
- c) Atmosphere pressure range: 50KPa~106KPa
- 7. Ultrasound might cause hazard on human body so long time radiation should be avoided. Refer to appendix B for sound output parameters.
- 8. Please use standard power cord as the input line of the network power supply for the adapter to reduce risk.
- 9. Shenzhen Well. D Medical Electronics Co., Ltd. shall not take any responsibility for any risk resulted from propelled / unauthorized re-fitment by the users.
- 10. The power supply plug is the standard three pins plug, its protective grounding pin(terminal) should be connected with the protective grounding line of the main power.

### **Execution Standard (Safety)**

### • Safety Standard:

Standard Number	Standard Name	
IEC60601-1:1988	Medical Electronic Device, Part I: General safety requirements	
+A1:1991 +A2:1995	Wiedical Electronic Device, Fait 1: General safety requirements	
IEC60601-1-2:2004	Medical Electronic Device, Part I to II: General Safety Requirement Parallel	
IEC00001-1-2.2004	Standard: Requirement and Testing of Electromagnetism Compatibility	
IEC60601-1-4:2000	Medical Electronic Device, Section I to IV: A Program-controlled Medical	
IEC00001-1-4.2000	Electronic System	
IEC60601-2-37:2004	Medical Electronic Device, Specialized Safety Requirements for Medical Ultrasound Diagnosis and Custodial Care Facility	
IEC61157:1992	Requirements for the Declaration of the Acoustic Output of Medical Ultrasound Diagnostic Apparatus	

### • EMC (Electromagnetic Compatibility) Standard:

Standard Number	Standard Name
IEC60601-1-2: 2001	Electromagnetic Compatibility for Medical Systems, comprised of:
IEC61000-4-2: 2001	Electrostatic Discharge Immunity
IEC61000-4-3: 2002	Radiated Field Immunity
IEC61000-4-4: A2/2001	Electrical Fast Transient/Burst Immunity
IEC61000-4-5: 2001	Voltage Surge Immunity
IEC61000-4-6: 2001	Immunity to Conducted Disturbance, Induced by Radio-frequency Fields
IEC61000-4-8: 2001	Power Frequency Magnetic Fields
IEC61000-4-11: 2001	Voltage Dips, Shorts and Variations

### **EMC** statement:

WED-380 shall not affect the basic performance of radio service and other equipments and can work well in its stated electromagnetic environment.

### Guidance and manufacture's declaration – electromagnetic emissions-For all EQUIPMENT and SYSTEMS

### Guidance and manufacture's declaration - electromagnetic emission

The WED-380 Full Digital Ultrasonic Diagnostic System is intended for use in the electromagnetic environment specified below. The customer of the user of the WED-380 Full Digital Ultrasonic Diagnostic Systemshould assure that it is used in such and environment.

<b>Emission test</b>	Compliance	Electromagnetic environment - guidance		
RF emissions CLSPR 11	Group 1	The WED-380 Full Digital Ultrasonic Diagnostic System 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 CLSPR 11	Class B			
Harmonic emissions IEC61000-3-2	Class A	The sample WED-380 is suitable for usage in any facility including household and the public low voltage supply network connecting to		
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	residence.		

### Guidance and manufacture's declaration – electromagnetic immunity-For EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

### Guidance and manufacture's declaration - electromagnetic immunity

The WED-380 Full Digital Ultrasonic Diagnostic System is intended for use in the electromagnetic environment specified below. The customer or the user of WED-380 Full Digital Ultrasonic Diagnostic System should assure that it is used in such an environment.

IEC 60601	Compliance	Electromagnetic environment - guidance
test level	level	
	•	Portable and mobile RF communications equipment should be used no closer to any part of the WED-380 Full Digital Ultrasonic Diagnostic System, including cables, than the advised separation distance calculated from the equation applicable to the frequency of the transmitter.  Recommended separation distance  d= 3.5
		Interference may occur in the vicinity of equipment marked with the following symbol:
	3Vrms 150 kHz to 80 MHz 3V/m 80 MHz to	3Vrms 1V 150 kHz to 80 MHz 3V/m 80 MHz to

NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 0.5V/m.

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 WED-380 Full Digital Ultrasonic Diagnostic Systemis used exceeds the applicable RF compliance level above, the WED-380 Full Digital Ultrasonic Diagnostic System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the WED-380 Full Digital Ultrasonic Diagnostic System.

# Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEMfor EQUIPMENT or SYSTEM that are not LIFE-SUPPORTING

### Recommended separation distances between portable and mobile RF communications equipment and the WED-380 Full Digital Ultrasonic Diagnostic System

The WED-380 Full Digital Ultrasonic Diagnostic System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the WED-380 Full Digital Ultrasonic Diagnostic System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the WED-380 Full Digital Ultrasonic Diagnostic System 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	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d = \left[ \frac{3.5}{V_1} \right] \sqrt{P}$	$d = \left[ \frac{3.5}{E_1} \right] \sqrt{P}$	$d = \left[ \frac{7}{E_1} \right] \sqrt{P}$
0.01	0.35	0.12	0.23
0.1	1.11	0.37	0.74
1	3.5	1.17	2.33
10	11.07	3.69	7.38
100	35	11.67	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distanced 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.

### Guidance and manufacture's declaration – electromagnetic immunity – for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration - electromagnetic immunity

The WED-380 Full Digital Ultrasonic Diagnostic System is intended for use in the electromagnetic environment specified below. The customer or the user of WED-380 Full Digital Ultrasonic Diagnostic System should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge(ESD) IEC61000-4-2	±6kV contact ±8 kV air	±6kV contact ±8 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	±2kV for power supply lines ±1kV for input/output lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV dofferemtoal mode ±2kV common mode	±1kV dofferemtoal mode	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	<5% UT (>95% dip in UT) for 0.5 cycle  40% UT (60% dip in UT) for 5 cycle  70% UT (30% dip in UT) for 25 cycle  <5% U <sub>T</sub> (>95% dip in U <sub>T</sub> ) for 5 sec	<5% UT (>95% dip in UT)  40% UT (60% dip in UT) for 5 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the WED-380 Full Digital Ultrasonic Diagnostic System requires continued operation during power mains interruptions, it is recommended that the WED-380 Full Digital Ultrasonic Diagnostic System be powered from an uninterruptible power supply or a battery.
Power frequency (50Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE  $\boldsymbol{U}_{_{\boldsymbol{T}}}$  is the a.c. mains voltage prior to application of the test level.

### **Warning**

When WED-380 works in strong electromagnetic environment exceeding its statement, its image might be interfered and the diagnoses could be influenced. At this time, please stop operating until the EMC interference is removed.

### **Warning**

When WED-380 works at the state of overlapping or paralleling with other equipments, there might be unexpected EMC problems; If it must work close to other equipments, please observe carefully and check if some equipment is influenced by unexpected EM coupling.

### **Warning**

Replacement of non-standard probe parts may cause unexpected EMC problem.

### Note

Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC standards (e.g. IEC 60950 for data processing equipment and IEC 60601-1-1 for medical equipment). Furthermore, all configurations shall comply with the valid version of the system standard IEC 60601-1-1. Everybody who connects additional equipment to the signal input or signal output part configures a medical system, and is therefore responsible that the system complies with the requirements of the valid version of the system standard IEC60601-1. IF in doubt, consult the technical service department or your local representative.

### Contraindication

- ◆ The equipment is not suitable for inspection on organs containing gas such as lungs, etc.
- ♦ It is recommended not to check the parts with wounds or acute inflammation to avoid cross infection.
- ◆ Patient in the following situations are not allowed to be checked with EC1-1 and EL3-1 probes:

vaginal infection, such as trichomonal vaginitis, colpomycosis, venereal disease etc; the unmarried, vagina deformity, menstrual period, postmenopausal vagina atrophy, difficulty in per vagina ultrasonic examination, colporrhagia, Pyrilamine placenta previa, etc.

### **Chapter One Summary**

### 1.1 Features

This equipment is high resolution linear/convex ultrasound scanning diagnostic equipment. It adopts micro-computer control and digital scan converter (DSC), digital beam-forming (DBF), real time dynamic aperture (RDA), real time dynamic receiving apodization, real time Dynamic receiving focusing (DRF), Digital frequency Scan (DFS), 8 segments TGC, frame correlation technologies to endue its image with clarity, stability and high resolution.

There are four display modes: B, B+B, B+M, M, 4B; And 256 gray scale.

The system can process real time image display, freeze, save, load, zoom, up and down flip, left and right flip, black and white flip, and capacity cine loop; Multi-level scanning depth, angle, dynamic range, acoustic power, frame correlation factor regulation and focus number, focal space, focus position, etc. It offers more than 40 body marks.

Date, clock display; Name, sex, age, doctor, hospital annotation; Distance, circumference, area, volume, heart rate measurement; preset two obstetric tables to measure GA, FW and EDD. Many probes are optional for clinic diagnosis demands.

PAL-D and VGA video output offers connection to external video image printer and big display and other equipments. High speed USB port provides real time image transfer to the PC.

Adoption of folded soft push keyboard and trackball provides immediate, convenient and flexible operation.

The equipment is jet molding enclosure and potable structure, the usage of non-industrial frequency transformer switching power supply, programmable parts (FPGA) and surface mounting technology (SMT) make the whole unit highly compact.

The equipment consists of the main unit and electronic convex array probe. Standard configuration is C3-1/60R/3.5MHz convex array probe. And L3-1/7.5Mhz high frequency linear array probe, C1-6/20R/5.0MHz micro convex probe, EC1-1/13R/6.5MHz endo-vaginal and EL3-1/7.5MHz endo-rectal probe for option.

### 1.2 Range of application

Application in abdominal, Obstetric, Cardiac, small parts sonography.

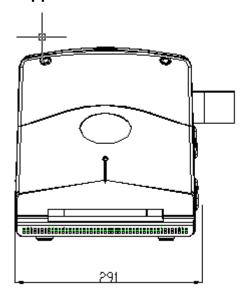
### 1.3 Safety classification:

- According to the degree of safety of application in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide:
  - WED-380 not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide;
- According to the mode of operation:
  - Continuous operation;
- According to the degree of protection against harmful ingress of water as detailed in the current edition of IEC
   529.
  - Main unit is general equipment, the probe is enclosed equipment protected against the effects of immersion, IPX7.
- According to the type of protection against electric shock:
   Class I equipment energized from an external electrical power source.
   equipment;
- According to the degree of protection against electric shock:

Type B

### **Chapter Two System Introduction**

### 2.1 Appearance



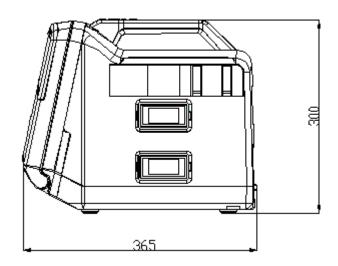


Figure 2-1. Appearance dimension sketch

### 2.2 Panel

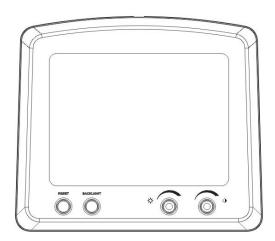


Figure 2-2. Front panel sketch

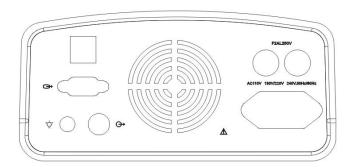


Figure 2-3. Back panel sketch

### 2.3 Technical specification

Model WED-380					
Probe		C3-1/60R/3.5MHz convex array	EL3-1/7.5MHz endo-rectal probe L3-1/7.5Mhz HF linear probe	C1-6/20R/5.0MHz micro convex probe	EC1-1/13R/6.5MHz endo-vaginal probe
Display dept	h (mm)		240 (max), 16	levels adjustable	
Maximal detect	depth (mm)	≥160	≥80	≥80	≥60
Lateral Resolution		$ \begin{array}{c} \leq 2 \\ (\text{depth} \leq 80) \\ \leq 3 \\ (80 < \text{depth} \leq 130) \end{array} $	≤1 (depth≤60)	≤3 (depth≤60)	≤1 (depth≤40)
(mm)	Axial	$ \begin{array}{c} \leq 2 \\ (\text{depth} \leq 80) \\ \leq 3 \\ (80 < \text{depth} \leq 130) \end{array} $	≤1 (depth≤80)	≤1 (depth≤60)	$\leq 1$ (depth $\leq 40$ )
Blind zone	e(mm)	≤5	≤3	≤8	≤7
Geometric	Horizontal	≤15	≤5	≤15	≤10
position precision	Vertical	≤10	≤5	≤10	≤5
Monitor	size	12 inch			
Display n	node	B、B+B、B+M、M、4B			
Image gray	scale	256 level			
Cine lo	op	≥500frame			
Image sto	rage	64 frames			
Scan an	gle	Adjustable			
Scan de	pth	40mm-240mm			
Acoustic p	oower	2 steps			
Dynamic 1	range	100dB-130dB			
Image f	lip	Up/down, left/right, black/ white			
Focus pos	sition	Adjustable			
Focal space		5 level			
Measurement		Distance, circumference, area, volume, heart. GA, FW, EDD			
Notation		Date, time, name, sex, age, doctor, hospital name, full screen words edit.			
output report		4 type			
posture mark		40			
USB port		High speed USB 2.0 (device)			
power consumption (MAX) 100VA					

### 2.4 Block Diagram

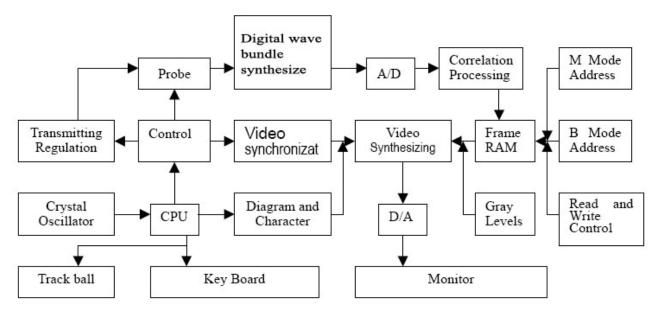


Figure 2-4 Electric principal block diagram

### 2.5 Basic principle

Digital Ultrasonic Diagnostic System works in this following procedure: different tissues of human body possess different densities and speeds of transmission of ultrasound, i.e. different acoustic impedance (product of media density and sound speed).when piezo-chip (transductor) gets certainly regulated electric impulse, it will produce ultrasound with certain frequency. when this ultrasound (sound energy) is injected into human body, different organ surfaces will produce reflection echo, the different size reflection is received by the transductor which emitted ultrasound and is changed into electric impulse, when this electric impulse is amplified, demodulated, digital scanned, shifted and some other handling, video standard signal is produced and organ cross-sectional images are displayed on the monitor.

### 2.6 Equipment constituent

### 2.6.1 Standard configuration pieces

- Mainframe
- ◆ C3-1/60R/3.5MHz convex array
- ◆ L3-1/7.5Mhz HF linear probe OR EC1-1/13R/6.5MHz endo-vaginal probe
- PS cable
- ◆ High speed USB cable
- ◆ 2 pieces of fuse tube F2AL250V
- Coupling gel 250ml
- User Manual
- Final examination report
- Packing List

### 2.6.2 Optional pieces

◆ C1-6/20R/5.0MHz micro convex probe

- ◆ EL3-1/7.5MHz endo-rectal probe
- ♦ Video printer

### Warning

Please select spare parts models prescribed above. The manufacturer will not assume the risks such as safety problem, non-expected drop of EMC performance that cause by arbitrary adoption of spare parts out of prescription.

### **Chapter Three Installation**

### 3.1 Operating environmental requirements

a) Environment temperature range:  $+5^{\circ}\text{C} \sim +40^{\circ}\text{C}$ 

b) Relative humidity range:  $\leq 80\%$ 

c) Atmosphere pressure range: 86KPa~106KPa

d) Power supply:  $AC110V \sim 130V/220V \sim 240V$ , 50Hz/60Hz

When using, avoid strenuous vibration, keep it away from devices with high field, intense magnetic field or high voltage; avoid strong sunlight blazing down on the display; keep the device well-ventilated, moisture proof and dustproof.

### 3.2 Unpacking inspection

After unpacking, check the device according to "Packing List" and install it according to requirements and methods described in "Installation" after affirm that there is no shipping damage.

### **Warning**

If there is breakage at unpacking check, it is banned to use the device to ensure security.

### **Warning**

The probe should be protected from felling off or crashing and the manufacturer assumes no responsibility for this kind of hazard.

#### 3.3 Installation

- 1. Check the power supply too see if it is in the expected range, then connect the equipment and the power socket with the cable (see figure 2-3).
- 2. A 96-core connector is used for electronic convex array probe (see figure 3-1).
- 3. Connection of 96-coreconnector. First, switch the locker on the probe connector to "OPEN", position the connector localization pin with the hole on the socket, then plug in the connector and switch the locker to "LOCK". When the locker is moved to "OPEN", unplug the connector to remove the probe from the main unit.

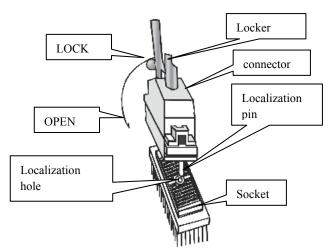


Figure 3-1 96-core probe connection sketch

#### Note

Avoid by all means unplugging or plugging the probe connector at state of log on in case the probe and main unit be damaged.

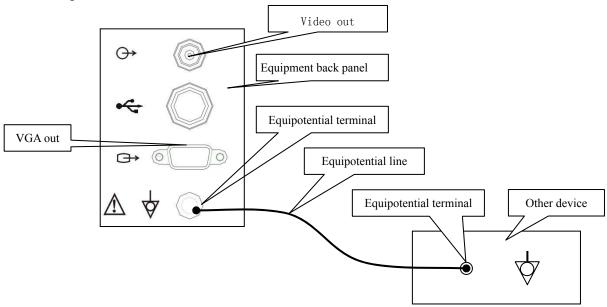
Once the probe is connected with the main unit, do not unplug nor plug it at discretion in case poor contact happen.

### **Warning**

Must not touch the contact pin in the probe connector.

### 3.4 Equipotential connection

See the figure:



### Warning

Equipotential: When this equipment is used together with other device, equipotential should be in consideration.

When the equipment is in use, the doctor and patient are under the risk of uncontrollable compensating current influence, which is caused by different electric potential between facilities and tangible current carrying parts. The most safe solution is set up a united equipotential network, and connect the medical equipments with the equipotential network in the treatment room.

### Chapter Four Keyboard and Trackball Operation

### 4.1 Screen display

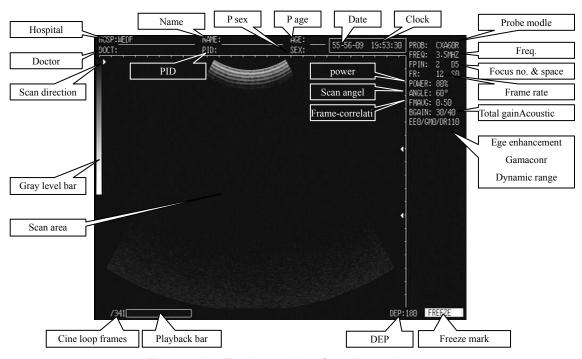


Figure 4-1 Equipment interface illustration

### 4.2 Operating keyboard



Figure 4-2. Operating keyboard sketch



Press these keys at annotation mode to put in characters at the cursor position.

Among the alphabet keys, there are some keys with dual functions:

SN	Key	Function
4	G	Total gain control key. There are four steps: 25, 30, 35, 40.  Press this key to set them circularly
5	P	In real-time status (single B mode), press this key to recall penetration sampling line.



At annotation, press this key to input space after cursor.



At annotation, press this key to delete the input characters.



Numbers are used for time, date settings, age notation and function menu and selection.

There are the following dual functions keys:

SN	Key	Function
1	1	Press this key to move cursor or sampling line left
2	2	Press this key to move cursor up
3	3	Press this key to move cursor down
4	4	Press this key to move cursor or sampling line right
5	0	Control the cursor moving speed by direction keys



Press this key to clear off the measuring marks, notation data and measurement results on the image (When some menu is displayed, it can not be cleared until the current task is finished).



Press this key to display the notation menu, and press the above mentioned numbers or letters for notation.

OB table OB Table

Press this key to display the OB table, and press the number keys to carry out the corresponding function.



### Image Post-process menu

Press this key to display image post-process menu, and press the number keys to carry out the corresponding function



Reset

Press this key to restart the system when malfunction and misoperation make the system "DEAD" (unable to start the system by pressing any other key).



### Frame-correlation factors regulation/M mode velocity option

This key has two functions.

At "B/M" mode, enter real time state, press this key to adjust the refresh velocity of "M mode image". There are four levels: 3.00S, 2.50S, 2.00S, 1.25S. At "M" mode, There are four levels: 6.00S, 5.00S, 4.00S, 2.50S. Press this key repeatedly to set the velocity circularly. The current velocity appears on the right of the screen.



At "B", "B/B" and "4B" modes, enter real time state, press this key to lighten up the "FM.AVG" on the screen

right top,And then press to adjust the parameters of frame correlation factors. The system provides 8 factors: 0.25, 0.35, 0.45, 0.50, 0.65, 0.75, 0.85, 0.95. Press this key continuously, the factors is set circularly. The current parameter appears on the right top of the screen (see figure 4-1).



#### Switch between probes

This equipment is fitted with two probe connectors (A, B). Press this key to switch the probes. The current probe model appears on the right top of the screen (see figure 4-1). The probe model and their codes are:

CA60R C3-1/60R/3.5MHz convex probe
CA20R C1-6/20R/5.0MHz convex probe
CA13R EC1-1/13R/6.5MHz endo-cavity probe

LA40 L3-1/7.5MHz HF linear probe or EL3-1/7.5MHz endo-rectal probe

### Tips:

- The device can automatically identify probes.
- When it is connected with two probes. The system default working probe is the one connecting to socket A.
- Please shut down the system first before replacing probes. Restart the system, it can realize automatic identification.



### Save image

At real time of freeze, press this key to save the current image: refer to "5.6.1 Image Saving" for details.



### Load image

Press this key to recall the stored image; refer to "5.6.2 Image loading" for details.



### Image up-down

Press this key to flip image up and down. As given below:





Figure 4-3. Image up and down flip sketch



### Image left-right

Press this key to flip image left and right. As given below:





Image left and right flip sketch Figure 4-4.



### Probe frequency switch

Press this key to change the working frequency of the probe. The frequency of each probe is given bellow:

CA60R ——2.5MHz、3.5MHz、5.0MHz (C3-1/60R/3.5MHz convex probe)

CA20R ——4.5MHz、5.0MHz、5.5MHz (C1-6/20R/5.0MHz convex probe)

CA13R ——5.5MHz、6.5MHz、7.5MHz (EC1-1/R13/6.5MHz endo-cavity probe)

LA40 ——6.5MHz、7.5MHz、8.5MHz(L3-1/7.5MHz HF linear probe or EL3-1/7.5MHz endo-rectal probe)

The current probe frequency displays on the up right of the screen (see figure 4-1).



#### Measurement

For volume, fetus weight measurement and histogram (see 5.4 for details).



### **Body mark**

At B, B/B, B/M, 4B modes, press this key to active body mark. There are 40 body marks, press this key repeatedly to display these marks circularly.

### 1. Abdomen

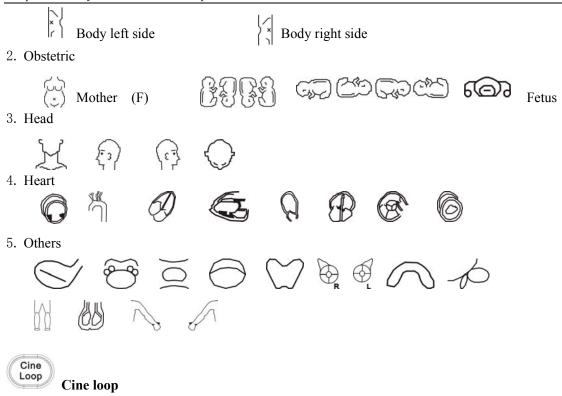


Body front (M)



Body front





At freeze state, press this key to enter cine loop, refer to "5.6.3 Cine Loop" for details.



For distance, circumference, area, volume measurement operating. Refer to chapter 5.



For menu selection when operating by trackball.

Confirm the contents when noting.

At real time or freeze, press this key to display body mark 🖌 .



At any state, press this key to enter B mode (default mode is single B at starting-up).

### Ba Double B display mode key

Press this key to enter BB mode. And there will be two B mode images displayed on the screen. One of them is a "Frozen" image and the other is a "real-time" image; Repress this key can make the two images switch between the states of "Frozen" or "real-time". Press "Freeze" key to freeze these two images.

### BM/M mode display key

Press this key to enter B/M mode. B mode and M mode images will display on the screen at the same time ("BM" or "B+M" for short). B mode real time image is on the left and M mode real time image is on the right.

Press this key again to enter M mode, then M mode image will be displayed on the screen. (Press this key to convert from BM to M, M to BM.)



### 4B display

Press this key to enter 4B mode and display 4B mode images. One is real time, the other three are frozen images; Press this key repeatedly to switch each image between "freeze" and "real time" circularly. Press freeze key to get

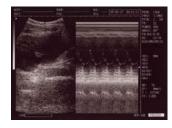
four "Frozen" images. adjusting keys are used to adjust focus position, dynamic range, scanning angle, zoom, cine loop (refer to "Chapter 5 Operation Procedures")



Single B mode



BB mode



BM mode



M mode



4B mode

Figure 4-5. Four display modes sketch



### Focus number selection

Press this key to lighten up the "FPIN" on the screen right top, press again to change the focus numbers. There are two focus at most. Press this key to switch between one focus to two.

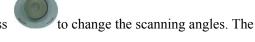


### **Focus space selection**

When set the focus number as two, their distance can be adjusted. There are 5 levels focus space D2, D3, D4, D5, D6 and press this key repeatedly to switch among them circularly.



### Scan angle selection key



	Type	C3-1/60R/3.5MHz Convex probe	C1-6/20R/5.0MHz Micro convex	EC1-1/R13/6.5M Endo-cavity	L3-1/7.5MHz HF linear probe EL3-1/7.5MHz Endo-rectal
		1	probe	probe	probe
	Angle	35° ∼60°	45° ∼90°	60° ∼120°	

Tips: Reduce the angle can improve the image frame rate and increase cine loop frames.



### Dynamic range adjusting key

Press this key to lighten up "DR" on the screen top right corner. Press to adjust the dynamic range between 100dB-130dB. 118 dB is recommended.



Press to adjust scan depth between 40mm-240mm. The current depth displays at bootom screen (see figure 4-1). The depth adjusting range of each probe is given below:

Probe mode	C3-1/60R/3.5MHz Convex probe	EL3-1/7.5 MHz Endo-rectal probe L3-1/7.5MHz HF linear probe	C1-6/20R/5.0MHz Micro convex probe	EC1-1/13R/6.5MHz Endo-cavity probe
Depth range (mm)	70~240	40~90	80~150	50~120

Table 4-1. Probes and their depth adjusting range



### Zoom key

At real time or freeze state, press this key to display or close sampling windows and zooming window.

Move "zooming window" and "sampling window" by trackball. Press Key to switch the current window.

\*\*Tips:\*\*

Change the sizes of "zooming window" and "sampling window" by pressing keys at the same time. The windows change pro rata. The maximum size of zooming window is a quarter of the image display area of the screen.



### Image freeze key

Press this key to switch between freeze and real time display.

### 4.3 Track ball

Track ball is fast, convenient in operation. In this equipment, the track ball functions at:

- Move measuring mark during measurement.
- Select menu items during menu operation.
- Move cursor at annotation.
- Move the sampling line at BM mode.
- Control movie playback one frame by frame at cine loop mode.
- Move the sampling window and zooming window at zooming state.
- Histogram statistic mode. Move the statistic sampling window.

#### Tips:

- Do not press too much when operating the trackball.
- Keep the ball surface clean.

### **Chapter Five Operation Procedures**

### 5.1 Start the equipment

Switch on the equipment, indicator light on the panel turns on and the start interface shows on screen.

Press any key (except key) to enter the state of scanning. Adjust the display brightness, contrast, TGC and overall gain (GAIN) to acquire a satisfying visual effect.



Figure 5-1. Start interface

### 5.2 Diagnosis

Apply some coupling gel on the diagnoses part and press the probe acoustical window on this part closely. The section sonogram of the tissue will display on the screen, move the probe slightly and find the proper depth and optimum position; at the same time, adjust the brightness, contrast, overall gain (GAIN), 8 TGC to acquire the best section sonogram of the part.

### Tips:

Adjust the total gain (GAIN) knob slowly.

#### Note

- 1. Do not press the probe too much to avoid breaking the probe or causing discomfort.
- 2. Do use proper probe and frequency for the target part.

### 5.3 Notation

Press Annotation ABC to activate notation menu.

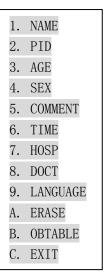
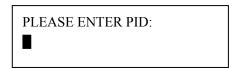


Figure 5-2 Notation menu

) to finfish input. key (e.g.

to select "2. PID" to put in patient ID, 8 characters at most. The PID input box is given bellow:



After input, press any key (except letter, number keys) to exit. To cancel input, you can press any key. The PID will display after "PID" on top of the screen.

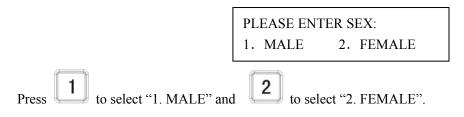
to select "3. AGE" to put in patient age, 3 characters at most. The age input box is given bellow:



After input, press any key (except letter, number keys) to exit. To cancel input, you can press any key. The age will

display after "AGE" on top of the screen. For example: input 27, then press any non-number key (e.g. finfish input.

to select "4. SEX" to put in patient sex. The input box is given bellow:



to select "5. COMMENT" to enter image notation. Move the track ball/ cursor the you can annotate anywhere in the image.

When finishing, press "COMMENT" key on the board to end this operation.

Press to select "6. TIME" to modify the system time and date. The time and date input box is given bellow:

YY-MM-DD HH-MM-SS

For example, the time is: 2006-9-22 9:35:30, then put in:

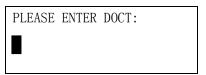
YY-MM-DD 060922 HH-MM-SS 093530

Press to select "7. HOSP" to put in hospital name in letter or number at most 18 characters. The hospital name input box is given bellow:



After input, press any key (except letter, number) to exit. To cancel input, you can press any key. The hospital name will display after "Hospital" at the bottom of the screen. (see figure 4-1 shows)

Press to select "8. DOCT" to put in doctor's name in letter or number at most 14characters. The doctor name input box is given bellow:



#### 9. LANGUAGE

Preinstall function.

Press to select "A. ERASE" to clear out image storage. The remind box is given bellow:

ERASE ALL STORAGE?
1. YES 2. NO

Press number key to confirm clearance. When processing, a word "ERASING..." displays on the upper

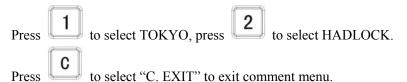
left screen to indicate that system is processing clearing and no other operation can be done. When the reminder disappears, the image storage is cleared.

Press 2 to give up and exit.

Press B to select "B.OBTABLE" to put in obstetric table. The system is built in two OB tables "TOKYO-HADLOCK". Table TOKYO is suitable for Asian, and Table HADLOCK is suitable for European. The remind box is given bellow:

PLEASE ENTER OBTABLE:

1. TOKYO 2 . HADLOCK



### Tips:

When image storage erasing is in process (system reminds "Erasing..."), please do not take other operations in case the equipment is damaged.

The trackball can be used for operating the menu: when the menu displays, move the trackball up and down to select the items, when the selected item is lightened, press "confirm" to enter it.

N-Patient

#### key functions:

- 1. At real time or freeze state, press this key to clear off the measuring marks, comments, measurement results in image area and doctor name, patient name, age and sex.
- 2. At report interface, clear off all the information and measurement results except "Hospital" and "sex".

### 5.4 Routine Measurement

Distance, circumference, area and volume can be measured by controlling the direction keys or trackball; Unit of distance and circumference is mm, unit of area is mm<sup>2</sup>. volume is cm<sup>3</sup>.

There are four measuring marks corresponding to measurement display:

- +: D1
- ×: D2
- **※**: D3
- ₩. D4

In circumference, area measurement, there two measuring marks corresponding to measurement display:

- +: C1, A1
- ×: C2, A2

### 5.4.1 Distance measurement

Operation steps:

Press "DIST" key, and the first cursor appears on the screen;

Press "Ref." key, the second cursor appears on the screen;

Move the cursor to the start point of this measurement by controlling the trackball, press "Ref." key again to confirm the start point;

Move another cursor to the end of this measurement, press "Cancel" to fulfill the measurement and exit; (Tips:

Press "Ref." key repeatedly to switch between the start and end points of the measurement).

Go on measuring just repeat step 1-4 to get at most 4 groups of distance measurement. The measuring results display on the screen right as the following figure shows:

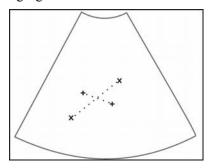


Figure 5-3. Distance measurement sketch

The four groups of data are D1, D2, D3, D4, among them

D1/D2 is the ratio of D1 and D2;

D3/D4 is the ratio of D3 and D4.

### 5.4.2 Circumference and Area Measurement

The circumference and area can be measured in two ways.

Press key to display this menu as given below:

Put in:
1.FREEHAND 2.ELLIPSE

Option 1 is FREEHAND measuring method and option 2 is ELLIPSE measuring method.

### a.Freehand method operation:

1.Press key to select freehand method and call out the measuring cursor, move the cursor to the start point of the measurement.

2.Press key and move the cursor along the edge of the measurement area to the end point by controlling the trackball;

3.Press key again to end the measuring of circumference and area.

4.Press key and repeat the above steps 2-3 to process another measurement. Two groups of data can be measured at most. And the measuring results display on the screen right as given below:

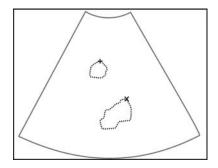


Figure 5-4 Circumference and area measuring sketch (Freehand method)

C1 and A1 are the circumference and area of the first group data;

C2 and A2 are the circumference and area of the second group data;

C1/C2 is the ratio of the two circumferences;

A1/A2 is the ratio of the two areas.

### b.Ellipse measuring method

- 1. At freeze state, Press key to select Ellipse method, an ellipse measuring mark display on the screen, which is named the measured area, can be moved to any place on the image by trackball.
- 2.Press key, then move the trackball to change the size of this measured area.

  Move trackball left and right, the measured area shrinks or enlarges horizontally; Move trackball up and down to shrink or enlarge the measured area vertically;

### Tips:

- Press key repeatedly to shift between moving the mark and adjust the size by trackball.
- 3.Press key, Move trackball to adjust the angle of the measured area.
- 4.Press key to finish measuring.
- 5.Press key and repeat the above steps 2-4 to process another measurement. Two group's data can be

measured at most. And the measuring results display on the screen right as given below:

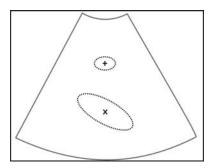


Figure 5-5 Circumference and area measuring sketch (Ellipse method)

C1 and A1 are the circumference and area of the first group data;

C2 and A2 are the circumference and area of the second group data;

C1/C2 is the ratio of the two circumferences;

A1/A2 is the ratio of the two areas.

### **5.4.3Volume measurement**

### Volume can be measured in two ways.

1. Volume measurement utilizes 3-axle method to measure 3 groups of distances and then calculate them.

To fulfill volume measurement, first, measure three distances and then press



key to get the volume.

If the measured distance data is less than three groups, pressing



does not get volume; if four distances

information are measured, when pressing key, the resu

key, the result is the value of the first three data (D1, D2, D3).

Operation procedure: (take kidney as an example)

- 1. Get the kidney cross section image and profile section image respectively and freeze them.
- 2. Measure the long axis and short axis lengths of kidney cross section with distance measurement method.
- 3. Measure the diameter of kidney profile section with distance measurement method.
- 4. Press key to fulfill volume measurement. The volume cost displays at the lower-right corner of the screen behind "Vm1" as the following figure shows:

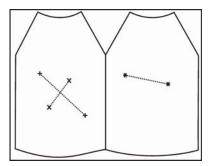


Figure 5-6. Double B mode volume measurement sketch (3-axil metod)

2. Utilizes ellipse measuring method to measure 2 groups of areas and then calculate them.

Operation procedure: (take kidney as an example)

- 1. Get the kidney cross section image and profile section image respectively and freeze them.
- 2. Measure the circumference and area of kidney cross and profile section with circumference and area measuring method.
- 3. Press key to fulfill volume measurement. The volume value will be calculated automatically and displays on screen right behind "Vm1" as the following figure shows:

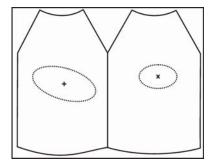


Figure 5-7. Double B mode volume measurement sketch (Ellipse method)

### Tips:

• If only a group of circumference and area are measured, Volume will not be displayed.

### 5.5 Cardiac Measurement

Obtain the satisfied image under the B/M or M mode and freeze. Press the key and the cardiac measurement menu will appear:

- 1. LV<VF>
- 2. AV
- 3. MV
- 4. PV
- 5. TV
- *(* III
- 7. EXIT

- 1. Left Ventricular
- 2. Aortic Valve
- 3. Mitral Valve
- 4. Pulmonary Valve
- 5. Tricuspid Valve
- 6. Heart Rate
- 7. Exit

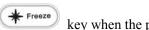
### 5.5.1 Left Ventricular Measurement

By measuring the diastolic period and systolic period: posterior wall of the right ventricular, anterior wall of the interventricular septum, posterior wall of the interventricular septum, endocardium of the posterior wall of the left ventricular, epicardium; to calculate the diastolic period and systolic period respectively:

thickness of the left cardiac wall, diameter of the right ventricular, diameter of the left ventricular, thickness of the posterior wall of the left ventricular, thickness of the interventricular septum, volume of the left ventricular, heartbeat flow, ECG output, systolic fraction and ejection fraction.

### Operation Procedure:

1. Enter the B/M mode, and move the trackball to change the position of the sampling lime. Press the



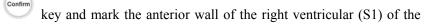
key when the proper M mode image appears;

- 2. Press the key and the cardiac measurement menu will appear;
- 3. Press the 1 key to select "LV<VF>", a vertical time bar will appear in the M image;
- 4. Move the time bar with the trackball to the end of the diastolic period and press the key, mark the

anterior wall of the right ventricular (D1) with the key. Some mark points of the diastolic period are described as follows and mark the following several points with the same method:

- D2—Posterior Wall of the Right Ventricular in the Diastolic Period
- D3——Anterior Wall of the Interventricular Septum in the Diastolic Period
- D4——Posterior Wall of the Interventricular Septum in the Diastolic Period
- D5—Endocardium of the Posterior Wall of the Left Ventricular in the Diastolic Period
- D6—Epicardium in the Diastolic Period
- 5. (D6) After marking, the second time bar will appear, move the time bar to the end of the diastolic period

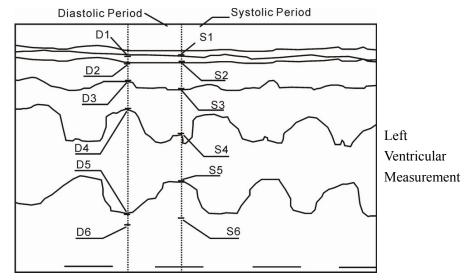
with the trackball and press the



systolic period with the system key. Some mark points of the diastolic period are described as follows and mark the following several points with the same method:

- S2—Posterior Wall of the Right Ventricular in the Systolic Period
- S3——Anterior Wall of the Interventricular Septum in the Systolic Period

- S4——Posterior Wall of the Interventricular Septum in the Systolic Period
- S5—Endocardium of the Posterior Wall of the Left Ventricular in the Systolic Period
- S6—Epicardium in the Systolic Period
- 6. (S6)After the marking finishes, the measurement results will display on the right side of the screen automatically.



RHWD—Thickness of the Right Cardiac Wall in the Diastolic Period (mm)

RHWS—Thickness of the Right Cardiac Wall in the Systolic Period (mm)

RVD—Right Ventricular Diameter in the Diastolic Period (mm)

RVS—Right Ventricular Diameter in the Systolic Period (mm)

LVDD—Left Ventricular Diameter in the Diastolic Period (mm)

LVDS—Left Ventricular Diameter in the Systolic Period (mm)

PLVWD—Thickness of the Posterior Wall of the Left Ventricular in the Diastolic Period (mm)

PLVWS—Thickness of the Posterior Wall of the Left Ventricular in the Systolic Period (mm)

IVSD—Thickness of the Interventricular Septum in the Diastolic Period (mm)

IVSS—Thickness of the Interventricular Septum in the Systolic Period (mm)

LVEDV—Left Ventricular Volume at the end of the Diastolic Period (ml)

LVESV—Left Ventricular Volume at the end of the Systolic Period (ml)

SF—Systolic Fraction (%)

EF—Ejection Fraction (%)

SV—Heartbeat Volume (ml)

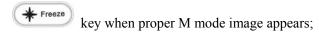
CO—ECG Output (ml)

#### 5.5.2 Aortic Valve Measurement

Calculate the aortic valve diameter, open size of the aortic valve and the ratio between the aortic valve and left atrium to study the aortic valve.

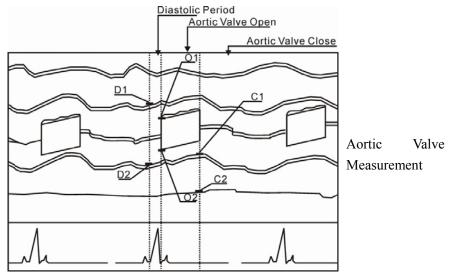
### Operation Procedure:

1. Enter the B/M mode and move the trackball to change the position of the sampling line. Press the



- 2. Press the key and the cardiac measurement menu will appear;
- 3. Press the 2 key to select "AV", and a vertical time bar will appear in the M image;

- 4. Move the time bar to the end of the diastolic period with the trackball and press the key, mark the anterior wall of the aortic valve (D1) and the posterior wall of the aortic valve (D2) with the second time bar will appear after the marking;
- 5. Move the time bar to the open point of the aortic valve with the trackball and press the key, mark the anterior lobe of the aortic valve (O1) and posterior lobe of the aortic valve (O2) with the same method, the third time bar will appear after the marking;
- 6. Move the time bar to the close point of the aortic valve with the trackball and press the key, mark the posterior wall of the aortic valve (C1) and posterior lobe arterial wall (C2);
- 7. When all the measurements finish, the calculation results of the aortic valve will display on the right side of the screen.



- AO—The Aortic Root Diameter at the end of the Diastolic Period (mm)
- LA—Diameter of the Left Ventricular at the end of the Systolic Period (mm)
- AVO—Distance between the Aortic Anterior Lobe and Posterior Lobe and the Open Point of the Aortic Valve (mm)
- LAR—Left Atrium/Aorta Ratio
- LVET—Left Ventricular Ejection Time (second)

#### 5.5.3 Mitral Valve Measurement

The research of the mitral valve allows the user to estimate the D-E and E-F displacement, D-E and E-F slope, D-E and E-F time on the D wave, E wave and F wave under the M mode and BM mode.

Operation Procedure:

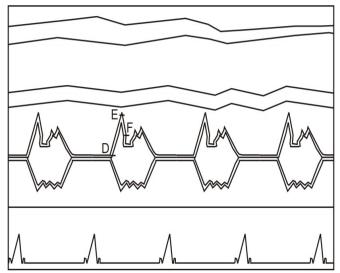
- 1. Enter the B/M mode and move the trackball to change the position of the sampling line with the trackball, press the key when the proper M mode image appears;
- 2. Press the key and the cardiac measurement menu will appear;
- 3. Press the 3 key to select "MV", move the cursor to the Q wave position of the M mode image area and

Mitral

Measurement

Valve

- 4. Mark the following mitral valve waves with the same method;
- E: E Wave
- F: F Wave
- 5. After the marking finishes, the measurement results will display on the right side of the screen automatically.



DE<EX>—Distance from Point D to E on the Y Axis (mm)

EF<EX>—Distance from Point E to F on the Y Axis (mm)

DE<TM>—DE Time (second)

EF<TM>—EFTime (second)

DE<SL>—slope= (Point E on the Y Axis –Point D on the Y Axis)/ (Point F on the X Axis-Point D on the X Axis) (mm/second)

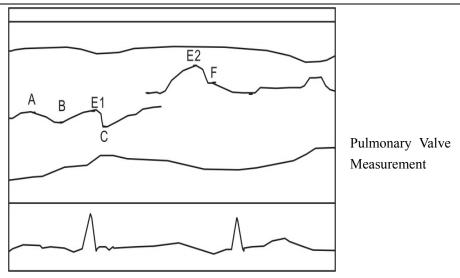
EF<SL>—slope= (Point E on the Y Axis –Point F on the Y Axis)/(Point F on the X Axis- Point E on the X Axis) (mm/second)

#### **5.5.4 Pulmonary Valve Measurement**

In this measurement, it is a characteristic calculation parameter. Calculate the pulmonary valve according to the following point marking position.

- A: Maximum Downward Position of the Valve of the Atrial Systolic Period
- B: Start Point of the Ventricular Systolic Period
- C: Maximum Open Point of the Lobule
- E1: Start Point of the Ventricular Diastolic Period
- E2: Complete Close Point of the Valve
- F: Start Point of the Atrial Systolic Period

Mark the above points with the method described above, when the marking finishes, the measurement results will display on the right side of the screen automatically.



#### A<DEP>——Depth:

The distance from point F to point A is the distance from the start point of the atrial systolic period to the maximum downward position of the pulmonary valve. The distance from point F to A on the Y axis is the maximum movement range of the pulmonary valve in the atrial systolic period.

A<DEP>Depth=AY-FY (mm)

AY is point A on the Y axis, and FY is point F on the Y axis.

#### EF<SL>——Slope:

When the initial blood flow from the atrium, E1 is the start point of the ventricular diastolic period and F is the inflow start point of the atrial systolic period.

EF<SL>Slope= (FY-E1Y) /(FX-E1X)(mm/second)

FY is point F on the Y axis, E1Y is point E1 on the Y axis, FX is point F on the X axis and E1X is point E1 on the X axis.

#### BC<DS>——Diameter:

BC is the open part of the pulmonary valve in the ventricular systolic period and the part on the Y axis the movement distance of lobule when the pulmonary valve open to the maximum.

BC<DS> diameter =CY-BY (mm)

CY is point C on the Y axis, and BY is point B on the Y axis.

#### BC<SL>——Slope:

BC<SL>Slope= (CY-BY)/ (CX-BX) (mm/second)

CY is point C on the Y axis, BY is point B on the Y axis, CX is point C on the X axis and BX is point B on the X axis.

RVET——Ejection Time of the Right Ventricular:

Ejection time of the right ventricular is the time from point B to E2 of the opening of the pulmonary valve.

RVET=E2X-BX (second)

E2X is point E2 on the X axis, and BX is point B on the X axis.

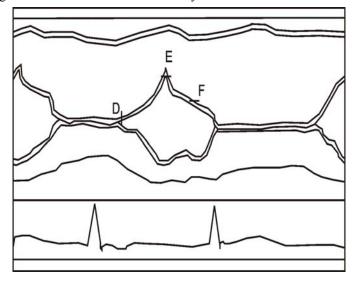
#### 5.5.5 Tricuspid Valve Measurement

Tricuspid valve measurement is similar to mitral valve measurement, and the following three points are used for:

- D: Open point of the tricuspid valve and the end of the systolic period of the right ventricular
- E: Maximum Point of the Tricuspid Valve Orifice
- F: The tricuspid valve closes completely

Mark the above points with the method described above, when the marking finishes, the measurement results

will display on the right side of the screen automatically.



Tricuspid Valve Measurement

DE<EX>— Distance from point D (right ventricular in the front of the tricuspid valve orifice) to point E (maximum tricuspid valve orifice) (mm)

EF<EX>—Distance from point E to point F on the Y axis (mm)

DE<TM>—DE time (second)

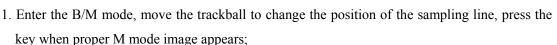
EF<TM>—EF time (second)

DE<SL>—Slope= (Point E on the Y axis–Point D on the Y axis)/ (Point F on the X axis – Point D on the X axis) (mm/second)

EF<SL>—Slope= (Point E on the Y axis–Point F on the Y axis) / (Point F on the X axis – Point E on the X axis) (mm/second)

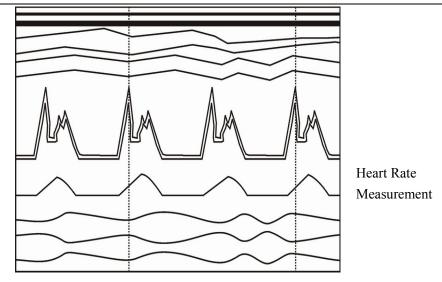
#### 5.5.6 Heart Rate Measurement

Operation Procedure:





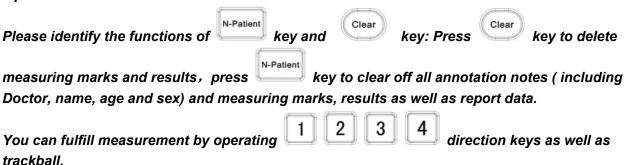
- 2. Press the key and the cardiac measurement menu will appear;
- 3. Press the 6 key to select "HR", a vertical time bar appears in the M image;
- 4. Move the time bar to the first wave peak with the trackball and press the appears; key, the second time bar appears;
- 5. Move the time bar to the third wave peak with the trackball and press the key.
- 6. The measurement finishes and the measurement results will display on the right side of the screen.



TM—Time (second)

HR— Heart Rate (times/minute)

Tips:



#### 5.6 Cine loop and image storage function

The system provides memory for Cine loop and image storage respectively.

#### 5.6.1 Image storage function

When getting a satisfying image, press to save the current image. At the same time, the current stored image serial number automatically displays at top left corner of the image area. Such as "SAVING......05". When image saving finishes, the serial number disappears. When an image is saved, the system enters freeze mode, press key to return to real time state.

The equipment can store 64 images at most, and these images will be automatically numbered as per their saving order. For example: There are images from number 01- 20, press key, then the currently saved image is

numbered 21; When the memory is full (i.e. there are already 64 images), then pressing key will display the following tips:

STORAGE IS FULL.ERASE NO.01?
1. Yes 2. No

Tips:, replace the stored image numbered 01; press 1 to replace it with current saved image; press 2 to exit this operation.

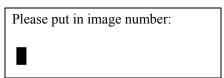
Select "No" to give up saving image. When pressing "Save" again, the system will remind you if you want to cover image numbered 02, reason by analogy in turn.

#### Tips:

When the image memory is full, if some stored image is loaded, then when processing saving, the system will remind you if you want to delete this loaded image and save the current there.

#### 5.6.2 Stored image recall

At real time or freeze, press "key to display the following dialog box:



put in the stored image number, e.g. 01, then press any key (except numbers and letters. Press



backspace key to clear the mistakes and input again) to load the first image. On the screen left bottom, 01/64

means: 01 is the serial number and 64 is the total amount of stored images in the memory. Press other images.



## Press

#### Tips:

You can not load any image from an empty memory area.

The input number should be from 01 to 64, when the input number is more than 64, the system will not take any operation.

key to return to real time or freeze state. Repeat the above steps to load other images.

#### 5.6.3 Cine loop function

After starting up, system enters real time state, first collect cine loop images, it will last for 30 seconds.

1. Switch the equipment into freeze mode. Press key to playbacks images in circulation.

2. During playback, press to enter manual playback, Press to play forward and backward. And

press key to return to auto-playback mode.

3. When playback at "B", "B/B" mode, switch between "B/B" and "B" to play the cine in difference windows.

4. To exit cine loop, press key.

#### Tips:

After changing image scanning mode, probe or display mode, cine loop can not be processed immediately. Normally cine loop can be done 30 seconds after scanning.

At cine loop mode, roll trackball can play cine by single frame. When roll trackball up, cine is played from small number to big, roll it down, the reverse. Press "Cine loop" key to go on auto playback.

Replace probe or change the scan angle, the cine loop frame may change.

#### 5.7 Obstetrics calculation

The equipment can calculate gestation age, expected date of delivery according to 7 parameters such as BPD, FL, AC, HC, CRL,GS, first day of the last menses. Therein, BPD can be used to calculate fetus weight.

At freeze state, Press key to display obstetrics table menu as given below:

TOKYO
1.BPD-FW
2.FL
3.AC
4.HC
5.CRL
6.GS
7.LMP
8.EXIT

Figure 5-8. Obstetrics table menu sketch

Press to select "1. BPD-FW", then measure the distance according to distance measurement method, the corresponding obstetrical table data display on screen right. As below:

BPD=061mm G.A=24W.2D EDD=06-04-23 FW=0490 g

BPD—Biparietal diameter

G.A — Gestation sac

EDD—Expected date of delivery

FW — Fetus weight

Press to select "2. FL", then measure the distance according to distance measurement method, the corresponding obstetrical table data display on screen right. As below:

FL=051mm G.A=28W.0D EDD=06-03-27

FL—Femur length.

Press to select "3. AC", then measure the AC use the Circumference and Area Measurement, the corresponding obstetrical table data display on screen right. As below:

AC=265mm G. A=30W. 4D EDD=07-07-06

#### AC——Abdomeninal circumference

Press to select "4. HC", then measure the HC use the Circumference and Area Measurement, the corresponding obstetrical table data display on screen right. As below:

HC=236mm G. A=25W. 1D EDD=07-08-13

#### HC—Head circumference

Press to select "5. CRL", then measure the distance according to distance measurement method, the corresponding obstetrical table data display on screen right. As below:

CRL=032mm G.A=10W.4D EDD=06-07-29

#### CRL—Crown rump length

Press to select "6. GS", then measure the distance according to distance measurement method, the corresponding obstetrical table data display on screen right. As below:

GS=035mm G.A=08W.0D EDD=06-08-17

#### GS—Gestation sac

Press to select "7. First day of last menses", a reminder displays:

Put in the first date of the last menses: MM—DD

This reminder ask to put in the first date of the pregnant woman's last menses in the date format MM-DD. For

example: May 11, put in 05-11. When the correct date is put, measuring result will displays at "EDD" on screen right in the format of YY-MM-DD, for example 07-02-21 means that the expected date of delivery is on February 21,2007.

#### Note

In expected date of delivery calculation, the system date must be correct.

The default standard pregnancy period in the system is 40 weeks. In last menses method measuring, if the time interval between the input date and the system date exceeds 40 weeks, the inward date will not be accepted and need to be put in again.

Under the condition of item 1, if the inward date is bigger than the current system date, it will be regarded as the date of the last year.

After measurement, press "Clear" key to clear the screen for the next measurement. Otherwise.



to select "8. Exit" to exit OB table.

#### 5.8 Report

The equipment will store the patient information, diagnosis annotation, measurement result and hospital, data, time, doctor and some other information in the report page with the diagnosis. The abdominal, cardiac, obstetrics and urological reports will generate automatically according to different measurement items, and store the last measurement results.

When the corresponding measurement finishes, press the



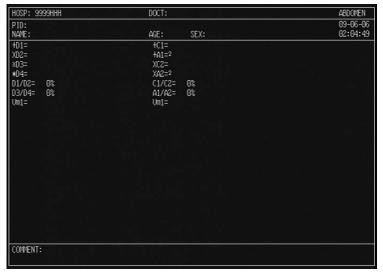
key to enter the freeze state, then press the

key, and the report menu will display:

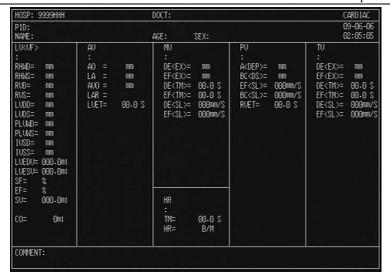
1.ABDOMEN 2.CARDIAC 3. OB 4. UROLOGY

Enter the corresponding number key to enter the related report and press any key to exit this menu.

#### **Abdominal Report, Urological Report:**



#### **Cardiac Report:**



#### **Obstetrics Report:**



#### **Prompt:**

- •You can press the ABC key on the report interface and then annotate information in the annotation box, but other contents can not be changed.
- •In the obstetrics report 1, 2, 3 means that biparietal diameter (BPD), femur length (FL), Crown-rump length (CRL) and gestational sac (GS) can be measured at most for three times, and AVG is the average value of the three measurement results. TOTAL-AVG is the average value of the gestational age (GA) and expected date of delivery (EDD).
- •In the obstetrics report, fetal weight (BPD, AC) is calculated through the biparietal diameter (BPD) and abdominal circumference (AC), and when the measured BPD and AC are unequal to zero, fetal weight will display here automatically.
- Press the Report key to exit the report.

Annotation

### 5.9 Image processing

Press key to display the image processing menu (as given below). It provides image positive-negative flip, GAMA calibration, statistic histogram, edge gain and other image processing functions.

- NORMAL
   SHARP1
   SHARP2
   THI
   POS-NEG
   GAMA
   HISTOGRAM
   EDGEE
   EXIT
- Press 1 2 3 to select NORMAL, SHARP1, SHARP2.

  Press 4 to switch on or switch off the THI. (R60 Probe)
- Press to select "5. POSI-NEGA" to change the image polarity as given below:





Figure 5-9. polarity sketch

Press to select "6. GAMA" to lighten up "GM" on the up right of the screen. There are 4 levels GM0, GM1, GM2, GM3, press to select them circularly.

#### Tips:

This function is set for video output and external devices (e.g. video printer) adjustment and is recommended to set at "OFF" during operation.

Press to select "7.HISTOGRAM" to process histogram statistics as the following procedure:

At freeze, press "post-process" key to display the menu, select "7.HISTOGRAM" to call out a rectangle window on the image, press "Measurement" key to calculate the gray scale pixel numbers. The result displays on screen right as the following figure shows:



Figure 5-10. Histogram sketch

Horizontal ordinate indicates gray scale degree, vertical ordinate indicates number.

PT indicates total quantity of pixel dots in the rectangular window.

Gm indicates the corresponding gray scale of the curve at the vertical peak.

Pm indicate the quantity of pixel dots at Gm gray scale.

From the above figure, in the rectangular area, the total number of pixel dots is 10000. At dray scale 46, there are 262 dots, the most image pixel dots.

Press to select "8.EDGEE" to lighten up the "EE" on the up right screen. Then edge enhancement is adjustable. There are 9 levels: EE0-EE8 which can be adjusted by pressing

#### Tips:

#### This function is a special item and recommended to set at "OFF" during operation.

Press b to select "9, EXIT" to exit the menu.

#### 5.10 Per rectum examination procedure

- 1. Empty the rectum before inspection, after cleansing enema, the patient take left lateral position, put some coupling gel around the endo-rectal probe tip and put on the rubber sleeve (one-time use).
- 2. During inspection, ask the patient to release the anus or take defecating, then breathe deeply to cooperate doctor's inspection. The first is anus digital examination to know the position, size, texture of the lesion and see if it is painful when pressing it and if there is blood on the finger.
- 3. Put the probe into anus about 2-3cm slowly, take a close look at the image, then go deep into the recta gradually and check each position. At the same time, press gut gently by putting hand on pubes at lower rump to enhance image definition.

#### 5.11 Vaginam examination procedure

1. Preparation before inspection: It is different from ultrasonic examination per abdomen, no need to suffuse the bladder. But please tell the patient that it is needed to put the probe into her vagina. Explain the course and

advantages of per vaginam ultrasonic examination and release her tension.

- 2. Patient posture: Take the posture of bladder lithotripsy.
- 3. Scanning method: Put some coupling gel into the disposable sterilizing plastic jacket or a condom and then cover it on probe, apply some coupling gel on the cover and separate the nymphae with left hand to expose vaginal orifice, hold the probe with right hand and put it into the vagina gently can check. The position of probe in vagina will influence the image definition. In general, put the probe closely against vagina vault or cervix. Sometimes it is depending, so move or rotate the probe for a better known of the cavum pelvis. For the moment, there is no hard and fast rule for image position. The near field can be the upper as well as the lower. Please identify the image direction. As same as per abdomen ultrasonic examination, first take vertical section scanning, and check the uterine position, size, outline and each stool section, muscle wall and endomembrane echo state as well as cervix vertical section. Wiggle the probe right and left to display the two ovaries' image. Then contra-rotate probe 90°to scan the uterine and two appendices' cross section. Since most of per vaginam ultrasonic examinations are taken on average examining table instead of special gynecologic examining table, probe operation might be influenced. Some measures can be taken, for example, for some fatty woman or with anteposition of uterus, ask her to hold fists and put it under the hips to raise the rump, which is better for probe operation and complete observation. Sometimes, the target organs are in a higher position, press the abdominal wall gently to make them approach the probe.
- 4. Limitation: Endo-vaginal probe adopts high frequency probe mostly, the focal area is within 10cm. Cysts out the range of 10cm can not be observed well thus abdomen examination is necessary to cover the shortage.

#### 5.12 Image print

Connect the VIDEO IN port of the video printer to the VIDEO OUT port on rear panel of the equipment, then operate according to video printer operation manual.

#### 5.13 Image upload to computer

Connect the USB communication port of the equipment to the computer's USB port.

The high speed USB2.0 mouthpiece can upload images to the computer at current time.

In the accompanying disc, there are USB device driver and software.

#### 5.14 Shut down the equipment

Turn power off.

Tips: It would be better to unplug the AC supply if do not use the equipment for a long time.

#### Note

Must not plug or unplug the power plug when the equipment is not shut down; If it needs to switch on the equipment immediately after just shutdown, please wait for 2 or 3 minutes to avoid breaking the equipment.

## **Chapter Six** Operating Instruction for Function of Puncture Guide

#### Warning

The puncture guiding line must be calibrated before performing a new puncture .If the puncture needle is not consistent with the puncture guiding line, please do not perform the puncture operation.

#### Warning:

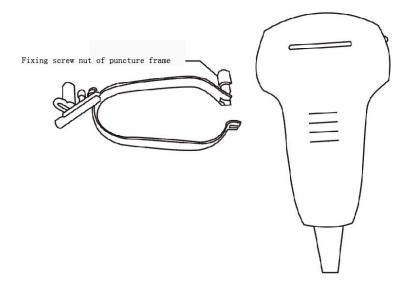
It is with risk when performing the puncture guided under ultrasound, thus it should be operated by operators with the proper qualification and capability, and the preparative work before operation such as examination of clotting time, BPC, electrocardiogram, blood pressure, sterilization of puncture set and puncture probe and signing of operation agreement should be done strictly.

#### Note:

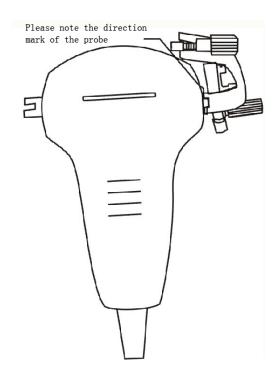
The puncture operation should be performed under the real-time status.

#### 6.1 Fixation of Puncture Frame and Probe

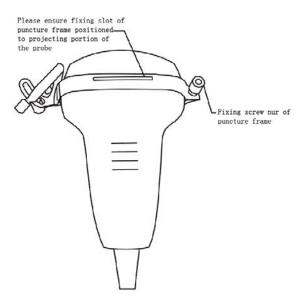
1) Put the probe aside, then loosen the fixing screw nut on the puncture frame.



2) Mount the puncture frame on the probe.

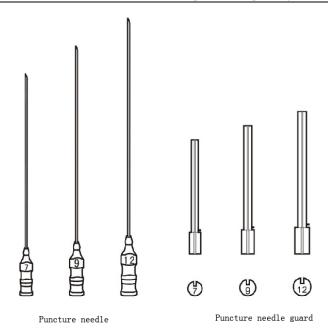


3) Buckle on the puncture frame and turn over the probe, then fasten the fixing screw nut of the puncture frame.



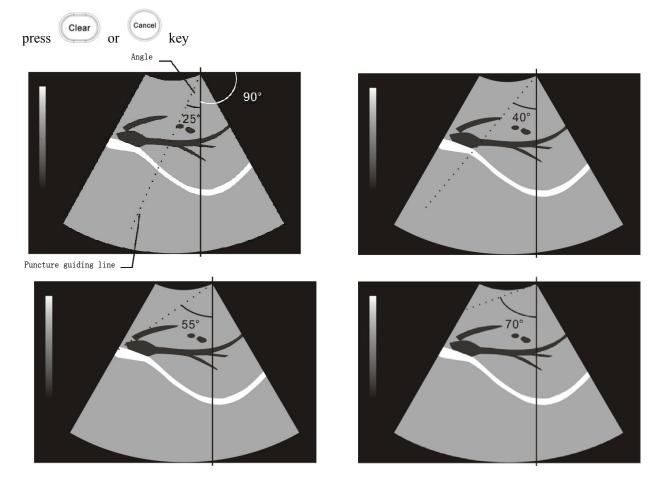
### 6.2 Selection of Puncture Needles

The puncture needles can be divided into 3 specification numbers such as No.7, No.9 and No.12. You can choose the proper puncture needle and needle guard based on the practical need. Please ensure that the specification number of selected puncture needle should be consistent with the selected needle guard.



## 6.3 Call out the Puncture Guding Line

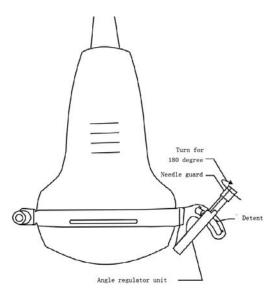
Under the real time estate (single B mode), press key, the screen will display the PT Sampling line, it calls puncture lead line, the trackball or left/right direction keys can move to confirm the position, if want to exit, please



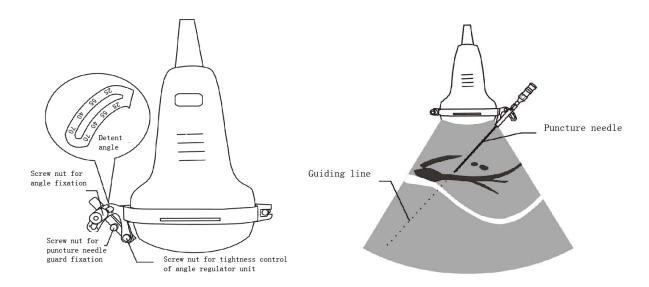
#### 6.4 Calibration of Puncture Line

1) Fix the selected puncture needle on the angle regulator unit, then turn the puncture needle guard in ward for 180

degree. Thus the puncture angle can be adjusted by the angle regulator unit on the puncture frame.

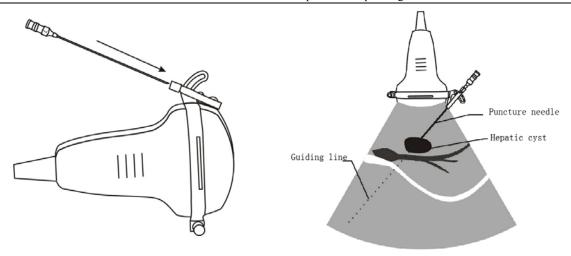


2) Please ensure that each type of angle should be identical with the detent (Detent Angle:  $25^{\circ}$ ,  $40^{\circ}$ ,  $55^{\circ}$ ,  $70^{\circ}$ ). The puncture needle angle should also be identical with the angle of puncture guiding line.



#### 6.5 Insertion of Puncture Needle

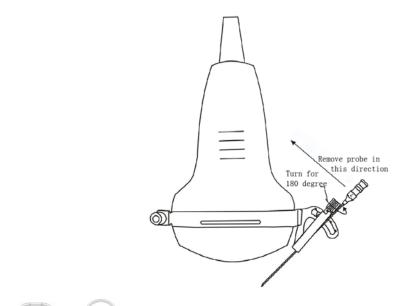
1) Please ensure that the tissue for puncture is on the puncture guiding line first. Then adjust the angle and insert the puncture needle slowly in the direction of needle guard



2) Please do not move the probe when inserting the puncture needle for ensuring the accuracy of the puncture operation.

#### 6.6 After Puncture

1) Turn the puncture needle guard outward for 180 degree to make the rabbet of the puncture needle guard outward, then remove the probe from it.



2) press or key to exit the puncture guiding line.

## **Chapter Seven** Check and Maintenance

#### 7.1 Check

Check the device power cord and probe cable and waterproof cover, if find any damage or breakage, must not use the device and replace the broken immediately.

#### 7.2 Service life

Bases on the manufacturer's design, production related files, this model's use life is six years. The Product's material will gradually aging, if the product continually use over the designed use life, it may bring the problem of the performance reduced and fault rate raise.

#### Note

The Discard the device according to local law. Do not discard it mixing with other household garbage.

#### Warning

The manufacturer shall not assume the responsibility of risks caused by using the device beyond its service life.

#### 7.3 Main unit maintenance

Instrumentation environment should accord with "3.1 operation environmental requirement".

If device enclosure needs cleaning, shutdown the device first and then wipe with alcohol sponges.

Device should not turn on and off frequently.

When the device does not work for a long time, pack the device according to the instructions on the packing. Store it properly in the warehouse. The storage environment should accord with "8.1 Transportation and storage environmental requirements".

#### 7.4 Probe maintenance

Probe is an expensive part and frangible. Never hit it or drop it on floor. When not working, place the probe in the

box and press key to set the probe at freeze state.

Please use medical ultrasound coupling gel during diagnoses. The water prevention level is IPX7, so do not let water exceed the acoustic window (see figure 7-1, 7-2, 7-3, 7-4,7-5). Do daily inspection on the probe enclosure to see if it is cracked and avoid liquid leakage to spoil the inner components

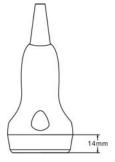
Check the probe regularly to see if it is filled with clean medical castor oil lest the existing air bubbles influence the image quality. If air bubbles appear, turn the probe oil filler hole up and screw off the sealing screw, turn the probe slowly to drive the air bubbles to the screw hole, infuse a little bit of castor oil into the screw hole with syringe with a needle, vent the air bubbles and fasten the sealing screw and finally clean the oil stain on the probe surface.

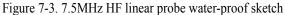


Figure 7-1.60R/3.5MHz convex probe water-proof sketch



Figure 7-2. Endocavity probe water-proof sketch





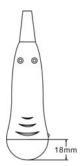


Figure 7-4. 20R/5.0MHz convex probe water-tight sketch



Figure 7-5. 7.5MHz rectal probe water-proof sketch

Once the probe is connected to the main unit, do not remove it at will to avoid poor contact.

#### Note

Probe might be damaged due to long time covered coupling gel.

#### Note

Clean the probe head after every use.

Do not clean the probe with a surgical brash neither soft brash. Only soft cloth can be used to clean it.

#### Note

Do not press the probe on the patient too long to avoid discomfort.

#### 7.5 Cleansing

- 1. When the enclosure needs cleaning, wipe it with soft dry cloths and then wipe gently with sponge dipped with 75% medical alcohol.
- 2. When the inner part of the equipment needs cleaning, power off the equipment first and open the enclosure and vacuum it.

#### **Warning**

To prevent accidents, please power off the equipment when cleaning it or the probe.

#### Caution

Please refer to instructions prescribed by the manufacturer closely when using detergents.

Be careful with cleaning of the display, because it is very easy to scratch and spoil. Please wipe it with dry soft cloth.

Please do not clean the inner part of the device.

Please do not place the device in liquid.

Do not leave any detergent on the device surface.

Though there will be no chemical reaction between the device enclosure and most of those detergents, We still suggest no detergent in cleaning lest the device surface is spoiled.

#### **Warning**

Must not use extender, ethylene oxide or any other organic solvent which tend to deface the probe's protective foil.

Must not place the probe in liquid or detergent.

Must keep the equipment or probe from any type of liquid's infiltration.

Must not clean device or probe by airing or heating.

#### 7.6 Correct usage of probe

In order to prolong probe's service life and obtain optimum performance, follow these instructions:

- 1. Periodic inspection on probe cable, socket and acoustic window.
- 2. Shutdown the device first and then connect or disconnect the probe.
- 3. Do not drop probe or flint body, and never hit the probe acoustic window, otherwise probe should be damaged.
- 4. Put the probe in the probe box when it is not in use.
- 5. Never heat the probe.
- 6. Never bend or pull probe cable, otherwise the internal connection should be broken.
- 7. Use coupling gel only on probe header and then clean probe.
- 8. Inspect probe acoustical window, enclosure and cable seriously after probe cleaning. Never use the probe again if any crack or breakage is found.

#### 7.7 Instrument test and calibration

1. Check the leakage current of the device annually referring to the following data.

	Test Items		Standard Requirements
Continuous leakage current under normal temperature (uA)	Leakage current to	Normal	≤100
	Shell	Single Malfunction	≤500
	Leakage current	Normal	≤100
	to Patient	Single Malfunction	≤500
Dielectric endurance temperature (V)	under normal	A- a <sub>2</sub>	4000V/1min No flashover No breakdown

2. Test the software of obstetrics, area, and circumference measurement; please refer to Appendix C for detailed data.

## **Chapter Eight Transportation and Storage**

#### 8.1 Environmental Requirements for Transportation and Storage

Environmental temperature: - 40°C ~+55°C;

Relative humidity: 10%~100%;

Atmospheric pressure: 50KPa~106KPa;

#### 8.2 Transportation

All marks printed on the packing box are in accordance with the requirements of GB191-2000 < Packing, Storage and Transportation Marks >. Simple shockproof installations are made in the packing box, which adapt to voyage, railway, highway and steamship transportation. Avoid rain, inversion and impact.

#### 8.3 Storage

- When the device is stored for more than 6 months, take out the device from the packing box. Electrify the
  device for 4 hours, and then put the device into the packing box according to the instructions sated on the
  packing box. Do not crisscross/piling devices or keep the device to floor, wall and ceiling.
- Keep the repository ventilative. Avoid direct sunshine and caustic gas.

## **Chapter Nine Malfunction Examination and Troubleshooting**

#### 9.1 Examination

Examine whether the supply power is in normal state. The power line of the main frame has been properly connected and inserted in the electric socket.

Examine whether the probe has been connected to the device correctly.

#### 9.2 Troubleshooting

#### Replacement of fuse

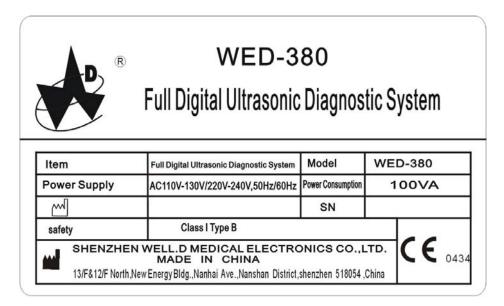
Position the driver into the slot on the fuse cap and press it, then contra-rotate it to loose the cap. Take off the fuse tube (protective tube) and replace it then put back the cap and take the reverse measure to fix the cap and fasten it. Fuse specification:  $\Phi 5 \times 20$ , F2AL250V.

#### Troubleshooting (see the following diagram)

No.	Malfunction phenomena	Troubleshooting
1	Open power switch of the device, with no	1. Examine power supply;
	signal appeared on the screen and the	2. Examine supply line and plug;
	indicator light is not on.	3. Examine whether the fuse is burned-out;
		4. Examine the lightness adjusting knob of the
		monitor.
2	Discontinuous striae and snow appear on	1. Examine power supply: strike fire interfere of the
	the screen.	other devices;
		2. Environmental examination: Electric and
		magnetic field interfere;
		3. Examine power and probe plugs: whether they are
		well connected.
3	Unclear image display	1.Adjust the brightness and contrast knobs on the
		front panel;
		2.Adjust the 8 level TGC and the total gain knob on
		the front panel;
		3.Clean the screen optical filter.
4	Unclear near field	1. Adjust the total gain knob on the front panel and
		the 8 level TGC;
		2. Adjust the focus position to the near field;
5	Unclear far field	1. Adjust the total gain knob on the front panel and
		the 8 level TGC;
		2.Adjust the focus number, space and position
		to set the focus in the far field.

## **Appendix A Labels Diagram**

1. WED-380 Main unit name plate diagram:



2. WED-380 device probe label diagram:



3. WED-380 device optional probe nameplate diagram:

C1-6/20R/5.0MHz







## 4. WED-380 Packing diagram:

Full Digital Ultrasonic Diagnostic System  Shenshen Well.D Medical Electronics Co. Ltd.  13E 12F North New Energy Bldg. Nanhai Blvd. Nanshan District-Shenshen, Guangdong 51896-84, Rr. China Tet-0086-755-26073353 Fac-0086-755-26411198 http://www.welld.com.cn	Storage and transportation condition:  Temperature-40°C-+55°C Relative homelidity range: 10%-100% Almosphie its pressure range 20% Pa-101KPa  MODEL: Q.TY: 1 N.W: G.W: MEAS: 435X365X463mm³	Full Digital Ultrasonic Diagnostic System  **D**  **O**  *	Storage and transportation condition:  Temperature -40°C - +55°C Relative humidity range: 10% - 100% Amouspheric pressure range: 50% Pa-1010KPa  MODEL: Q.TY: 1 N.W: G.W: MEAS: 435X365X463mm³

Modification on the above information may not be further notified.

## Appendix B

## Acoustic output reporting table

#### B mode

Nominal frequency:3.5MHz

Trans ducer Model: C3-1/60R/3.5MHz

Manufactured By: SHENZHEN WELL.D MEDICAL ELECTRONIC CO.,LTD.

					TIS		TIB	
	Index labe	I	MI		Non-	scan	Non-	TIC
				Scan	A <sub>aprt</sub> ≤1cm <sup>2</sup>	A <sub>aprt</sub> >1cm <sup>2</sup>	scan	
Max	imum index v	/alue	0.85	0.98	-	-	-	(a)
	P <sub>ra</sub>	(MPa)	1.46					
	Р	(mW)		115.2	-		-	#
	Min.of [ $P_{\alpha}(z_s)$ ,	$I_{zpta,\alpha}z_s)]$ (mW)				-		
	Zs	(cm)				•		
Associated	$Z_{bp}$	(cm)				-		
acoustic	Z <sub>b</sub> (cm)					-		
parameters	Z at max. $I_{pi,\alpha}$ (cm)		5.30					
	d <sub>eq</sub> (Z <sub>b</sub> )	(cm)					-	
	f <sub>awf</sub>	(MHz)	2.91	2.91	-	-	-	#
	Dim of A <sub>aprt</sub>	X (cm)		1.64	-	-	-	#
		Y (cm)		1.30	-	-	-	#
	t <sub>d</sub>	(µsec)	0.52					
	prr	(Hz)	3787					
Other information	p <sub>r</sub> at max. I <sub>pi</sub>	(MPa)	2.48					
	d <sub>eq</sub> at max. I <sub>pi</sub>	(cm)					-	
	I <sub>pa,α</sub> at max. M	I (W/cm <sup>2</sup> )	207.9					
	F-F	PIN	1	1	-	-	-	#
Operating control	Pow	er,%	80	80	-	-	-	#
conditions	Ang	le,°	30	30				
	Focus	position	7	7				

#### Notes:

#### M mode(Inc B mode)

#### Nominal frequency:3.5MHz

Transducer Model: C3-1/60R/3.5MHz

Manufactured By: SHENZHEN WELL.D MEDICAL ELECTRONIC CO.,LTD.

					TIS		TIB	
	Index labe		MI		Non-	scan	Non-	TIC
				Scan	A <sub>aprt</sub> ≤1cm <sup>2</sup>	A <sub>aprt</sub> >1cm <sup>2</sup>	scan	
Max	imum index v	/alue	0.89	0.49	-	0.036-	0.11	(a)
	P <sub>ra</sub>	(MPa)	1.51					
	Р	(mW)		82.0	-		4.7	#
	Min.of [ $P_{\alpha}(z_s)$ ,	$I_{zpta,\alpha}z_s)]$ (mW)				2.61		
	Z <sub>s</sub>	(cm)				2.94		
Associated	$Z_{bp}$	(cm)				2.94		
acoustic	Z <sub>b</sub>	(cm)					5.07	
parameters	Z at max. I <sub>pi,α</sub> (cm)		5.30					
	d <sub>eq</sub> (Z <sub>b</sub> )	(cm)					0.35	
	f <sub>awf</sub>	f <sub>awf</sub> (MHz)		2.91	-	2.90	2.90	#
	Dim of A <sub>aprt</sub>	X (cm)		2.35	-	2.34	2.34	#
		Y (cm)		1.30	-	1.30	1.30	#
	t <sub>d</sub>	(µsec)	0.53					
	prr	(Hz)	4166					
Other information	p <sub>r</sub> at max. I <sub>pi</sub>	(MPa)	2.58					
	d <sub>eq</sub> at max. I <sub>pi</sub>	(cm)					0.34	
	I <sub>pa,α</sub> at max. M	I (W/cm <sup>2</sup> )	203.9					
	F-F	PIN	1	1	-	1	1	#
Operating	Pow	er,%	80%	80%	-	80%	80%	#
Operating control	Ang	le,°	30	30		30	30	#
conditions	Focus	position	7	7	-	7	7	#
	M Sp	eed,S	1.25	1.25	-	1.25	1.25	#

#### Notes:

#### B mode

#### Nominal frequency:5.0MHz

Transducer Model:C1-6/20R/5.0MHz

Manufactured By: SHENZHEN WELL.D MEDICAL ELECTRONIC CO.,LTD.

		by. SHENZIII			TIS		TIB	
	Index label		МІ			scan	Non-	TIC
				Scan	A <sub>aprt</sub> ≤1cm <sup>2</sup>	A <sub>aprt</sub> >1cm <sup>2</sup>	scan	
Max	imum index v	/alue	0.64	0.19	-	-	-	(a)
	P <sub>ra</sub>	(MPa)	1.26					
	Р	(mW)		10.0	-		-	#
	Min.of [ $P_{\alpha}(z_s)$ ,	$I_{zpta,\alpha}z_s)]$ (mW)				-		
	Z <sub>s</sub>	(cm)				-		
Associated	$Z_{bp}$	(cm)				-		
acoustic	Z <sub>b</sub> (cm)					1		
parameters	Z at max. $I_{pi,\alpha}$ (cm)		2.98					
	d <sub>eq</sub> (Z <sub>b</sub> )	(cm)					-	
	f <sub>awf</sub>	(MHz)	3.87	3.87	-	-	-	#
	Dim of A <sub>aprt</sub>	X (cm)		0.52	-	-	-	#
		Y (cm)		0.79	-	-	-	#
	t <sub>d</sub>	(µsec)	0.43					
	prr	(Hz)	4784					
Other information	p <sub>r</sub> at max. I <sub>pi</sub>	(MPa)	1.87					
	d <sub>eq</sub> at max. I <sub>pi</sub>	(cm)					-	
	I <sub>pa,α</sub> at max. M	I (W/cm <sup>2</sup> )	117.2					
	F-F	PIN	1	1	-	-	-	#
Operating	Pow	er,%	80	80	-	-	-	#
control conditions	Ang	le,°	90	90				
	Focus	position	6	6	-	-	-	#

#### Notes:

#### M mode(Inc B mode)

#### Nominal frequency:5.0MHz

Transducer Model: C1-6/20R/5.0MHz

Manufactured By: SHENZHEN WELL.D MEDICAL ELECTRONIC CO.,LTD.

					TIS		TIB	
	Index labe		MI			scan	Non-	TIC
				Scan	A <sub>aprt</sub> ≤1cm <sup>2</sup>	A <sub>aprt</sub> >1cm <sup>2</sup>	scan	
Max	imum index v	/alue	0.66	0.22	0.025	-	0.05	(a)
	P <sub>ra</sub>	(MPa)	1.29					
	Р	(mW)		11.6	1.35		1.35	#
	Min.of [ $P_{\alpha}(z_s)$ ,	$I_{zpta,\alpha}z_s)]$ (mW)				-		
	Zs	(cm)				-		
Associated	$Z_{bp}$	(cm)				-		
acoustic	Z <sub>b</sub>	(cm)					2.68	
parameters	Z at max. $I_{pi,\alpha}$ (cm)		3.00					
	d <sub>eq</sub> (Z <sub>b</sub> )	(cm)					0.31	
	f <sub>awf</sub>	f <sub>awf</sub> (MHz)		3.86	3.88	-	3.88	#
	Dim of A <sub>aprt</sub>	X (cm)		0.63	0.63	-	0.63	#
		Y (cm)		0.79	0.80	-	0.80	#
	t <sub>d</sub> (µsec)		0.43					
	prr	prr (Hz)						
Other information	p <sub>r</sub> at max. I <sub>pi</sub>	(MPa)	1.93					
	d <sub>eq</sub> at max. I <sub>pi</sub>	(cm)					0.30	
	I <sub>pa,α</sub> at max. M	I (W/cm <sup>2</sup> )	119.1					
	F-F	PIN	1	1	1	-	1	#
Operating	Pow	er,%	80%	80%	80%	-	80%	#
control	Ang	le, °	90	90	90	-	90	#
conditions	Focus	oosition	6	6	6	-	6	#
	M Sp	eed,S	1.25	1.25	1.25	-	1.25	#

#### Notes:

#### B mode

Nominal frequency:7.5MHz

Transducer Model: L3-1/7.5MHz

Manufactured By: SHENZHEN WELL.D MEDICAL ELECTRONIC CO.,LTD.

					TIS		TIB	
	Index labe	I	MI		Non-	scan	Non-	TIC
				Scan	A <sub>aprt</sub> ≤1cm <sup>2</sup>	A <sub>aprt</sub> >1cm <sup>2</sup>	scan	
Max	imum index v	/alue	0.54	0.64	-	-	-	(a)
	P <sub>ra</sub>	(MPa)	1.30					
	Р	(mW)		24.0	-		-	#
	Min.of [ $P_{\alpha}(z_s)$ ,	$I_{zpta,\alpha}z_s)]$ (mW)				-		
	Zs	(cm)				-		
Associated	$Z_{bp}$	(cm)				-		
acoustic parameters	Z <sub>b</sub>	(cm)					-	
parameters	Z at max. I <sub>pi</sub> , <sub>α</sub>	(cm)	4.9					
	$d_{eq}(Z_b)$	(cm)					-	-
	f <sub>awf</sub>	(MHz)	5.70	5.70	-	-	-	#
	Dim of A <sub>aprt</sub>	X (cm)		1.02	-	-	-	#
	DIIII OI Aaprt	Y (cm)		0.71	-	-	-	#
	t <sub>d</sub>	(µsec)	0.28					
	prr	(Hz)	5649					
Other information	p <sub>r</sub> at max. I <sub>pi</sub>	(MPa)	3.41					
	d <sub>eq</sub> at max. I <sub>pi</sub>	(cm)					-	
	I <sub>pa,α</sub> at max. M	I (W/cm <sup>2</sup> )	109.6					
Operating	F-I	PIN	1	1	-	-	-	#
control	Pow	er,%	80%	80%	-	-	-	#
conditions	Focus	position	3	3	-	-	-	#

#### Notes:

## M-mode(Inc B mode)

#### Nominal frequency:7.5MHz

Transducer Model: L3-1/7.5MHz

Manufactured By: SHENZHEN WELL.D MEDICAL ELECTRONIC CO.,LTD.

					TIS		TIB	
	Index label		MI		Non-	scan	Non-	TIC
				Scan	A <sub>aprt</sub> ≤1cm <sup>2</sup>	A <sub>aprt</sub> >1cm <sup>2</sup>	scan	
Max	imum index v	/alue	0.56	0.60	0.029	-	0.045	(a)
	P <sub>ra</sub>	(MPa)	1.34					
	Р	(mW)		22.1	1.06		1.06	#
	Min.of [ $P_{\alpha}(z_s)$ ,	$I_{zpta,\alpha}z_s)]$ (mW)				-		
	Zs	(cm)				-		
Associated	$Z_{bp}$	(cm)				-		
acoustic	Z <sub>b</sub> (cm)						2.47	
parameters	Z at max. I <sub>pi</sub> , <sub>α</sub>	(cm)	4.90					
	$d_{eq}(Z_b)$	(cm)					0.20	
	f <sub>awf</sub>	(MHz)	5.70	5.70	5.70	-	570	#
	Dim of A <sub>aprt</sub>	X (cm)		1.01	1.00	-	1.00	#
		Y (cm)		0.70	0.70	-	0.70	#
	t <sub>d</sub>	(µsec)	0.28					
	prr	(Hz)	5681					
Other information	p <sub>r</sub> at max. I <sub>pi</sub>	(MPa)	3.52					
	d <sub>eq</sub> at max. I <sub>pi</sub>	(cm)					0.19	
	I <sub>pa,α</sub> at max. M	I (W/cm <sup>2</sup> )	109.7					
	F-F	PIN	1	1	1	-	1	#
Operating control	Pow	er,%	80%	80%	80%	-	80%	#
conditions	Focus	oosition	3	3	3	-	3	#
	M Sp	eed,S	1.25	1.25	1.25	-	1.25	#

#### Notes:

#### B mode

#### Nominal frequency:6.5MHz

#### Transducer Model:EC1-1/13R/6.5MHz

Manufactured By: SHENZHEN WELL.D MEDICAL ELECTRONIC CO.,LTD.

					TIS		TIB	
	Index label		MI		Non-	scan	Non-	TIC
				Scan	A <sub>aprt</sub> ≤1cm <sup>2</sup>	A <sub>aprt</sub> >1cm <sup>2</sup>	scan	
Max	imum index v	/alue	0.64	0.23	-	-	-	(a)
	P <sub>ra</sub>	(MPa)	1.38					
	Р	(mW)		10.0	-		-	#
	Min.of [ $P_{\alpha}(z_s)$ ,	$I_{zpta,\alpha}z_s)]$ (mW)				-		
	Z <sub>s</sub>	(cm)				-		
Associated	$Z_{bp}$	(cm)				-		
acoustic	Z <sub>b</sub> (cm)					-		
parameters	Z at max. $I_{pi,\alpha}$ (cm)		2.48					
	d <sub>eq</sub> (Z <sub>b</sub> )	(cm)					-	
	f <sub>awf</sub>	(MHz)	4.66	4.66	-	-	-	#
	Dim of A <sub>aprt</sub>	X (cm)		0.63	-	-	-	#
		Y (cm)		0.79	-	-	-	#
	t <sub>d</sub>	(µsec)	0.31					
	prr	(Hz)	4807					
Other information	p <sub>r</sub> at max. I <sub>pi</sub>	(MPa)	2.05					
	d <sub>eq</sub> at max. I <sub>pi</sub>	(cm)					-	
	I <sub>pa,α</sub> at max. M	I (W/cm <sup>2</sup> )	120.1					
	F-F	PIN	1	1	-	-	-	#
Operating control	Pow	er,%	80	80	-	-	-	#
conditions	Ang	le,°	120	120				
	Focus	oosition	3	3	-	-	-	#

#### Notes:

#### M-mode(Inc B mode)

#### Nominal frequency:6.5MHz

Transducer Model: EC1-1/13R/6.5MHz

Manufactured By: SHENZHEN WELL.D MEDICAL ELECTRONIC CO.,LTD.

					TIS		TIB	
	Index labe		MI			scan	Non-	TIC
				Scan	A <sub>aprt</sub> ≤1cm <sup>2</sup>	A <sub>aprt</sub> >1cm <sup>2</sup>	scan	
Max	imum index v	/alue	0.65	0.23	0.014	-	0.026	(a)
	P <sub>ra</sub>	(MPa)	1.41					
	Р	(mW)		10.2	0.62		0.62	#
	Min.of [ $P_{\alpha}(z_s)$ ,	$I_{zpta,\alpha}z_s)]$ (mW)				-		
	Zs	(cm)				-		
Associated	$Z_{bp}$	(cm)				-		
acoustic	Z <sub>b</sub>	(cm)					2.36	
parameters	Z at max. $I_{pi,\alpha}$ (cm)		2.34					
	d <sub>eq</sub> (Z <sub>b</sub> )	(cm)					0.26	
	f <sub>awf</sub> (MHz)		4.66	4.66	4.61	-	4.61	#
	Dim of A	X (cm)		0.62	0.62	-	0.62	#
	Dim of A <sub>aprt</sub>	Y (cm)		0.80	0.79	-	0.79	#
	t <sub>d</sub>	(µsec)	0.31					
	prr	(Hz)	4807					
Other information	p <sub>r</sub> at max. I <sub>pi</sub>	(MPa)	2.05					
	d <sub>eq</sub> at max. I <sub>pi</sub>	(cm)					0.25	
	I <sub>pa,α</sub> at max. M	I (W/cm <sup>2</sup> )	124.1					
	F-F	PIN	1	1	1	-	1	#
Operating	Pow	er,%	80%	80%	80%	-	80%	#
control	Ang	le,°	120	120	120	-	120	#
conditions	Focus	oosition	3	3	3	-	3	#
	M Sp	eed,S	1.25	1.25	1.25	-	1.25	#

#### Notes:

#### B mode

#### Nominal frequency:7.5MHz

Transducer Model:EL3-1/7.5MHz

Manufactured By: SHENZHEN WELL.D MEDICAL ELECTRONIC CO.,LTD.

					TIS		TIB	
	Index labe	I	MI			scan	Non-	TIC
				Scan	A <sub>aprt</sub> ≤1cm <sup>2</sup>	A <sub>aprt</sub> >1cm <sup>2</sup>	scan	
Max	imum index v	/alue	0.84	0.78	-	-	-	(a)
	P <sub>ra</sub>	(MPa)	2.06					
	Р	(mW)		28.6	-		-	#
	Min.of [ $P_{\alpha}(z_s)$ ,	$I_{zpta,\alpha}z_s)]$ (mW)				1		
	Z <sub>s</sub>	(cm)				-		
Associated	$Z_{bp}$	(cm)				-		
acoustic parameters	Z <sub>b</sub> (cm)					-		
parameters	Z at max. $I_{pi,\alpha}$	(cm)	2.50					
	$d_{eq}(Z_b)$	(cm)					-	
	f <sub>awf</sub>	(MHz)	5.96	5.96	-	-	-	#
	Dim of A <sub>aprt</sub>	X (cm)		1.05	-	-	-	#
	Dilli Ol Aaprt	Y (cm)		0.75	-	-	-	#
	t <sub>d</sub>	(µsec)	0.28					
	prr	(Hz)	5681					
Other information	p <sub>r</sub> at max. I <sub>pi</sub>	(MPa)	3.44					
	d <sub>eq</sub> at max. I <sub>pi</sub>	(cm)					-	
	I <sub>pa,α</sub> at max. M	I (W/cm <sup>2</sup> )	231.1					
Operating	F-F	PIN	1	1	-	-	-	#
control	Pow	er,%	80	80	-	-	-	#
conditions	Focus	position	3	3	-	-	-	#

#### Notes:

## M-mode(Inc B mode)

#### Nominal frequency:7.5MHz

#### Transducer Model:EL3-1/7.5MHz

Manufactured By: SHENZHEN WELL.D MEDICAL ELECTRONIC CO.,LTD.

					TIS		TIB	
	Index labe		MI			scan	Non-	TIC
				Scan	A <sub>aprt</sub> ≤1cm <sup>2</sup>	A <sub>aprt</sub> >1cm <sup>2</sup>	scan	
Max	Maximum index value			0.72	0.021	-	0.042	(a)
	P <sub>ra</sub>	(MPa)	2.03					
	Р	(mW)		26.4	0.78		0.78	#
	Min.of [ $P_{\alpha}(z_s)$ ,	$I_{zpta,\alpha}z_s)]$ (mW)				-		
	Zs	(cm)				-		
Associated	$Z_{bp}$	(cm)				-		
acoustic							2.08	
parameters			2.50					
	$d_{eq}(Z_b)$	(cm)					0.21	
	f <sub>awf</sub>	(MHz)	5.96	5.96	5.96	-	5.96	#
	Dim of A <sub>aprt</sub>	X (cm)		1.05	1.04	-	1.04	#
	DIIII OI Aaprt	Y (cm)		0.75	0.75	-	0.75	#
	t <sub>d</sub>	(µsec)	0.28					
	prr	(Hz)	5681					
Other information	p <sub>r</sub> at max. I <sub>pi</sub>	(MPa)	3.39					
	d <sub>eq</sub> at max. I <sub>pi</sub>	(cm)					0.20	
	I <sub>pa,α</sub> at max. M	I (W/cm <sup>2</sup> )	240.0					
	F-F	PIN	1	1	1	-	1	#
Operating control	Pow	Power,%		80	80	-	80	#
conditions	M sp	eed,s	1.25	1.25	1.25		1.25	
	Focus	oosition	3	3	3	-	3	#

#### Notes:

## **Appendix C Gestational Table**

Head circumference (HC)
Table Set1: Hadlock,F.P.,et al.Method

НС	WEEKS	S. D	НС	WEEKS	S. D
mm	w. d.	±days	mm	w. d.	± days
56	12.0	8	210	23. 1	11
63	12.3	8	217	23.5	11
70	12.6	8	224	24.3	15
77	13. 2	8	231	25. 1	15
84	13.5	8	238	25.6	15
91	14. 1	8	245	26. 4	15
98	14. 4	8	252	27.3	15
105	15.0	8	259	28. 1	15
112	15. 3	8	266	29.0	15
119	15.6	8	273	29.6	15
126	16. 3	8	280	30.5	21
133	16.6	8	287	31.4	21
140	17. 2	8	294	32.4	21
147	17.6	8	301	33. 3	21
154	18.3	11	308	34.3	21
161	18.6	11	315	35. 2	19
168	19. 4	11	322	36. 3	19
175	20.0	11	329	37.3	19
182	20.4	11	336	38.4	19
189	21. 1	11	343	39.4	19
196	21.6	11	350	40.5	19
203	22. 3	11			

Femur length (FL)
Table Set1: Tokyo University Method

FL	WEEKS	S. D	FL	WEEKS	S. D
mm	w. d.	±days	mm	w. d.	±days
8	12.3	10	42	24.5	24
10	13.0	10	44	25. 2	25
12	13.4	10	46	26.0	25
14	14. 1	10	48	27.0	25
16	14.5	10	50	28.0	25
18	15. 2	10	52	29.0	30
20	16.0	10	54	29.5	30
22	16. 4	10	56	30. 2	30
24	17.1	10	58	31.3	32
26	17.6	10	60	33.0	38
28	18.4	14	62	34.0	42
30	19. 2	17	64	35.0	46
32	20.5	17	66	36. 5	50
34	21.5	18	68	38.0	57
36	22.3	19	70	40.0	64
38	23.0	21	72	40.2	64
40	24.0	22			

Femur length (FL)
Table Set2: Hadlock, F. P. ,et al. Method

FL	WEEKS	S. D	FL	WEEKS	S. D
mm	w. d.	±days	mm	w. d.	±days
8	12. 3	10	46	25. 2	15
10	13.0	10	48	26. 1	15
12	13. 4	10	50	26.6	15
14	14. 1	10	52	27.5	15
16	14. 5	10	54	28. 4	15
18	15. 2	10	56	29.4	15
20	16.0	10	58	30. 2	21
22	16. 4	10	60	31. 1	21
24	17. 1	10	62	32. 1	21
26	17.6	10	64	33. 1	21
28	18.4	14	66	34.0	21
30	19. 2	14	68	34.6	21
32	20.0	14	70	35.6	21
34	20. 5	14	72	36.6	22
36	21.3	14	74	37.6	22
38	22. 1	14	76	38.6	22
40	22.6	14	78	39.6	22
42	23. 5	14	80	40.6	22
44	24. 4	15	82	42.0	22

## Crown-rump length (CRL) Table Set1: Tokyo University Method

CRL	WEEKS	S. D	CRL	WEEKS	S. D
mm	w. d.	±days	mm	w. d.	±days
6	6.3	7	54	12.4	7
8	6.6	7	56	12.5	7
10	7. 1	7	58	13.0	7
12	7.4	7	60	13. 1	7
14	7.6	7	62	13. 2	7
16	8. 1	7	64	13.3	7
18	8.4	7	66	13.4	7
20	9. 1	7	68	13.5	7
22	9.2	7	70	13.6	7
24	9.4	7	72	14.0	8
26	9.6	7	74	14. 1	8
28	10.2	7	76	14. 2	8
30	10.3	7	78	14. 3	8
32	10.4	7	80	14.4	8
34	10.6	7	82	14. 5	8
36	11.0	7	84	14.6	8
38	11. 1	7	86	15.0	8
40	11.3	7	88	15. 1	14
42	11.4	7	90	15. 2	14
44	11.6	7	92	15. 3	14
46	12.0	7	94	15. 4	14
48	12. 1	7	96	15. 5	14
50	12. 2	7	98	15.6	14
52	12.3	7	100	16.0	14

# Crown-rump length (CRL) Table Set2: Hadlock,F.P.,et al.Method

CRL	WEEKS	S. D	CRL	WEEKS	S. D
mm	w. d.	±days	mm	w. d.	±days
4	6. 1	3	68	13. 1	6
6	6.3	3	70	13. 1	6
8	6.5	3	72	13.3	6
10	7. 1	3	74	13.3	6
12	7.3	3	76	13.5	6
14	7. 5	3	78	13.6	6
16	8.0	3	80	14.0	6
18	8.2	3	82	14. 1	6
20	8.4	4	84	14.2	6
22	8.6	4	86	14.3	6
24	9. 1	4	88	14.5	6
26	9.3	4	90	14.6	6
28	9.4	4	92	15. 1	6
30	9.6	4	94	15. 2	6
32	10. 1	5	96	15.3	6
34	10.2	5	98	15. 4	6
36	10.4	5	100	15.6	6
38	10.5	5	102	16. 1	6
40	10.6	5	104	16. 2	6
42	11.1	5	106	16. 3	7
44	11. 1	5	108	16. 5	7
46	11.3	5	110	16.6	7
48	11.4	6	112	17. 1	7
50	11.5	6	114	17.2	7
52	11.6	6	116	17.3	7
54	12.0	6	118	17.5	7
56	12. 1	6	120	17.6	7
58	12.2	6			
60	12.3	6			
62	12.4	6			
64	12.6	6			
66	12.6	6			

# Gestational Sac (GS) Table Set1: Tokyo University Method

GS	WEEKS	S. D	GS	WEEKS	S. D
mm	w. d.	±days	mm	w. d.	±days
10	4.0	7	42	9. 1	14
12	4. 1	7	44	9.3	14
14	4.4	7	46	9.4	14
16	5. 0	8	48	10.0	15
18	5. 1	8	50	10. 1	15
20	5.4	8	52	10.3	15
22	6.0	11	54	10.4	15
24	6. 1	11	56	10.6	15
26	6.6	12	58	11. 1	16
28	7. 1	12	60	11.3	16
30	7.3	12	62	11.4	16
32	7.4	12	64	11.6	16
34	8.0	13	66	11.8	16
36	8. 1	13	68	12. 1	17
38	8.3	13			
40	8.6	13			

## Gestational Sac (GS) Table Set2: Hadlock,F.P.,et al.Method

GS	WEEKS	S. D	GS	WEEKS	S. D
mm	w. d.	±days	mm	w. d.	±days
6	5. 0				
8	6.0				
10	6.0				
12	6. 2				
14	6. 4				
16	7.0				
18	7.2				
20	7.2				
22	7.4				
24	7.4				
26	8.0				
28	8.2				
30	8.4				
32	8.4				
34	8.6				
36	9.0				
38	9.3				
40	9.3				
42	9. 5				
44	10.0				
46	10.0				
48	10. 2				
50	10. 4				
52	11.0				
54	11.2				
56	11.6				
58	12.0				
60	12. 4				
62	13.0				
64	13.0				

# Biparietal diameter (BPD) Table Set1: Tokyo University Method

BPD	WEEKS	S. D	BPD	WEEKS	S. D
mm	w. d.	±days	mm	w. d.	±days
16	11.3	7	56	23. 0	11
18	11.6	7	58	23. 5	11
20	12.0	7	60	24. 2	12
22	12.4	7	62	25.0	12
24	13.0	7	64	25.6	12
26	13.6	7	66	26. 3	13
28	14.2	7	68	27.3	13
30	14.6	7	70	28.0	13
32	15. 2	7	72	29. 0	14
34	16.0	8	74	29. 5	14
36	16. 3	8	76	30. 1	15
38	17.0	8	78	31. 1	16
40	17. 5	8	80	32. 1	16
42	18.2	9	82	33.0	18
44	19.0	9	84	34.0	20
46	19. 5	10	86	35. 5	25
48	20. 2	10	88	37. 0	25
50	21.0	10	90	39. 0	25
52	21.4	10	92	42.0	25
54	22. 2	10			

# Biparietal diameter (BPD) Table Set2: Hadlock,F.P.,et al.Method

BPD	WEEKS	S. D	BPD	WEEKS	S.D
mm	w. d.	±days	mm	w. d.	±days
14	11.6	7	60	24. 4	16
16	12.2	9	62	25. 1	16
18	12.6	9	64	25.6	16
20	13. 1	9	66	26. 4	16
22	13.4	9	68	27.3	16
24	14. 1	9	70	28. 1	16
26	14.4	9	72	28.6	16
28	15.0	9	74	29. 5	16
30	15. 4	9	76	30.4	22
32	16.0	9	78	31.2	22
34	16. 4	9	80	32. 1	22
36	17.0	9	82	33.0	22
38	17.4	9	84	33.6	22
40	18. 1	14	86	34.5	22
42	18.5	14	88	35. 4	22
44	19. 2	14	90	36. 4	24
46	19.6	14	92	37.3	24
48	20.4	14	94	38. 2	24
50	21.1	14	96	39. 1	24
52	21.6	14	98	40. 1	24
54	22.3	14	100	41.1	24
56	23. 1	14			
58	23.6	14			

# Abdominal circumference (AC) Table Set1: Hadlock,F.P.,et al.Method

AC	WEEKS	95% Conf.	AC	WEEKS	95% Conf.
mm	w. d.	Limits(d)	mm	w. d.	Limits(d)
100	15. 4	13. 7-17. 5	235	27.5	25. 5-29. 9
105	16. 1	14. 2-18. 0	240	28. 1	26. 0-30. 4
110	16. 4	14. 6-18. 4	245	28.5	26. 5-30. 9
115	16.6	15. 0-18. 8	250	29. 1	27. 0-31. 4
120	17. 2	15. 4-19. 2	255	29. 5	27. 5-31. 9
125	17.6	15. 9-19. 7	260	30. 1	27. 1-33. 1
130	18. 1	16. 2-20. 2	265	30.4	27. 6-33. 6
135	18.4	16. 6-20. 6	270	31. 1	28. 1-34. 1
140	19. 1	17. 1-21. 1	275	31.4	28. 6-34. 6
145	19.4	17. 5-21. 5	280	32. 1	29. 1-35. 1
150	20.0	18. 0-22. 0	285	32.4	29. 6-35. 6
155	20.3	18. 4-22. 4	290	33. 1	30. 1-36. 1
160	20.6	18.8-22.8	295	33.4	30. 6-36. 6
165	21.2	19. 3-23. 3	300	34. 1	31. 1-37. 1
170	21.5	19. 7-23. 7	305	34.4	31. 6-37. 6
175	22. 1	20. 2-24. 2	310	35. 1	32. 1-38. 1
180	22.4	20. 6-24. 6	315	35.4	32. 6-38. 6
185	23. 1	21. 1-25. 1	320	36. 1	33. 6-38. 6
190	23.4	21. 6-25. 6	325	36.4	34. 1-39. 1
195	24.0	21. 8-26. 2	330	37. 1	34. 6-39. 6
200	24.4	22. 3-26. 7	335	37.4	35. 1-40. 1
205	24.6	22. 7-27. 1	340	38.0	35. 6-40. 6
210	25. 3	23. 2-27. 6	345	38. 5	36. 2-41. 2
215	25.6	23. 7-28. 1	350	39. 1	36. 7-41. 7
220	26. 2	24. 1-28. 5	355	39. 5	37. 2-42. 2
225	26.6	24. 6-29. 0			
230	27. 2	25. 1–29. 5			

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