B10 5000Q

Color Doppler System

Operation Manual



WUXI BIOMEDICAL TECHNOLOGY CO.,LTD

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Preface

Statement

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Manufacturer's responsibility

The manufacturer should be responsible for the safety, reliability and performance of this machine only under the following conditions, i.e.:

The assembling operation, extension, readjustment, improvement and maintenance are done by the qualified personnel approved by the manufacturer.

The related electrical devices conform to national standards.

The machine is used according to the conditions and requirements described in this manual.

User notice

I To ensure operation safety and long-term stable performance of the system, it's strongly

recommended reading this manual to get a full knowledge on the function, operation and maintenance before operating the system.

- I Pay special attention to contents of "Warning", "Caution" and "Notice" in this manual.
- I The manufacturer takes no responsibility for any damage or harm caused by incorrect operation or maintenance inconsistent with instructions of the manufacturer or its agent thereof.
- I Following messages which can be read throughout this manual are supposed to be paid special attention to.

Label guide

△WARNING

A WARNING label applies to information that may cause severe personal injury, death or actual property loss if neglected.

△CAUTION

A CAUTION applies to information that may cause mild personal injury or property loss if neglected.

(I)NOTE(I)

A NOTE label applies to information on installation, operation or maintenance, which is very important but poses no risk potential.

Warranty

- I The manufacturer guarantees 12months of warranty for the main unit and its probe(s), 6 months for accessories from the date of shipment, and that the new system is free from any fault in material or workmanship. During warranty period, the manufacturer provides free repairing and damaged part replacement.
- I The warranty only applies to faults occurred in operation under conditions specified by this manual. So, please make sure the system is used within the application scope recommended by this manual.

- I The warranty doesn't apply to damage caused by accidents, misuse, abuse, falls, modification or alteration to any part or component of the system.
- Surface damage is not included in the free repair or replacement range. Battery replacement, training material supply, etc. are not free, either.
- I The manufacturer takes no responsibility for any damage caused by other system or unauthorized connection to other systems.
- I The manufacturer takes no responsibility for any loss, damage or harm caused by delayed service request.
- I Please report to the manufacturer after-sale service department if the system has any malfunction. Model number, series number and a brief description of the malfunction are supposed to be provided in the report.

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Chapter 1 General Information

1.1 Brief introduction

- I This manual gives introduction on Vivid-C1 which is a hi-tech color Doppler ultrasound diagnostic imaging system (hereinafter referred to as the system).
- I This manual consists of several independent chapters. Partial contents in some chapters are identical. All chapters are compiled to provide users with reading convenience and content consistency.
- I This manual provides general guidance on the system operation only. Please refer to related medical literatures for clinical significance and pathological basis of each function. Reading some reference books related to ultrasound diagnosis is helpful for better understanding of this manual.
- I Operation of the system is not complicated since its parameters have been preset before delivery so that the best image quality can be achieved for most patients. Therefore, there is no need to reset the parameters frequently. Anyhow parameters can be easily reset by perusing of this manual if it is really required.
- Any query on operation of this system, please turn to the manufacturer's service engineer or its authorized distributor for support.

DNOTE

This operation manual only introduces how to operate the system and cannot be used as a training material on ultrasound mechanism, anatomy, scanning technology and application. A good knowledge of the above skills is essential for operation of this system and other related fittings.

1.2 Working principle

Ultrasound diagnosis technique is to use the ultrasonic as information carrier, the ultrasonic probe transmits ultrasonic to human body, and through the same probe (or called as transducer) receive echo with information on human body tissue, then through information extraction and processing to realize the inspection and diagnosis on human body tissue, it

has some advantages in safety, no wound, direct viewing, real time, repeatable inspection, convenient operation, wide application, inexpensive price and stronger discriminability to parenchyma. It has taken possession of very important position at the current four image diagnosis techniques in medicine, it has been widely applied to clinic diagnosis, family planning and getting well and health protection, the ultrasonic diagnostic instrument has become a popular and conventional diagnosis system.

The ultrasonic impulse echo is commonly used to detect and extract the diagnosis information in the ultrasonic diagnosis system.

Depending upon different diagnosis information display mode, the products are generally classified into such four types: Type A: Amplitude Modulation Display, Type-B: Brightness Modulation Display; Type M: Motion Mode Scope and Type D: Doppler type.

A-mode display: echo amplitude for single ultrasonic beam interface, it is called as amplitude modulation mode to display strong and weak echo on the basis of impulse wave amplitude.

B-mode display: the tangential echo image consisted with the ultrasonic bean radial, strong and weak echo for interface is indicated by intensity, which belongs to two-dimension images for brightness modulation display.

M-mode display: single-beam ultrasonic cardiogram displaying cardiac motion echo curve at levels, also a kind of brightness modulation display. Axis-Y (vertical direction) represents interface depth while Axis-X (horizontal direction) represents time, that is, we get a time-based scan curve, a position-time curve for calculation of cardiac measurement.

D-mode display: the body internal organs' motion states are displayed based on Doppler principle, that is, by detecting and processing the echo's Doppler frequency shift signals reflected from motional viscera and blood into sound, wave, color or brightness signals.

Ultrasonic Doppler diagnosis system mainly include the following three types: continuous wave Doppler image diagnosis system, pulsed wave Doppler image diagnosis system, and real-time 2D color Doppler flow image diagnosis system.

Continuous wave Doppler image diagnosis system is earliest applied in diagnosis. Its probe has transducer which transmitting continuous ultrasonic wave signal at certain frequency. When the wave encounters the red blood cell group in the target blood flow, echo signal, namely ultrasonic wave of changed frequency, is created. Another transducer in the probe will detect the echo signal and convert it into electrical signal and then send to machine, where the signal will be subjected to high frequency amplification, frequency mixing with electrical signal of original transmitting frequency and demodulation. The resultant difference frequency signal will then be converted into diagnosis use sound, wave or flow images depending on different processing and displaying methods. This imaging method is difficult to measure any distance and can not position organs and tissues, so it is not a convenient method for diagnosis application.

Pulsed wave Doppler image diagnosis system emits intermittent ultrasonic signals, the "pulsed" is hence named. This system has a gate circuit, which controls the generation of transmission signal as well as the receiving and amplification of gated echo signals. It allows, by intercepting the time quantum of echo, selecting the measured distance and identifying the positions of organs and tissues. Because of pulsed signal transmitting and receiving mode, both the transmitting and receiving tasks may be undertaken by a same transducer in the probe, this is very useful to simplify probe mechanical structure, avoid improper coupling between received and the transmitted signals and furthermore improve image quality. With the introduction and development of pulsed Doppler technology, directional detection, frequency spectrum processing and computer coding technologies, the ultrasonic Doppler diagnosis system may be used for not only identifying distance but also judging flow direction and velocity. That is, it may provide to doctors various diagnosis information and allow stepping into quantitative measurement from qualitative measurement.

Real-time 2D color ultrasonic Doppler flow image diagnosis system is the latest scientific and technological achievement in the field of ultrasonic Doppler cardiovascular diagnosis during late 80s. it smartly combines together the pulsed Doppler technology, 2D (type-B) real-time ultrasonic imaging and M-type ultrasonic cardiogram so as to allow displaying flow direction and relative velocity simultaneously on direct-viewing 2D section, and as a result, provide both time and space information of cardiovascular system. Furthermore, by computer-based digitalization and image processing technologies, the imaging diagnosis instrument is so configured to have additional physiological monitoring function, which allows providing various valuable information relating to flow velocity, volume, flow rate, acceleration, vessel diameter, arterial index. Hence the Instrument of this type is often called "color B-mode Instrument" or "color Doppler".

Ultrasonic frequency is above 20KHZ. It is normally from 1 to 10MHZ for common medical diagnosis. Ultrasonic wave length is short and readily forms one beam, which offers satisfied linear oriented transmission. Nonetheless diffusion angle is formed at the side edges of far and sound fields. Therefore focused beam is normally applied in the medical ultrasonic diagnosis to improve imaging.

Resolution of ultrasonic wave is defined to be the capacity that distinguishes the shortest distance between two neighbored interfaces. Normally should frequency be higher, wave length is shorter, resolution is higher and penetration capacity is poorer and vice versa. To examine superficial organs like hypothyroid, galactophore and eyeball, high-frequency probe, e.g. 7.5MHz probe is used. To examine deep viscera like heart and abdomen, low-frequency probe, e.g. 3.5MHz convex array probe is used to increase the penetration capacity.

1.3 Biological effects

During the ultrasonic examination, ultrasonic is sent into the human body and reacted with the physiological region and peripheral tissues to be examined. Some sent ultrasonic is reflected on the probe to gain graphics. Others are consumed in tissues. Specified high ultrasonic energy reacts with tissues to produce the biological effect which may be technical or thermal effect. Although biological effect is generated from the use of diagnostic ultrasonic, normally it is not required for diagnosis even may be hazardous on certain conditions.

There is no report that diagnostic ultrasonic cause obvious biological effect on human so far. It is usually believed in that frequency, intensity and exposure time of diagnostic ultrasonic will not present hazardous biological effect. Nonetheless research on the biological effect still goes on.

Clinic physician shall at its own discretion determine the advantage and disadvantage of diagnostic ultrasonic examination.

In March 1993, AIUM issued the official declaration on clinic application safety of ultrasonic, saying that advantages and effectiveness of diagnostic ultrasonic as medical diagnostic system has been proven with many evidence including application in the pregnant woman since it was used from the late 1950s. AIUM hereby declares the clinic application of ultrasonic safe. For there is no evidenced report stating biological effect on patient or system operator has been caused by normal radiation of current ultrasonic diagnostic system. Though existence of such biological effect may be determined in the future, existing information shows that diagnostic ultrasonic is greatly beneficial to patient and presents minor danger if any.

AIUM issued the declaration on ultrasonic examination for obstetrics, stating that AIUM advocates responsible application of diagnostic ultrasonic and severely opposes application for mind, social, amusement or purposes other than medical treatment. It is improper and contrary to medical occupation ethics if applying 2D or 3D ultrasound just for watching fetus and gaining fetus photos, or distinguishing the fetus sex without medical evidence. Although the issue is still open that there is biological effect on patient if exposed to ultrasonic diagnostic system, the biological effect will be determined possibly in the future. Therefore carefully use the ultrasonic in favor of patient.

1.3.1 Thermal effect

As other energies, ultrasonic energy is attenuated and turned into thermal energy when it passes through tissues. Too much thermal energy will increase the tissue temperature even cause tissue damage. Thermal effect is mainly related to tissue characteristics or control parameters.

Physical characteristics of tissue determine the generation and transmission of thermal energy including acoustic impedance, attenuation, absorption and penetration.

Time average intensity of ultrasonic energy is determined by the ultrasonic parameters including output frequency, pulse height, pulse period, pulse cycle, beam shape and beam motion. All are affected by probe type, operation mode, focus depth, sampling volume and

position and output control device. Motion direction and stay of probe are also two affecting factors if changed by the operator. By parameter setting operator can minimize the thermal effect.

1.3.2 Mechanical effect

Ultrasonic energy reacts with tissues and produces mechanical effects as the thermal effect generation. One most important mechanical effect is the cavitation effect when ultrasonic pressure works on the minor air bubbles in the tissue. It is evidenced by laboratory test on small animal species that cavitation effect causes mechanical damage of cell like minor rupture and bleeding. Mechanical effect is mainly related to tissue characteristics or control parameters.

Physical characteristics of tissue can influence generation and effect of cavitation, including existence and size of minor air bubble and sensitivity of tissue to cavitation effect.

Main factor is the ultrasonic field parameters to affect cavitation effect, like ultrasonic output frequency, pulse peak amplitude and possible pulse period. All these can be controlled by the operator via control functions of instrument.

1.3.3 Measurements to be taken by the operator

Try optimizing the gain and other graphic improvement functions before he increases sound power output or changes other control parameters obviously affecting sound power output.

Learn and practice skills to determine dissection structure and quickly improve the graphic. Freeze the graphic if required diagnostic information is acquired. As it takes certain time to increase the tissue temperature, less exposure time can greatly reduce the possibility of damage.

Change the position of probe, entrance angle or probe type, if possible, in order to avoid damaging tissues.

Less penetration depth of high-frequency probe.

Less energy of linear array probe.

Do not focus on the skeleton or tissue with less blood. Do not let ultrasonic beam through eyes or focusing near eyes.

1.3.4 ALARA principle

There is one simple practice for application of ultrasonic energy---ALARA (as low as reasonably achievable). In the other words, ultrasonic irradiation shall be used as low as reasonably achievable. In practice, we should keep the total ultrasonic irradiation as low as reasonably achievable while proper diagnosis is acquired.

Control parameters not greatly affecting the graphic quality shall be set in the manner that sound power output keeps the minimum value. Other control parameters that change graphic quality and increase sound power output shall be set as low as possible provided that diagnostic graphic image can be properly acquired.

1.4 Clinical application

- I Abdomen section (adults and pediatrics): to detect abnormalities from the structure images of liver, kidney, pancreatic gland, gall bladder, spleen, gastrointestinal tract and urogenital organ.
- Abdomen section (obstetrics and gynecology): to detect and discover abnormalities from the structure images of fetus, womb and pelvis so as to estimate the fetal age and weight and evaluate the fetal heart function.
- I Chest section (adult and pediatric): to analyze M-mode image so as to detect abnormalities of the heart structure and function.
- I Skin section (organella): to detect abnormalities from the rough evaluation of images of breasts, thyroid, and testicles, etc.
- I Skin section (peripheral vessel): to detect and evaluate the vascular stenosis and occlusion from the images of peripheral vessels and flow measurement.
- I Neonatal head section: to detect abnormalities of the cerebral volume and structure from the image of neonatal head.
- I Urological section: to detect the left/right kidney, bladder and calculate residual urine volume, etc.
- I Musculoskeletal section: to detect and discover abnormalities from the structure images of fetus and musculoskeletal in the application of obstetric and gynecology.
- I Transvaginal section: to detect and discover abnormalities from the structure images of uterus, ovary, ovarian follicular, etc.
- Endo-rectal section: to calculate the length, weight and height of prostate.

1.5 Inapplicability

In ultrasonic examination, ultrasonic waves are applied to human body. Depending on the energy transducer, the ultrasonic frequency varies between 2.0M and 10.0MHz. Ultrasound has no ionizing property in nature.

The mean value of the output sound power conforms to the milliwatt-grade requirement and can change with transducer frequency, size and focusing point. Ultrasound will attenuate and scatter when passing through or reflecting from body tissues.

The ultrasonic examination has been implemented for many years and studies on influence of different sound power have also been ongoing. Until now, no proof has been discovered that ultrasonic examination below the directive standard of Food and Drug Administration (FDA) has adverse effect on human body.

Repeated or long-time application of ultrasound under large power may heat or even injure the tissue, some people even think exposure to low power irradiation may also lead to permanent or accumulated genetic or physical influence. Before the viewpoint is verified, operators should avoid unnecessary ultrasonic irradiation.

Now, experts in medical science consider it a deliberate decision to limit the sound power standard for fetus to be lower than that for adults.

△WARNING

- Ø The system is not suitable for inspection on organs containing with gas such as lung, etc.
- Ø It is recommended not to check the parts with wounded or acute inflammation to avoid the cross-infection.
- Ø Patient in the following situations are not allowed to be checked with vagina and rectum probes:
 - ① inflammation of the vagina, such as trichomonas virginities, colpomycosis, venereal disease etc;
 - ② the unmarried, deformity of vagina, menstrual period, postmenopausal vagina atrophy, person with difficulty carry on the vagina ultrasonic examination, colporrhagia, placenta previa patient, etc.
- Ø The following patients are prohibited to use the puncture examination:
 - 1) high blood pressure
 - ② coronary heart disease
 - 3 disturbance of blood coagulation
 - 4 bleeding tendency patient.

Chapter 2 Safety Precautions

2.1 General safety information

Safety of the operator or the examinee, and reliability of the system are generally considered during designing and manufacturing. However the following safety preventive instructions should be followed.

- 1. According to GB9706.1-1995 (Medical electrical system--Part 1: General requirements for safety), the system belongs to type BF, class I system. Therefore, at any time the patient is not supposed to touch or operate the system.
- 2. Conforming to GB 9706.1-1995, Medical electrical system—Part 1:General requirements for safety; supporting continual operation. In addition, according to electromagnetic compatibility requirements, the system conforms to class A (noise release) and grade B (interference resistance).
- 3. The system should be placed far away from power generators, X-ray systems, radio stations and transmission lines so as to prevent electromagnetic noise in the scanning process; otherwise image abnormalities may be caused. We suggest equipping the system with an independent circuit. If the system shares a power supply with other electrical or electronic system, poor or abnormal image quality may be resulted in.
- 4. Do not modify the system parameters. If it is absolutely needed, ask the manufacturer or its authorized agent to provide service.
- 5. Before delivery, the system has been adjusted to optimal working state. Excepted the specified operations in this manual, do not adjust any preset control or switch.
- 6. In case of any malfunction, please turn off the system immediately and contact the manufacturer or its authorized agent.
- 7. To connect the system with an electronic or mechanical system manufactured by another company, contact the manufacturer or its authorized agent before connecting.
- 8. Avoid operation or storage in the following environments:
 - I The ambient temperature is lower than -40°C or higher than 55°C. (The normal operation temperature range is 5°C-40°C.)
 - I The atmospheric pressure is below 70kPa or above 106kPa.
 - I The system is exposed to poisonous gas.

- I The humidity is rather high (the relative humidity for operation should be below 80% and for storage should be below 90%).
- I The system is exposed to water vapor.
- I The system is exposed to mist or splashing water.
- I The system is exposed to dust.
- I The system is exposed to high-density petroleum gas.
- I The system is exposed to salt mist.
- I The system is exposed to explosive gas or dust.
- I The system is exposed to violent impact or vibration.
- I The basal plate of the system is placed with an inclination of more than 10 degrees.
- I The voltage of the AC power supply is severely low.
- I The AC voltage fluctuates violently in operation.
- I The system is exposed to direct solar irradiation.
- I The operation room is not well ventilated.

ÂWARNINGÂ:

- Ø The system is not intended for treatment.
- Ø The system is neither a therapeutic system nor therapeutic system.
- Ø The system is not supposed to be applied for fetal sex diagnosis of non-medical purpose.
- Ø Incorrect operation of the system in hospitals or organizations may lead to invalidity of the system or harm human health.

DNOTED:

- u The system is not intended for home use.
- u The system should be operated by qualified personnel or under the guidance of qualified personnel.

2.2 Safety signs

*	BF mode system: represent B-mode system having F-mode application parts; B-mode system: When electric leakage is permitted, it can provide anti-electric shock protection of particular degree.	
IO	I and O on the power switch mean ON (on) and OFF (off) respectively.	
	This sign is a safety warning. Make sure you understand the operation function before use. The operation function is introduced in the manual.	
IPX7	Liquid immersion-proof degree.	
\bigvee	Equipotentiality symbol.	
Signs applied to	interior of the system	
	Dangerous voltage (higher than 1,000V AC or 1500V DC)	
-	This sign is used for indicating the connection point of the system safety grounding wire with ground. In system safety requirements, conductive parts of class I system should be connected to protective grounding wires.	

2.3 Environment safety preventive measurements

Avoid operation and storage in the following environments:

	T	<u> </u>
	water vapor exposure; do not operate the system with wet hands.	direct solar irradiation
	sharp temperature variance (the normal operation temperature is 5°C-40°C)	near heat-emitting systems
S NOT	rather high humidity; poor ventilation (the normal relative humidity for operation should be lower than 80%)	violent shakes or vibration
	near chemical materials or explosive gas	do not let dust or metal articles fall into the system
00 sh	do not disassemble or open the system; the company won't shoulder any responsibility for any result caused thereby	please do not turn off the fans at the side or the back of the system
A CONTRACTOR OF THE PARTY OF TH	before the system is well connected, do not plug it in; otherwise, it may cause faults	take the plug rather than the wire for pulling out the power line

2.4 Physical safety preventive measurements

So far, there is no proof indicating that correct operation of ultrasonic diagnosis systems can cause harm to the patient or the operator. While unknown adverse events may occur in the future, as far as it goes, its benefit far exceeds the unproved risks.

In theory, ultrasonic waves may exert adverse influence in two cases. Firstly, whining passing through the human body, ultrasonic waves will generate heat. Doppler effect can produce more heat. However, the heat, produced by even Doppler effect, is low, so much so that no system can detect it. Secondly, ultrasonic waves may produce air bubble. However, it hasn't been proved until now.

In a word, it hasn't been proved that ultrasonic waves have adverse effect on the human body.

Following are control parameters that can directly influence the ultrasonic intensity:

- I Focus depth: The pulse repetition rate changes with focus depth.
- I Probe selection: Probe replacement can influence irradiation zone. New probes have different acoustic properties and, therefore, can produce different frequency signals and sound power. In addition, sound power output setting parameters, frame frequency, depth, sector width, linear density, quantity and positions of emission focus zones may also be modified.
- I Freeze: Start/stop image acquisition. Therefore, the ultrasonic irradiation should be started/stopped correspondingly.
- I Linear density: change the pulse recurrence interval.
- I Quantity and positions of focus zones: to change the quantity and positions of emission focus zones.
- I The imaging mode can be changed by selecting mode keys (B, 2B, 4B, B/M, M, CF, PDI, PW).
- I Control parameters indirectly influencing ultrasonic intensity: The ultrasonic intensity can be indirectly influenced. These control parameters can influence the imaging mode, the pulse repetition frequency, the focus depth, the pulse length and the probe selection. Imaging mode selection decides the ultrasonic beam type: B refers to the scanning mode, and M refers to static or non-scanning mode. Static ultrasonic beams can concentrate energy into a certain site while moving or scanning ultrasonic beams can scatter energy in a certain region. The time to concentrate ultrasonic beams into a region accounts for only a fraction of the time under non-scanning mode. Pulse repetition frequency refers to the quantity of ultrasonic energy pulses within a special time period. The higher the pulse repetition frequency is, the larger the quantity of energy pulses within a special time period will be. The following control parameters can influence the pulse repetition frequency: focus depth, display depth, quantity of focus zones, and sector width. The focuses of ultrasonic beams can affect the readability of images. To maintain or enhance the readability at different focuses, the output should be modified in the focus zone. Output modification can optimize the system. Different focus depths are needed for different detection. The readability of important structures can be improved by setting the focus at correct depths.

Pulse width refers to the time length for continual activation of ultrasonic pulse burst. The longer the pulse is, the higher the time-mean intensity will be; the higher the time-mean intensity is, the larger the possibility of heat and bubble production will be. Probe selection can indirectly influence the intensity. Tissue attenuation changes with frequency. The higher the probe operation frequency is, the more sharply the ultrasonic energy will be attenuated. Low probe frequency is needed for deep scanning under the same output intensity. If the output and gain exceed certain values while the image quality is not increased correspondingly, low-frequency probes are needed.

I Receiver control: These control measurements can be used to improve image quality. They have no direct influence on the output but can affect the reception of ultrasonic echoes. These control measurements include receiver gain, TGC, dynamic range and image processing. Before output increase, the receiver control may first be optimized.

2.5 Electric safety preventive measurements

According to classification with regard to protection against electric shock, the system belongs to type BF, class I. For protection against electric shocks, the casing is basically insulated, and, besides, protection measurements such as protective earth, etc. are taken. For using the system, the power socket should be of standard three-pole type, and the grounding terminal should be reliably connected to the earth. In addition, the following points should be paid attention to:

The power cable should conform to the power cable of the system (AC, 100-260V); the system should be well grounded (otherwise, noise may be produced).

All connecting parts (power cable and optional items) should be correctly connected to the system. The probes should be well connected before system start. Installation and disassembly of the probes should be conducted when power is cut off.

When the system has been started but ultrasonic probes haven't been mounted, do not touch the metal part of the ultrasonic probe socket by any means. Under such condition, touching the ultrasonic probe socket may lead to electric shock accidents.

An interval of at least 5 minutes is required between shutdown and restart (turn on the power supply of the system).

Do not open the casing without permission.

For fuse tube replacement, first cut off the power supply and then screw off the lid of the tube fuse holder at the back of the host. Please mount a 2A/250V low-breaking ϕ 5x20mm tube fuse and find out the reason for the fault.

In case of any malfunction, cut off the power supply in time and inform the authorized

maintainers or the manufacturer.

2.6 Safety preventive measurements in fetus examination

Ultrasonic examination has been applied for as long as two decades with not a single adverse effect report. There has been no reports on its harm in clinical studies, either. However, the following two conditions should be paid special attention to in application of the system:

Firstly, ultrasonic waves (especially transvaginal ultrasonic waves) have been extensively applied to early stage of gravidity and prefertilization.

Secondly, to examine the fetus or the ovaries, the ultrasonic beam should be weakened at the bottom of the vaginal canal.

∆WARNING∆

In hospitals, both doctors and patients may contact dangerous and uncontrollable compensating current, which is produced by potential difference between connecting systems and conductive parts prone to be touched in the ward. The most reliable solution to this problem is to use continual iso-potential connection. This medical system should be connected to the iso-potential connection grid of the ward via a connection joint with an angular socket.

2.7 Maintenance and protection

2.7.1 Cleaning

The system and the probes should be wiped with warm water or alcohol dipped soft cloth at least once every month for cleaning. Do not use paint diluents, ethylene oxide or other organic solvents for cleaning since they may damage the probe film. Take care not to let sterilizing solvent or water enter the system or other accessories.

Use the system and probes in completely sterilized environment. Do not sterilize the system, probes or accessories by heating or with gas.

Probes should be cleaned by wiping with soft cloth dipped with warm water or a pad dipped with 3.4% glutaric dialdehyde solvent (e.g. Cidex PlusTM) at least once a week. Do not use paint diluents or other organic solvents since they may damage the active film surface of the probes. Do not dip the probe into any liquid or cleaning solvent and do not let any liquid enter the system or the probes.

The probes should be used in sterilized environment. Do not perform gas or heat sterilization on the system. Do place sterilized latex sleeves on the probes, the probe lines and the system. The sterilized latex sleeves are available from the manufacturer or a its local distributor.

Do NOT:

- I use paint diluents, ethylene oxide or other organic solvents for cleaning since they may damage the active probe film surface.
- I dip the probe into any liquid or cleaning solution.
- I let any liquid enter the system or the probes.
- I sterilize the system, the probes or accessories by heating or with gas.

△WARNING

Do not dip the probe line or connector into solvent. Even though the probe surface has a waterproof layer (IPX7), it is limited to the head part, so care should be taken in ultrasonic coupling agent application and cleaning and sterilization of the probe surface.

2.7.2 Use the probes correctly

To length the service life of probes and get the best performance, the probes should be manipulated with as much care as possible with the following considerations born in mind:

Regularly check whether the probe line and connector are damaged.

Before probe replacement, turn off the system first so that the probe can be identified correctly and the lives of the system and the probe can be lengthened.

Take care not to drop the probes on the floor or let them knock against other hard objects or surfaces. Incorrect operation will affect their performance.

If not used, the probes should be put back onto the supports and stored.

Do not heat the probes. If they are cooler than the ambient temperature, stand them for temperature recovery before use.

Do not bend or twist the probe line; otherwise, part wires in the probe line may be broken.

Use authorized ultrasonic coupling agents only. Unauthorized lubricant or lotions, mineral oil in particular, will finally damage the probe and the probe line.

The coupling agent can only be applied to the probe head and should be wipe away after used.

Put the probe in a box for long-time storage.

Chapter 3 Operation Preparations

ÂWARNING**Â**

Check the main unit and its accessories carefully before operating the system. Replacement should be taken if there is any evident defectiveness or aging symptom which may impair the safety or performance. Make sure that the system is in proper working condition.

3.1 System appearance



Figure 3-1 System appearance

3.2 Check before power on the system

Confirm whether the power line is properly connected.

Connect the probe to the system before starting the system. Installation or dismantlement of the probe must be implemented under the situation of power off.



u If there is no probe or the probe is not properly connected to the system, the system will

display error during its self-check when it is powered on. Please turn off the system and connect the probe properly.

u The system shall be far from generator, X-ray system, broadcasting station or transmission line so as to avoid electromagnetic interference during scanning process. Otherwise, abnormal image will be incurred. We suggest adopting independent circuit and safe ground lead for ultrasonic diagnostic system system. The image quality will be poor or abnormal when the system adopts the same power supply with other electrical or electronic systems.

MARNI NG

In hospital, both physicians and patients may get hazardous and uncontrollable compensating current which is formed owing to the potential difference between the connecting system in ward and conducting parts that are easily to be touched. The safest solution is to adopt continuous equipotential connection. The system should be connected to the power grid in the hospital with equipotential connections.

3.3 Power on the system

Push power button on the left-top of keyboard.

After system preheating and software self-check, the main interface will display and the system is ready for work.



Since the system is equipped with Windows XP platform, system preheating and software self-check will take about 3-5 minutes. Please wait with patience.

3.4 Power off the system

To shutdown the system, power button on the left-top of keyboard, the system software will exit and implement the shutdown operation.



Since the system is equipped with Windows XP platform, it takes about 1-2 minutes for software self-check while shutting down. Please wait with patience.

Chapter 4 Operation Procedures

4.1 Description of operation control panel



Figure 4-1 Schematic diagram of operation control panel

4.1.1 Functional keyboard

1) B mode



- 1. Enabled under unfreezing state.
- 2. Switch sweep mode to B mode.
- 2) CF mode



- 1. Enabled under unfreezing state.
- 2. Switch sweep mode to mode of Color Doppler Blood Flow.

3) PW mode



- 1. Enabled under unfreezing state.
- 2. Switch sweep mode to Pulse Doppler mode.

4) M mode



- 1. Enabled under unfreezing state.
- 2. Switch sweep mode to M mode.

5) 2B mode



- 1. Enabled under unfreezing state.
- 2. Switch sweep mode to 2B mode.

6) 4B mode



Press twice times.

- 1. Enabled under unfreezing state.
- 2. Switch sweep mode to 4B mode.

7) PDI mode



- 1. Enabled under unfreezing state.
- 2. Switch sweep mode to Energy Doppler mode.

8) 3D mode (optional)



- 1. Enabled under unfreezing state.
- 2. Switch sweep mode to 3D mode.

This function is optional and the function key is disabled on some machine types.

9) Indication key



- 1. Enabled under freeze state.
- 2. Mark indicating arrow on screen.
- 3. Select the direction of arrow through rotating multifunctional encoder 6.
- 4. Determine marking position through trackball.
- 5. Determine marking through confirmation key.

10) Deletion key



1. Enabled under freeze state.

- 2. Delete the measure result on screen.
- 3. Delete previous measure result for single press.
- 4. For continuously twice rapid presses, the screen will prompt whether to delete all displayed results on the screen or not. Select "OK", all the measure results, indicating arrows and character notes on the screen will be deleted.

11) Body mark key



- 1. Enabled under freeze state.
- 2. Body mark at right lower corner in sweep area on the screen.
- 3. Select different body markers through rotating multifunctional encoder 6.

12) Measurement key



- 1. Enabled under freeze state.
- 2. Press to enter simple measurement mode; press measurement key for several times to select the measurement modes circularly, including distance, ellipse and track etc..
- 3. Measurement marker displays in image area on screen, which can be used to implement distance, ellipse, track and other relevant simple measurements through coordination of trackball, confirmation key and multifunctional encoder 6; measurement result displays at the right upper corner of image display area.
- 4. During measurement process, it's available to reposition the position of measurement point at the other end by pressing the measurement key.
- 5. During ellipse measurement, the length of short axis is regulated through multifunctional encoder 6 in order to determine the size of ellipse.
- 6. During track measurement, it's available to delete the measurement track points one by one through deletion key.
- 7. Meanwhile, the menu of measurement software package applicative under current mode is displayed at right side of the screen. It's available to select corresponding measurement items for measurement through multifunctional encoder 1, trackball or

confirmation key.

- 8. Rotate multifunctional encoder 1 to select corresponding measurement items; press multifunctional encoder 1 to open measurement folder menu/select corresponding measurement functions.
- 9. Or, select corresponding measurement items through trackball; press confirmation key to open measurement folder menu/select corresponding measurement functions.

13) Notation key



- 1. Enabled under freeze state.
- 2. Mark character notes on screen.
- 3. Input note characters through standard keyboard.
- 4. After input, it's available to move to marking position through trackball and determine through confirmation key.

14) Sampling key



- 1. Enabled under unfreezing state, M, CF, PW and PDI mode.
- 2. Under M Mode, press sampling key to select the left and right positions of M sampling line through trackball; determine by confirmation key.
- 3. Under CF mode, press sampling key to select the position of color sampling box/regulate the size of color sampling box through trackball; the function switching of selecting the position of color sampling box/regulating the size of color sampling box is realized through pressing the sampling key again, and the prompt column at lower part of screen will show prompt characters on current function state of trackball; determine by confirmation key.
- 4. Under PW mode, press sampling key to select the sampling position of pulse Doppler

through trackball; determine by confirmation key.

5. Under PDI mode, press sampling area key to select the position of energy sampling box/regulate the size of energy sampling box through trackball; the function switching of selecting the position of energy sampling box/regulating the size of energy sampling box is realized through pressing the sampling area key again, and the prompt column at lower part of screen will show prompt characters on current function state of trackball; determine by confirmation key.

15) Confirmation key



- 1. Under freeze/unfreezing state, enabled when coordinating with other function keys to confirm the functional operation.
- 2. Press confirmation key to determine corresponding functional operations.

16) Leftward/rightward overturning key



- 1. Enabled under freeze/unfreezing state.
- 2. Realize the leftward/rightward overturning function of image.

17) System setup key



- 1. Enabled under freeze state.
- 2. Press system setup key to implement corresponding system setup (setup of name of hospital, operating doctor, name of instrument, measure formula of obstetric department and software upgrade etc.).

18) Report key



- 1. Enabled under freeze state.
- 2. Press report key to enter report system to implement corresponding report edition, print, saving and other operations.

19) Probe switching key



- 1. Enabled under freeze/unfreezing state.
- 2. Press probe switching key to select the probe needed or select corresponding department application in the meantime.

4.1.2 Probe selection

When there are more than one probes are connected with the system, desired probe can be selected according to clinical purpose by pressing "Probe" key as in Figure 4-2. choose the desired probe then press "OK" to confirm.

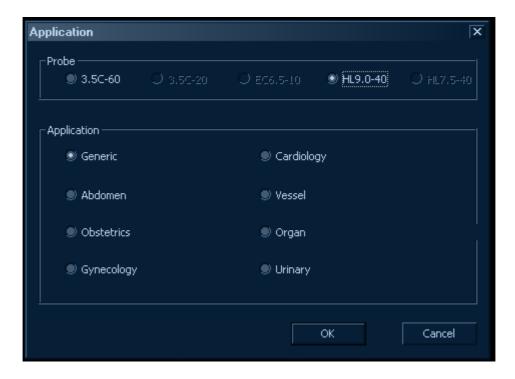


Figure 4-2 Probe selection



- u The system will take several seconds to change the probe. Please wait with patience.
- u If there is no probe or the probe is not properly connected to the system, the system will display error during its self-check when it is powered on. Please turn off the system and

connect the probe properly.

⚠WARNING**⚠**

Installation or dismantlement of the probe must be implemented under the situation of power off, otherwise the probe or system will be damaged.

4.2 Description to screen interface

After preheating and software self-check, the system will turn to main interface A as Figure 4-3. turn the encoder, choose color flow mode, press the encoder to confirm the system will turn to main interface B as Figure 4-4. Definition and function description of each part is listed in Table 4-3.



Figure 4-3 Main screen interface A



Figure 4-4 Main screen interface B

Part No.	Definition	Function Description
1	Top information display column	Display information of name of hospital, operating doctor, time and date
2	Top information display column 2	Display information of patient's name and number of medical record
3	Top information display column 3	Display the output parameter of power supply
4	Top information display column	Display the model information of current used probe

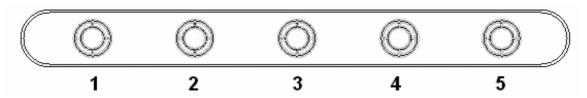
	T	
5	Submenu of measure software	Display the measure software package applicative under current mode, it's available to select corresponding measure items for measurement through multifunctional encoder 1, trackball or confirmation key (refer to 4.1.1 Functional Keyboard)
6	Display area of measure result	Display measure result under freeze state
7	Image and measure area	Display ultrasonic image under current mode; measure area under freeze state
8	TGC, scale area	Display TGC curve, current ultrasonic image scale and number and position of focus
9	Imaging parameter area	Display the imaging parameters under current mode and available to display respectively current imaging parameters under B, M, CF, PW and PDI Mode
10	Preview area of saved image	Display current saved image
11	Display area of current state	Display current operation state; display under unfreezing state as per current operation mode: B mode, 2B mode, 4B mode, M mode, CF mode, PW mode or PDI mode; display under freeze state as per current operation state: Cine, Measurement
12	Multifunctional encoder prompt	Display the operation function items corresponding to multifunctional encoder 1-5 under current state, refer to the description in Chapter 4.3
13	Display of video frame number	Display total frame number of film video and frame number information of current image
14	Grey/color strip	Display information of screen gray scale and color strip
15	Color sampling box	Display the position of parameter sampling box
16	Position marker of probe	Display the position relationship between ultrasonic image and probe

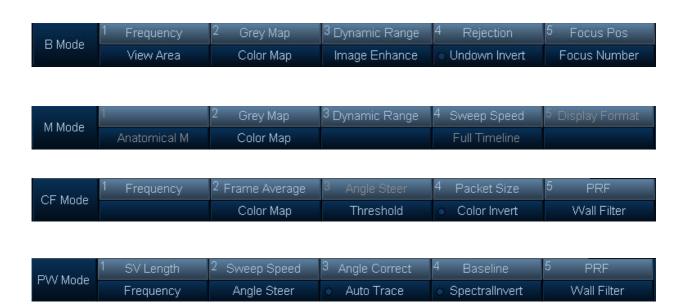
17	Subfunction menu	Display subfunction menu under current mode, regulate corresponding subfunction parameters. Refer to the description in Chapter 4.4
18	Position marking area	Display the position marker of current human body in examination
19	Prompt column of operation guidance	Prompt current operation method and give function guidance

Table 4-2 Definition and function description

4.3 Introduction on multifunctional encoder

- I The positions of multifunctional encoder 1-5 corresponding to operation panel can be referred in Figure 4-5.
- I The correspondence between multifunctional encoder 1-5 and screen display area 12 (prompt column of multifunctional encoder) is shown in Figure 4-5.





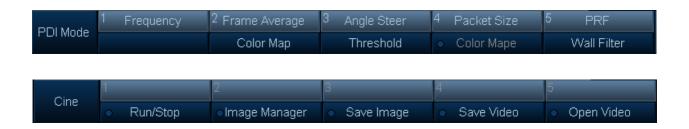


Figure 4-5 Multifunctional encoder 1-5 and function prompt column

It's available to select corresponding different functional operation items as per the prompt column of multifunctional encoder after pressing multifunction encoder 1-5; the enabled function at present is displayed in highlighted light blue in prompt column of multifunctional encoder on screen and the dark blue means disabled function that can be activated by pressing corresponding encoder, just as shown in Figure 4-6.



Figure 4-6 Press multifunctional encoder 1-5 to select different functional operations

It's available to regulate corresponding different function parameters as per the display in prompt column of multifunctional encoder by rotating multifunctional encoder 1-5; there is an arc progress bar above prompt column during regulation, which displays the regulation value of current parameter, just as shown in Figure 4-7.

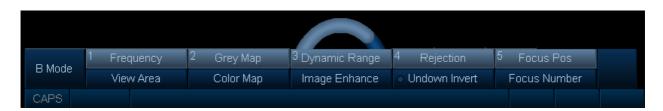


Figure 4-7 Rotate multifunctional encoder 1-5 to regulate function parameter



- When multifunctional encoder is rotated for regulation, the regulation increases or decreases at a unit value; but, when the encoder is rotated continuously, the regulation value will automatically speed up and will increase or decrease at the value larger than unit value, thereby, operator can get needed parameter value through few regulation operations.
- u The operation of function parameter displayed in prompt column of multifunctional encoder is different under different operation modes; under unfreezing state, if the parameters of other modes have to be regulated under current mode, for example, to revise the parameter value of B Mode again under CF mode, two ways are available:

- ① Switch to B mode by pressing B Mode key and press CF mode key again to return to CF mode after regulating relevant parameter value of B mode to be revised through multifunctional encoder 1-5.
- ② Switch sub-menu and prompt column of multifunctional encoder to the mode parameter to be regulated for corresponding parameter regulation through sub-menu, refer to the description in Chapter 4.4 (for such way, current operation mode maintains).

4.4 Introduction on sub-menu

- The position of submenu key corresponding to operation panel can be referred to in Figure 4-1.
- I The key of sub-menu and the sub-menu under different modes are shown in Figure 4-8.

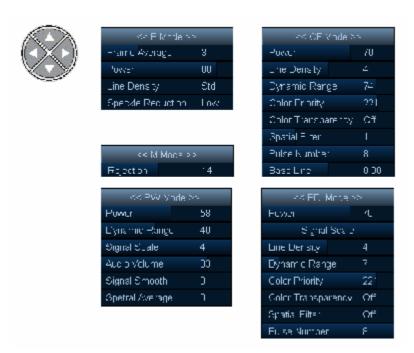


Figure 4-8 Key of sub-menu and sub-menu under different modes

- I The submenu key is enabled under unfreezing state.
- Under unfreezing state, it's available to activate sub-menu by pressing any one of upward, downward, leftward rightward keys on submenu key and the sub-menu of current mode is displayed in default way (the sub-menu under different operation modes is different).

- It's available to select corresponding parameter regulation items through the upward and downward keys on submenu key; the enabled function parameter at present is displayed in highlighted light blue in sub-menu and dark blue means disabled parameters.
- I It's available to regulate current enabled parameters through leftward and rightward keys on submenu key. Current parameter regulation value is displayed in progress bar and characters during regulation.
- I The sub-menu is different under different operation modes. When sub-menu is called, it's defaulted as the operation parameters of current mode; if the parameters of other modes have to be regulated, it's available to select mode item through upward and downward keys and then select the mode for the parameters to be regulated through leftward and rightward keys. The subsequent parameter regulation operation is the same to aforementioned way.

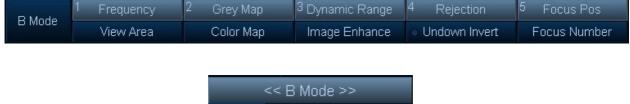
(I)NOTE(I)

When switching parameter regulation mode through sub-menu (B, M, CF, PW and PDI mode), the mode of parameter operation displayed in prompt column of multifunctional encoder at lower part of screen is switched at the same time; at this moment, if necessary, it's available to regulate relevant parameters through multifunctional encoder 1-5. Refer to the description in Chapter 43.

Chapter 5 Operation Instruction on B Mode

5.1 Introduction on B mode

- I Usage: B mode displays the anatomical structure of soft tissue through two-dimensional image for diagnostic analysis and measure.
- I The default mode after start is B Mode. When returning to B Mode from other modes, the B mode key shall be pressed for entry.
- I The prompt column of multifunctional encoder and sub-menu of B mode are shown in Figure 5-1.



<< B Mode >>
Frame Average 3
Power 88
Line Density Std
Speckle Reduction Low

Figure 5-1 Prompt column of multifunctional encoder and sub-menu of B mode

5.2 Operation under B mode

5.2.1 Gain

Adjustment of gain in B mode makes total gain of two-dimensional gray image increase or decrease, thus obtaining brighter or darker image.

Under thawed state, gain value can be adjusted by total gain adjusting shuttle (see table 4-1).

Gain value changes in accordance with probe, but it has nothing to do with precise position of total gain adjusting shuttle.

B Mode gain has nothing to do with CF mode, PW mode, mode PDI gain, and the gains under these modes all can be controlled independently, but do not interact. The gain on screen shall be displayed in Gn (dB), when rotating total gain adjusting shuttle, gain value will be increased or decreased in an unit of 1dB; but when continuously rotating shuttle, adjusting value will be accelerated in an automatic manner, it will also be increased or decreased in an unit of more than 1dB, in this way, it is facilitating operators to obtain required gain value by less adjusting operation.

Gain value will return to the default gain value when probe, etc are changed.

In combination with TGC control, gain value can obtain suitable image effect.

5.2.2 Depth

Regulate the image depth under B mode, control the depth of anatomical structure imaging under B mode; please increase depth to display the structure with deeper distance; the depth can be reduced if most display parts are at the bottom and the image at such position is not concerned.

The image depth under B mode is regulated through multifunctional encoder 6 under unfreezing state (refer to Table 4-1).

The range of depth regulation is relevant with probe and the depth is displayed in D (cm) on screen

The depth regulation will affect the frame frequency of image. Generally, the larger the depth range is, the lower the frame frequency is.

5.2.3 Frequency

The system adopts wide-frequency probe technology and it's available to regulate the frequency of B mode as per application needs to get proper two-dimensional grey image.

The frequency of B Mode is regulated through multifunctional encoder 1 under unfreezing state (refer to Table 4-1). The regulation way can be referred in the description in Chapter 4.3.

The regulation range of frequency of B Mode is relevant with probe and the frequency is displayed in Freq (MHz) on screen.

The frequency regulation of B mode will affect the penetrability and resolution of image. Generally, the higher the frequency is, the poorer the penetrability is and the higher the resolution is.

5.2.4 View area

It's available to regulate the view area as per application needs to get proper image observation range.

The view area is regulated through multifunctional encoder I under unfreezing state (refer to

Table 4-1). The regulation way can be referred in the description in Chapter 4.3.

The regulation range of view area is relevant with probe and the regulation changes the transverse observation range of image on screen.

The regulation of view area will affect the frame frequency of image. Generally, the larger the view area value is, the lower the frame frequency is.

5.2.5 Grey map

It's available to regulate the grey map as per application needs to get the image with proper gray scale.

The grey map is regulated through multifunctional encoder 2 under unfreezing state (refer to Table 4-1). The regulation way can be referred in the description in **Chapter 4.3**,

Select different grey maps to change the display effect of image gray scale on screen,

5.2.6 Color map

The color map function colorizes the traditional grey image or Doppler frequency spectrum of B mode and M mode to strengthen user's ability to identify the image or Doppler frequency spectrum of B mode and M mode. Color map is not the Doppler Color mode.

The effect of color map can be regulated as per application needs to get the image suitable for identification.

The effect of color map is regulated through multifunctional encoder 2 under unfreezing state (refer to Table 4-1). The regulation way can be referred in the description of Chapter 4.3.

Select different effects of color map to change the color display effect of image on screen; meanwhile, the grey bar changes correspondingly as well.

5.2.7 Dynamic range

The dynamic range controls how does echo intensity change to grey gradient. The regulation of dynamic range is helpful to optimize the tissue texture of different anatomical structures.

It's available to regulate the dynamic range as per application needs to get proper grey image.

The dynamic range value is regulated through multifunctional encoder 3 under unfreezing state (refer to Table 4-1). The regulation way can be referred in the description in Chapter 4.3.

Select different dynamic range values to change the display effect of image gray scale; the dynamic range is displayed in DR (dB) on screen.

5.2.8 Image enhance

The image enhance reveals tiny difference and edge of tissue structure through enhancing gray scale difference corresponding to the edge of anatomical structure so as to highlight the vessel or organ.

It's available to regulate the enhance value as per application needs to get distinct edge image.

The enhance value is regulated through multifunctional encoder 3 under unfreezing state (refer to Table 4-1). The regulation way can be referred in the description in Chapter 4.3.

Select different enhance values to change the display effect of image edge on screen.

5.2.9 Rejection

The rejection function eliminates the low-level echo caused by noise through rejecting the echo signal with low amplitude so as to reduce the influence of noise on ultrasonic image.

The rejection value can be regulated as per application needs to get the image with fewer noises.

The rejection value is regulated through multifunctional encoder 4 under unfreezing state (refer to Table 4-1). The regulation way can be referred in the description in Chapter 4.3.

Select different rejection values to change the display effect of low-level echo of image on screen.

5.2.10 Up/Down invertion

The Up/Down invertion function obtains the ultrasonic image in line with actual anatomical position during the sweep examination via vagina or rectum through vertically inverting the image.

The Up/Down invertion function can regulate the up and down position of image as per the application needs of different probes.

The Up/Down invertion function is regulated through multifunctional encoder 4 under unfreezing state (refer to Table 4-1). The regulation way can be referred in the description in Chapter 4.3.

(I)NOTE(I):

When observing the inverted image, please notice the marking direction of probe to avoid the confusion between the direction of view image and the direction of actual anatomical tissue.

5.2.11 Focus pos & number

To increase focus number and regulate the position of focus area can strengthen the sweep to assigned area, enhance the resolution of assigned area and obtain distinct image of the area you're interested in.

The focus number and position of focus area can be regulated as per application needs so as to obtain the distinct image of assigned area.

The focus number and position are regulated through multifunctional encoder 5 under unfreezing state (refer to Table 4-1). The regulation way can be referred in the description in Chapter 4.3.

The focus position is marked with triangular symbol at screen scale; the focus number is marked with the number of triangular symbol at screen scale with maximum number being 4; when the number of triangular marker is 0, the focus is set as automatic dynamic focusing.

The regulation of focus number will affect the frame frequency of image. Generally, the larger the focus number is, the lower the frame frequency is.

5.2.12 Frame average

The frame average treatment implements filtering treatment to multi-frame image in time area and reduces the speckle noise so as to obtain more smooth and mild image.

The frame average value is regulated through submenu key (refer to Table 4-1). The regulation way can be referred in the description in Chapter 4.4.

The regulation of frame average treatment will affect the instantaneity of image. Generally, the stronger the frame average treatment is, the poorer the instantaneity is.

5.2.13 Acoustic power

The acoustic power regulation changes the acoustic power output of the system so as to regulate the strength of two-dimensional grey image of B mode.

The regulation of acoustic power shall comply with ALARA (As Low As Reasonably Achievable) principle.

The acoustic power of B mode has no relationship with that of CF, PW and PDI mode, under which the acoustic power can be controlled independently without mutual influence.

The value of acoustic power is regulated through submenu key (refer to Table 4-1). The regulation way can be referred in the description in Chapter 4.4.

The acoustic power is displayed in percentage in submenu on screen.

5.2.14 Line density

The regulation of line density changes the transverse line density of two-dimensional image of B Mode so as to balance the transverse spatial resolution and frame frequency and obtain proper optimal image.

The line density is regulated through submenu key (refer to Table 4-1). The regulation way can be referred in the description in Chapter 4.4.

The line density value is displayed in submenu on screen in two grades, namely standard (Std) and high density (High).

The regulation of line density will affect the frame frequency of image. Generally, the higher the line density is, the lower the frame frequency is.

5.2.15 Speckle reduction

The speckle reduction function reduces the speckle noise of two-dimensional image of B Mode through spatial filtering treatment to obtain smoother image.

The speckle reduction is regulated through submenu key (refer to Table 4-1). The regulation way can be referred in the description in Chapter 4.4.

The speckle reduction value is displayed in submenu on screen in three grades, namely low (Low), medium (Med) and high (High).

The regulation of speckle reduction will affect the image details. Generally, the higher the speckle reduction value is, the larger the damage to image details.

5.3 Operation under 2B mode and 4B mode

The 2B mode and 4B mode display 2 or 4 frames B images on screen, which is convenient for operators to observe multi images at the same time and for image comparison. The usage is basically same to B mode.

Press 2B mode key to enter 2B mode; press 4B mode key to enter 4B mode.

The operations under 2B mode and 4B mode are the same to that of B mode.

Under 2B mode, press 2B mode key to switch active image windows between the 2 B images.

Under 4B mode, press 4B mode key to switch active image windows between the 4 B images.

Chapter 6 Operation Instruction on M Mode

6.1 Introduction on M mode

Usage: M mode observes the movement image of tissue under ultrasound through displaying the tissue displacement (movement) of signal vector within a period; it's generally used to observe the movement of heart.

Press M mode key to enter M Mode; M Mode is used in combination with B mode and the orientation of sampling line of M mode is displayed on the image of B mode.

The prompt column of multifunctional encoder and sub-menu of M mode are shown in Figure 6-1.

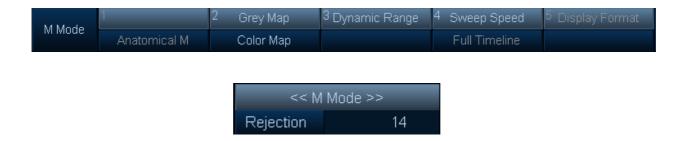


Figure 6-1 Prompt column of multifunctional encoder and sub-menu of M mode

6.2 Operation under M mode

6.2.1 Sampling line of M mode

The sampling line of M mode determines the position of single vector displayed in M Mode on B image so as to observe the movement image of the position on M image.

In actual application, put the sampling line (interested movement area) of M mode close to the center of the image of B mode as far as possible so as to obtain better M image.

Under unfreezing state, the sampling line of M Mode is regulated through sampling area key, confirmation key and trackball (refer to Table 4-2); when regulating, firstly press sampling area key to activate sampling line regulation, then move the trackball leftward and rightward and move the sampling line to the needed position, finally press confirmation key to exit the regulation.

The sampling line of M mode is displayed on B image in dashed line on screen.

6.2.2 Depth

Regulate the image depth under M Mode, control the depth of anatomical structure imaging under M mode; please increase depth to display the structure with deeper distance; the depth can be reduced if most display parts are at the bottom and the image at such position is not concerned.

The image depth under M mode is regulated through multifunctional encoder 6 under unfreezing state (refer to Table 4-1).

The range of depth regulation is relevant with probe and the depth is displayed in D (cm) on screen

The depth regulation will affect the frame frequency of image and frequency of M mode. Generally, the larger the depth range is, the lower the frame frequency and frequency of M mode (Hz) are.

6.2.3 Grey map

It's available to regulate the grey map as per application needs to get the image with proper gray scale.

The grey map is regulated through multifunctional encoder 2 under unfreezing state (refer to Table 4-1). The regulation way can be referred in the description in Chapter 4.3.

Select different grey maps to change the display effect of image gray scale on screen.

6.2.4 Color map

The color map function colorizes the traditional grey image or Doppler frequency spectrum of B Mode and M mode to strengthen user's ability to identify the image or Doppler frequency spectrum of B mode and M mode. Color map is not the Doppler Color mode.

The effect of color map can be regulated as per application needs to get the image suitable for identification.

The effect of color map is regulated through multifunctional encoder 2 under unfreezing state (refer to Table 4-1). The regulation way can be referred in the description of Chapter 4.3.

Select different effects of color map to change the color display effect of image on screen; meanwhile, the grey bar changes correspondingly as well.

6.2.5 Dynamic range

The dynamic range controls how does echo intensity change to grey gradient. The regulation of dynamic range is helpful to optimize the tissue texture of different anatomical structures.

It's available to regulate the dynamic range as per application needs to get proper grey image.

The dynamic range value is regulated through multifunctional encoder 3 under unfreezing state (refer to Table 4-1). The regulation way can be referred in the description in Chapter 4.3.

Select different dynamic range values to change the display effect of image gray scale; the dynamic range is displayed in DR (dB) on screen.

6.2.6 Sweep speed

The sweep speed is used to observe more or fewer movement events on screen through changing the density of sampling line within unit time and controlling the timeline of M image.

The sweep speed value is regulated through multifunctional encoder 4 under unfreezing state (refer to Table 4-1). The regulation way can be referred in the description in Chapter 4.3.

Select different sweep speed values to change the timeline of M image. The sweep speed is displayed in the scale of X axis of M image on screen (unit: s).

The different sweep speed values will affect the frequency of M image and are displayed in M Freq (Hz) on screen. Generally, the higher the sweep speed is, the higher the frequency of M image is.

6.2.7 Rejection

The rejection function eliminates the low-level echo caused by noise through rejecting the echo signal with low amplitude so as to reduce the influence of noise on ultrasonic image.

The rejection value can be regulated as per application needs to get the image with fewer noises.

The rejection value is regulated through submenu key under unfreezing state (refer to Table 4-1). The regulation way can be referred in the description in Chapter 4.4.

Select different rejection values to change the display effect of low-level echo of image on screen.

The rejection of M mode is independent to that of B Mode and the regulations have no influence on each other.

Chapter 7 Operation Instruction on CF/PDI Mode

7.1 Introduction on CF mode

Usage: Color Blood Flow (CF) mode increases color code qualitative information related to relative speed and direction of tissue movement in the image of B mode through ultrasonic Doppler effect so as to mark the movement situation of anatomical tissue in the image of B mode.

Press CF mode key to enter CF mode.

The prompt column of multifunctional encoder and sub-menu of CF mode are shown in Figure 7-1.





Figure 7-1 Prompt column of multifunctional encoder and sub-menu of CF mode

7.2 Introduction on PDI mode

Usage: Energy Doppler (PDI) mode is a kind of blood flow imaging mode, which is used to reflect the ultrasonic Doppler signal strength of movement tissue, but not the frequency shift of signal; under PDI mode, the system classifies color blood flow through the number of movable reflector without consideration of movement speed. Therefore, there is hardly confusion phenomenon

Under CF mode, press PDI mode key to enter PDI mode.

The prompt column of multifunctional encoder and sub-menu of PDI mode are shown in Figure 7-2.

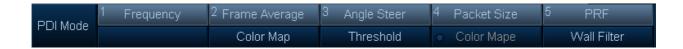




Figure 7-2 Prompt column of multifunctional encoder and sub-menu of PDI mode

7.3 Operation under CF/PDI mode

7.3.1 Sampling box of CF/PDI mode

The sampling box of CF/PDI mode determines the position and size of color Doppler image displayed under CF/PDI mode on B image.

Under unfreezing state, the sampling box of CF/PDI mode is regulated through sampling area key, confirmation key and trackball (refer to Table 4-2); during regulation, firstly press sampling area key to activate sampling box regulation and then select the position of color sampling box/regulate the size of color sampling box through trackball; the function of selecting the position of color sampling box/regulating the size of color sampling box can be realized through pressing sampling area key again and the prompt characters on function state of current trackball will be displayed in prompt column at lower part of screen; determine through confirmation key.

The sampling box of CF/PDI mode is displayed on B image in dashed line on screen.

7.3.2 Gain

The regulation of gain of CF/PDI mode magnifies or decreases the overall intensity of echo treated in color blood flow window so as to obtain ideal color image.

The gain value is regulated through general gain regulation encoder under unfreezing state (refer to Table 4-1).

The gain values change with the probe and have no relationship with the precise position of general gain regulation encoder.

The gain of CF/PDI mode is irrelevant with that of B mode and PW mode, under which the gains can be controlled independently without mutual influence.

The gain is displayed in Gn (dB) on screen. The gain value will increase or decrease with 1dB as unit when rotating general gain regulation encoder; but, when the encoder is rotated continuously, the regulation value will automatically speed up and will increase or decrease with the unit larger than 1dB, thereby, operator can get needed gain value through few regulation operations.

The gain value will return to the default value during changing probe and other operations.

7.3.3 Frequency

To change the frequency of CF/PDI mode so as to adapt to the observation demands of the tissue with different movement speeds. Generally, the frequency of CF/PDI mode shall be enhanced when observing the low-speed blood flow.

The frequency of CF/PDI mode is regulated through multifunctional encoder 1 under unfreezing state (refer to Table 4-1). The regulation way can be referred in the description in Chapter 4.3.

The regulation range of the frequency of CF/PDI mode is relevant with probe and the frequency is displayed in CF/PDI Freq(MHz) on screen; meanwhile, the speed value represented by color strip on screen will change correspondingly when the frequency of CF/PDI mode changes.

7.3.4 Frame average

The frame average treatment of CF/PDI mode implements filtering treatment to multi-frame color image in time area and reduces the speckle noise so as to obtain more smooth and mild image.

The frame average value is regulated through multifunctional encoder 2 (refer to Table 4-1). The regulation way can be referred in the description in Chapter 4.3.

The higher frame average value makes the display time of color image longer, which strengthens the visibility of fluid.

The regulation of frame average treatment will affect the instantaneity of image. Generally, the stronger the frame average treatment is, the poorer the instantaneity is.

7.3.5 Color map

Generally, the movement direction of color blood flow map is defined as red toward the direction of probe and blue deviating from the direction of probe (red getting close and blue deviating).

The selection of color map allows operators to mark the movement direction and speed with special colors so as to strengthen the ability to identify color image.

The selection of color map is regulated through multifunctional encoder 2 under unfreezing state (refer to Table 4-1). The regulation way can be referred in the description in Chapter 4.3.

Select different color maps to change the color display effect of Doppler blood flow on screen; meanwhile, the color strip will change corresponding as well.

7.3.6 Angle steer

The angle steer function enables operators to meet the angle requirement needed by ultrasonic Doppler effect without moving the probe through steering the color sampling box leftward and rightward in order to obtain the needed information of movement tissue.

The angle steer function is only suitable for linear-array probe and applied for imaging of peripheral vessels.

The angle steer is regulated through multifunctional encoder 3 (refer to Table 4-1). The regulation way can be referred in the description in Chapter 4.3.

The angel steer function can steer leftward (15°), to middle (0°) or rightward (15°).

7.3.7 Threshold

The threshold distributes the grade of gray scale range at the stop position of color information so as to select more color images or more grey images of B mode.

The threshold is regulated through multifunctional encoder 3 (refer to Table 4-1). The regulation way can be referred in the description in Chapter 4.3.

The threshold restricts the low-level echo in inner wall of vessel covered by color blood flow, which is helpful to reduce the color overflow of vessel wall.

7.3.8 Packet size

The packet size controls the sampling number of single color blood flow vector so as to enhance or reduce the color sensitivity and color average precise, balance the quality and

frame frequency of color image and obtain proper optimal image.

The packet size is regulated through multifunctional encoder 4 (refer to Table 4-1). The regulation way can be referred in the description in Chapter 4.3.

The value of packet size affects the quality and frame frequency of color image. Generally, the magnification of the size of sampling packet will enhance the quality of color image, but reduce frame frequency.

7.3.9 Color invertion

Generally, the movement direction of color blood flow map is defined as red toward the direction of probe and blue deviating from the direction of probe (red getting close and blue deviating).

The color invertion function observes the blood flow movement in another angle, such as red deviation (negative speed) and blue getting close (positive speed) in order to allow the operator to observe the color image of blood flow in preferring way.

The color invertion is regulated through multifunctional encoder 4 (refer to Table 4-1). The regulation way can be referred in the description in Chapter 4.3.

7.3.10 PRF

To change the PRF of CF/PDI mode so as to adapt to the observation demands of the tissue with different movement speeds. Generally, the PRF has to be enhanced when observing the high-speed blood flow in order to avoid confusion.

The PRF is regulated through multifunctional encoder 5 (refer to Table 4-1). The regulation way can be referred in the description in Chapter 4.3.

The regulation range of PRF is relevant with probe and the PRF is displayed in PRF(kHz) on screen; meanwhile, the speed value represented by color strip on screen will change correspondingly when PRF changes.

7.3.11 Wall filter

The wall filter conceals useless movement through filtering the low-speed color signal so as to eliminate the color artifact caused by breath or other activities of patients and obtain distinct and effective color image.

The wall filter is regulated through multifunctional encoder 5 (refer to Table 4-1). The regulation way can be referred in the description in Chapter 4.3.

The wall filter value is displayed in WF on screen.

7.3.12 Acoustic power

The acoustic power regulation changes the acoustic power output of the system so as to regulate the strength of color image of CF/PDI mode.

The regulation of acoustic power shall comply with ALARA (As Low As Reasonably Achievable) principle.

The acoustic power of CF/PDI Mode has no relationship with that of B/PW mode, under which the acoustic power can be controlled independently without mutual influence.

The value of acoustic power is regulated through submenu key (refer to Table 4-1). The regulation way can be referred in the description in Chapter 4.4.

The acoustic power is displayed in percentage in submenu on screen.

7.3.13 Line density

The regulation of line density of color blood flow changes the transverse line density of color image of CF/PDI mode so as to balance the transverse spatial resolution and frame frequency and obtain proper optimal image.

The line density of color blood flow is regulated through submenu key (refer to Table 4-1). The regulation way can be referred in the description in Chapter 4.4.

The line density value of color blood flow is displayed in submenu on screen in seven grades from 1-7.

The regulation of line density of color blood flow will affect the frame frequency of image. Generally, the higher the line density is, the lower the frame frequency is.

7.3.14 Color transparency

The regulation of color transparency changes the transparency of color image of CF/PDI Mode so as to permeate the color image to observe the tissue structure behind color.

The color transparency is regulated through submenu key (refer to Table 4-1). The regulation way can be referred in the description in Chapter 4.4.

The regulation value of color transparency is displayed in submenu on screen in ten grades, namely Off and Grade 0.1-0.9.

7.3.15 Spatial filter

The regulation of spatial filter implements filtering treatment to color image on two-dimensional plane, which makes image pixel reduce and makes the color image more smooth. The spatial filter is regulated through submenu key (refer to Table 4-1). The regulation way can be referred in the description in Chapter 4.4.

The regulation value of spatial filter is displayed in submenu on screen in five grades, namely Off and Grade 1-4.

7.3.16 Base line

The base line regulates the positions of color confusion points (i.e. red and blue) to hold higher speed ratio of the blood flow of a direction.

The default base line is midpoint displayed in color and is displayed in central position of color strip on screen.

The zero speed ratio is corresponding to the base line and the overall PRF range maintains.

The position of base line is regulated through submenu key (refer to Table 4-1). The regulation way can be referred in the description in Chapter 4.4.

The regulation value of the position of base line is displayed in submenu on screen.

Chapter 8 Operation Instruction on PW Mode

8.1 Introduction to PW mode

Usage: under Pulse Doppler (PW) mode, energy is sent to the body of patient from ultrasonic probe and the received ultrasonic echo after treatment draws the difference between sending and receiving signal frequencies (the difference is incurred by movable objects in the route passed by ultrasonic signal, such as the movement of blood flow) so as to provide the measure data on movement tissue and fluid speed to make the operator observe the blood flow data selectively in sampling volume area; PW Mode is applied to display the information of direction, speed ratio and frequency spectrum of blood flow in selected anatomical area.

Under PW mode, signal result is taken on in sound through the speaker of system and is displayed in graph on screen in the meantime; the X axis in the figure means timeline and Y axis means the change of frequency that is expressed in speed ratio of positive direction and negative direction.

Press PW mode key to enter PW mode; PW mode is used in combination with B mode and the orientation of SV of PW mode is displayed on the image of B mode.

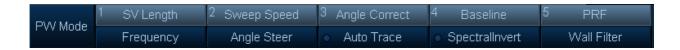
PW mode can operate with CF mode at the same time. It's available to enter three modes (B mode, PW mode and CF mode) after pressing CF mode key and PW mode key.

The time zero of frequency spectrogram of PW mode (track start) takes on left of the graph and moves rightward with time lapse.

The base line of frequency spectrogram of PW mode (represent zero speed ratio, no frequency spectrum change and no blood flow detected) spans the screen horizontally in solid line; by rule, the movement with direction toward probe is deemed positive and appears above the base line, and the movement with direction deviating from the probe is deemed negative and appears below the base line.

Generally, the blood flow moves unevenly and moves to different directions at different speed ratios; therefore, the displayed frequency spectrum image is combined by the frequency spectrums with different gray scale values; the strong signal is displayed as on and the weak one is displayed as grey with different gradients.

The prompt column of multifunctional encoder and sub-menu of PW mode are shown in Figure 8-1.



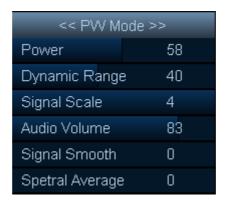


Figure 8-1 Prompt column of multifunctional encoder and sub-menu of PW mode

8.2 Operation under PW mode

8.2.1 Position of SV of PW mode

The SV of PW mode determines the position and length of the information of direction, speed ratio and frequency spectrum of blood flow concerned by PW mode on B image.

The SV of PW mode is oriented at assigned position of special vessel concerned by operators.

Under unfreezing state, the position of SV of PW mode is regulated through sampling area key, confirmation key and trackball (refer to Table 4-2); during regulating, firstly press sampling area key to activate sampling box regulation and then select the up, down, left and right positions of SV through trackball, finally determine by confirmation key.

The SV of PW mode is displayed on B image in dashed line on screen.

8.2.2 SV length of PW mode

The SV of PW Mode determines the position and length of the information of direction, speed ratio and frequency spectrum of blood flow concerned by PW Mode on B image.

The SV length of PW mode is regulated through multifunctional encoder 1 under unfreezing state (refer to Table 4-1). The regulation way can be referred in the description in Chapter 4.3.

The value of SV length of PW mode changes with the probe and is displayed in SV (mm) on screen.

The change of SV length of PW mode affects the precise of sampling result and Doppler sound output. Generally, the shorter the SV length is, the more exact the sampling result is owing to much sensitivity; the longer the SV length is, it's much possible to listen to Doppler sound

better (or sample large vessel or area).

The SV of PW mode is displayed on B image in dashed line on screen.

8.2.3 Gain

The regulation of gain of PW mode magnifies or decreases the intensity of frequency spectrum signal so as to obtain ideal frequency spectrum image.

The gain value is regulated through general gain regulation encoder under unfreezing state (refer to Table 4-1).

The gain values change with the probe and have no relationship with the precise position of general gain regulation encoder.

The gain of PW mode is irrelevant with that of B mode, CF mode and PDI mode, under which the gains can be controlled independently without mutual influence.

The gain is displayed in Gn (dB) on screen. The gain value will increase or decrease with 1dB as unit when rotating general gain regulation encoder; but, when the encoder is rotated continuously, the regulation value will automatically speed up and will increase or decrease with the unit larger than 1dB, thereby, operator can get needed gain value through few regulation operations.

The gain value will return to the default value during changing probe and other operations.

8.2.4 Frequency

To change the frequency of PW mode so as to adapt to the observation demands of the tissue with different movement speeds. Generally, the frequency of PW mode shall be enhanced when observing the low-speed blood flow.

The frequency of PW mode is regulated through multifunctional encoder 1 under unfreezing state (refer to Table 4-1). The regulation way can be referred in the description in Chapter 4.3.

The regulation range of the frequency of PW mode is relevant with probe and the frequency is displayed in PW Freq(MHz) on screen; meanwhile, the speed scale of Y axis of frequency spectrogram on screen changes correspondingly when the frequency of PW mode changes.

8.2.5 Sweep speed

The sweep speed controls the update speed of frequency spectrogram to observe more or fewer frequency spectrum cycles on screen.

The sweep speed value is regulated through multifunctional encoder 2 under unfreezing state (refer to Table 4-1). The regulation way can be referred in the description in Chapter 4.3.

Select different sweep speed values to change the timeline of PW frequency spectrum. The sweep speed is displayed in the scale of X axis of frequency spectrogram on screen (unit: s).

8.2.6 Angle steer

The angle steer function enables operators to meet the angle requirement needed by ultrasonic Doppler effect without moving the probe through steering SV leftward and rightward in order to obtain the needed information of movement tissue.

The angle steer function is only suitable for linear-array probe and applied for imaging of peripheral vessels.

The angle steer is regulated through multifunctional encoder 2 (refer to Table 4-1). The regulation way can be referred in the description in Chapter 4.3.

The angel steer function can steer leftward (15°), to middle (0°) or rightward (15°).

If current mode is triple mode (B, PW and CF mode), the color sampling box of CF mode steers with the SV of PW mode at the same time.

8.2.7 Angle correct

The angle correct function estimates the speed of blood flow at the direction that forms certain angle with Doppler vector through calculating the angle between the Doppler vector and the blood flow to be measured so as to optimize the precise of the speed of blood flow.

The angle correct is regulated through multifunctional encoder 3 (refer to Table 4-1). The regulation way can be referred in the description in Chapter 4.3.

The angel correct is displayed in CA (degree) on screen. The angel value increases or decreases with 1° as unit; but, when the encoder is rotated continuously, the regulation value will automatically speed up and increase or decrease with unit larger than 1°, thereby, operators can get needed angel correct value through few regulation operations.

8.2.8 Auto trace

The auto trace function automatically calculates the maximum, minimum and average of the speed on frequency spectrogram through automatically obtaining the envelope of frequency spectrum graph, which is convenient for operator's observation.

The auto trace function is regulated through multifunctional encoder 3 (refer to Table 4-1). The regulation way can be referred in the description in Chapter 4.3.

The auto trace function marks the envelop curve of frequency spectrogram with yellow solid line on screen and automatically implements calculation with relevant results displayed in VMax, VMin and VMean (cm/s) on screen.

8.2.9 Base line

The base line (standing for zero rate, no spectrum changes and failing to detect blood flow) of PW mode spectrum graph uses sold line to step across the screen horizontally; normally, the movement moving towards probe is positive, it appears above the base line, while the movement deviating from probe is negative, which appears below the base line.

The position of base line should be adjusted by flying shuttle (see table 4-1), and see illustration in Chapter 4.3 for adjusting methods.

For adjustment of base line, under circumstance that graduation of speed scale does not change, re-install the Range of scale so as to contain faster and slower blood flow and eliminate confusion.

Base line will stop changing when the adjusting base line (any direction) reaches its maximum value, but it will not adjust circularly.

8.2.10 Spectral invertion

As spectral inversion, the spectrum graphs are vertically inverted so as to make the positive speed appear below base line, and negative speed appear above base line.

Spectral inversion should be adjusted by flying shuttle 4 (see table 4-1), and see illustration in Chapter 4.3 for adjusting methods.

When operator changes the angle of probe to adopt the anatomical structure, blood flow will be moved in the same direction, but Doppler message will invert, at the moment, spectral inversion is easier to be operated than the direction of inverting probe.

8.2.11 Pulse repetition frequency (PRF)

Change pulse recurrence frequency of PW mode to adopt the observing requirements of tissues at different moving speed, thus containing faster / slower speed of blood flow; it is needed to turn up pulse recurrence frequency in order to avoid confusing when inspecting the blood flow at a high speed.

Pulse recurrence frequency should be adjusted by multifunctional flying shuttle 5 (see table 4-1), and see illustration in Chapter 4.3 for adjusting methods.

The adjusting Range of pulse recurrence frequency is related to probe, and it can be displayed in PRF (kHz) on screen; meanwhile, if pulse recurrence frequency is changed, the speed scale of the Y-axis of spectrum graph on screen would change accordingly, moreover, if the current mode is triple mode (B, PW and CF mode), the speed value represented by the color bar in CF mode will change accordingly.

8.2.12 Wall filter

Wall filter can eliminate low level noises above and below the base line by filtering the noises caused by vasomotion in Doppler Message, so the operator will not see these unnecessary noises in spectrum graph and hear them in Doppler sound.

Wall filter should be adjusted by multifunctional flying shuttle 5 (see table 4-1), and see illustration in Chapter 4.3 for adjusting methods.

The value of wall filter is displayed by WF on screen.

8.2.13 Sound power

The adjustment of sound power changes sound power output of system, to adjust the strength of spectrum gram in PW mode.

The adjustment of sound power should comply with the principle of ALARA (As Low As Reasonably Achievable) .

Sound power in PW mode has nothing to do with B, CF or PDI mode, and all these sound powers under these modes can be controlled independently but do not affect each other.

The adjustment of sound power can be adjusted by sub-menu buttons (see table 4-1), and see illustration in Chapter 4.4 for adjusting methods.

The sound power should be displayed in percentage on screen sub-menu.

8.2.14 Dynamic range

Dynamic range of PW mode controls how to transform echo intensity into gray gradient, adjustment of dynamic range is helpful to optimize the veins and smoothness of spectrum graph.

The value of dynamic range should be adjusted by the sub-menu buttons under the unfreezing condition (see table 4-1), and see illustration in Chapter 4.4 for adjusting methods.

The dynamic range in PW mode has nothing to do with dynamic range in B mode, all they can be controlled independently but do not affect each other.

Eliminate spectrum by reducing the value of dynamic range so as to confirm whether width expansion is real, also by increasing dynamic range, spectrum can be filled.

8.2.15 Audio volume

Audio volume controls the size of audio output, so that the operator can hear moderate Doppler sound so as to evaluate the correct angle and position of probe.

Audio volume should be adjusted by the sub-menu buttons under the unfreezing condition

(see table 4.1), and see illustration in Chapter 4.4 for adjusting methods.

The value of audio volume should be displayed in percentage on screen.

8.2.16 Single smooth

Single smooth acquires smoother and softer spectrum graph by dealing with spectrum.

Single smooth should be adjusted by the sub-menu buttons under unfreezing status (see table 4-1), and see illustration in Chapter 4.4 for adjusting methods.

Chapter 9 General Measurement & Calculation

9.1 Summary

- Purpose: to provide supporting data for clinical diagnosis by measurement and calculation of distance, area, circumference, volume, surface area, ratio, slope, angle, %stenosis, time, speed, etc.
- I Measurement and calculation are carried out under "Freeze" status only. If the operator presses "Measure" key under unfreezing status, the system will pop up a window reminding "Measurement can only do under freeze mode".
- I Functional encoders related to measurement and calculation: encoder 1 for menu selection and confirmation, encoder 6 for adjustment of the size of the ellipse to be measured.
- Functional keys related to measurement and calculation: please see below Table 9-1. (Refer to Chapter 4.1 for details.)

Icon	Value	Function description	
Clear	Delete	 functional under freeze status delete measurement and calculation value in screen single press: delete previous measurement or calculation result twice continuous quick presses: the system will pop up a window if the operator wants to delete all measurement or calculation results. Choose "OK" and press "Set" key to delete all measurement and calculation results, arrows and annotations. 	
Measure	Measurement	 functional under freeze status single press: activate general measurement and calculation function multi-press: circling among measurement and calculation of distance, circumference or trace, etc when the measurement mark displays in the screen, distance, circumference or trace, etc can be measured and calculated by the combination of scrolling the trackball, turning the functional encoder 6 and pressing "Set" key. during the process of measurement and calculation, press "Measure" key to choose another starting measurement and calculation point. under ellipse measurement and calculation, turn encoder 	

		6 to adjust the ellipse size
		7. under trace measurement and calculation, press
		"Delete" key to delete the measured and calculated
		traces one by one
		8. also there is a window in the right screen displaying
		available measurement and calculation menus under
		present mode. Measurement and calculation can be also
		activated by the combination of scrolling the trackball,
		turning the functional encoder 6 and pressing "Set" key.
		9. turn encoder 1 to select related measurement and
		calculation menu, press the encoder to selected required
		measurement and calculation
		10. or scrolling the trackball to related measurement and
		calculation menu, press "Set" key to selected required
		measurement
\bigcirc	Set	1. functional key under "Freeze" mode
		2. to confirm measurement or calculation

Table 9-1 Functional keys related to measurement and calculation



- I This chapter only introduces basic operation of measurement and calculation. For detailed professional measurement and calculation for varies departments, please refer to the Instruction Manual of Advanced Application.
- I Different measurement and calculation results are highlighted with different color.
- I General measurement and calculation results display in the top left screen. Please refer to Part 6 in Figure 4-3.
- I General measurement and calculation menus display in the left screen. Please refer to Part 5 in Figure 4-3.
- I When the system is in real-time working mode, all measurement or calculation results will disappear.
- I Measurement or calculation results obtained from ultrasonic image is supplementary information for clinical diagnosis. Reliability and precision depend both on the system itself and the formula or data applied for measurement or calculation. If necessary, please read related research articles or studies to learn more information on the operation and recommended application ranges of the formula or data.

9.2 Operation

9.2.1 General measurement and calculation settings

Press "System" key, select "Measure Setting" and the system will pop up a window as Figure 9-1.

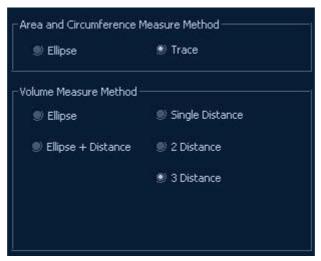


Figure 9-1 General measurement settings

- For area and circumference measurement and calculation method, either Ellipse or Trace can be set as default setting.
- For volume measurement and calculation method, Ellipse, Single Distance, Ellipse + Distance, 2 Distances or 3 Distances can be set as default setting.

9.2.2 Description on general measurement and calculation key value

- I Under freeze status, press "Measure" key to activate general measurement and calculation function. Press this key repeatedly circling among measurement and calculation of distance, circumference or trace, etc.
- I Measurement and calculation mode differs accordingly to different working mode.
- I Different measurement and calculation modes under different working mode are listed as Table 9-1.

Press	Working mode			
Measure key	B, 2B, 4B, CF, PDI	B M, M	PW	
1	Distance	Tissue Depth	Speed	
2	Ellipse, B Ellipse	Time Interval	TA MAX/MIN/MEAN	
3	Trace, B Trace	Depth Slope	Slope Time Interval	
4			Time Interval	

Table 9-2 General measurement and calculation key value

9.2.3 Description on general measurement menu

- I Under freeze status, press "Measure" key to activate general measurement and calculation function, the menu will pop up and display in the left of screen.
- I Turn encoder 1 to select related measurement and calculation menu, press the encoder to selected required measurement and calculation.
- I Or scrolling the trackball to related measurement and calculation menu, press "Set" key to selected required measurement and calculation.
- I Different measurement and calculation under different working mode are listed as Table 9-2.



Table 9-3 General measurement and calculation menu

9.3 B mode measurement & calculation

- I Under B mode, distance/circumference & area (ellipse)/circumference & area (trace) can be measured and calculated by pressing "Measure" key.
- I Under B mode, %stenosis, A/B ratio, Volume and Angle can be measured and calculated through the measurement menu.
- I 2B, 4B, CF, and PDI modes are the same measurements and calculations as B mode which is not described in this manual.

9.3.1 Distance measurement & calculation

- I Under B mode, press "Measure" key once and a window will pop up displaying "B Distance" at the left of the screen.
- I Scroll the trackball to the measurement and calculation starting point, press "Set" key to confirm.
- I Scroll the trackball to the measurement and calculation ending point, press "Set" key to confirm.
- I Measurement and calculation results will display in the window (Depth of the starting point, distance):

Dep XXX cm

Len XXX cm

(I)NOTE(I)

Press "Measure" key again any time to select desired starting point or ending point during the process of measurement and calculation.

9.3.2 Circumference & area (Ellipse) measurement & calculation

- I Under B mode, continuously press "Measure" key twice and a window will pop up displaying "B Ellipse" at the left of the screen.
- I Scroll the trackball to the measurement starting point, press "Set" key to confirm.
- I Scroll the trackball to the measurement ending point, press "Set" key to confirm.
- I Or turn encoder 6 to adjust the ellipse size. Refer to Figure 4-1 and Table 4-1.

I Measurement and calculation results will display in the window (Depth of the starting point, circumference and area):

Dep XXX cm Len XXX cm Area XXX cm²

(I)_{NOTE}(I)

Press "Measure" key again any time to select desired starting point or ending point during the process of measurement and calculation.

9.3.3 Circumference & area (Trace) measurement & calculation

- I Under B mode, continuously press "Measure" key 3 times and a window will pop up displaying "B Trace" at the left of the screen.
- I Scroll the trackball to the measurement and calculation starting point, press "Set" key to confirm.
- I Scroll the trackball to draw the measurement and calculation trace.
- I Press "Set" key and the starting trace and ending trace will be automatically connected.
- I Measurement and calculation results will display in the window (Circumference, area):

Len XXX cm Area XXX cm²

(I)NOTE(I)

- Press "Measure" key again any time to select desired starting point or ending point during the process of measurement and calculation.
- u Press "Delete" key once to delete the previous trace.

9.3.4 %stenosis measurement & calculation

Under B mode, Press "Measure" key, turn encoder 1 (refer to Figure 4-1 and Table 4-1) or scroll the trackball, highlighting "Generic" then press "Set" key to activate %stenosis measurement & calculation. I %stenosis can be measured by calculating vascular diameter or area. Measurement and calculation formula are as follows:

```
% Stenosis = (D1-D2)/D1; (D1, D2 are the diameter distances measured)
```

- % Stenosis = (A1-A2)/A1; (A1, A2 are the section areas measured)
- I Distance, area measurement and calculation methods can be referred to Chapter 9.3.1-9.3.3.
- I Measurement and calculation result displays as follows (%stenosis):

```
% Stenosis XXX XXX
```

9.3.4 Ratio measurement & calculation

- Under B mode, Press "Measure" key, turn encoder 1 (refer to Figure 4-1 and Table 4-1) or scroll the trackball, highlighting "Generic" then press "Set" key to activate A/B Ratio measurement & calculation.
- I A/B ratio can be obtained by measuring and calculating vascular diameter or area. Measurement and calculation formula are as follows:

```
A/B Ratio = (D1-D2)/D1; (D1, D2 are the diameter distances measured)
```

A/B Ratio = (A1-A2)/A1; $(A1 \cdot A2)$ are the section areas measured)

- I Distance and area measurement methods can be referred to Chapter 9.3.1-9.3.3.
- I Measurement and calculation result displays as follows (A/B Ratio):

A/B Ratio XXX XXX

9.3.5 Volume measurement & calculation

- I Under B mode, Press "Measure" key, turn encoder 1 (refer to Figure 4-1 and Table 4-1) or scroll the trackball, highlighting "Generic" then press "Set" key to activate Volume measurement & calculation.
- Volume can be obtained by measuring and calculating Single Distance, 2 Distance, 3 Distance, Ellipse or Ellipse + Distance. Calculation formula are as following Table 9-3.

Measurement method	Calculation formula
Single Distance	п/6× A ³
2 Distance	$\Pi/6\times A\times B^2(A>B)$
3 Distance	п/6×A×B×C

Ellipse	п/6×A×B²(A: ellipse long axis; B: ellipse short axis)
Ellipse + Distance	п/6×A×B×C

- I Distance, area measurement and calculation methods can be referred to chapter 9.3.1-9.3.3.
- I Measurement and calculation result displays as follows (Volume cm³):
 Volume XXX cm³

(I)_{NOTE}(I)

2 Distance, Ellipse + Distance measurement and calculation methods are usually carried out under 2B mode as the tissue horizontal section and vertical section images are required to be measured and calculated at the same time.

9.3.5 Angle measurement & calculation

- Under B mode, Press "Measure" key, turn encoder 1 (refer to Figure 4-1 and Table 4-1) or scroll the trackball, highlighting "Generic" then press "Set" key to activate Angle measurement & calculation.
- I Angle can be obtained by measuring and calculating the angle of two lines.
- I Distance, area measurement and calculation methods can be referred to Chapter 9.3.1-9.3.3.
- I Measurement and calculation result displays as follows (Angle degree):

Angle XXX deg

9.4 M mode measurement & calculation

- I Under M mode, tissue depth, time interval and depth slope can be measured and calculated by pressing "Measure" key.
- I Under M mode, %stenosis, A/B Ratio and HR can be measured and calculated through the "Measure" menu.
- I B|M, M modes are the same measurement and calculation methods as M mode which is

not described in this manual.

9.4.1 Tissue depth measurement & calculation

- I Under M mode, press "measure" key once to activate Tissue Depth measurement and calculation.
- I Scroll the trackball to the measurement and calculation starting point, press "Set" key to confirm.
- I Scroll the trackball to the measurement and calculation ending point, press "Set" key to confirm.
- I Measurement and calculation results will display in the window (Depth of the starting point, distance):

Dep XXX cm
Dis XXX cm

(I)NOTE(I)

Press "Measure" key again any time to select desired starting point or ending point during the process of measurement and calculation.

9.4.2 Time interval measurement & calculation

- I Under M mode, continuously press "Measure" key twice and a window will pop up displaying "M Time Interval" at the left of the screen.
- I Scroll the trackball to the measurement and calculation starting point, press "Set" key to confirm.
- I Scroll the trackball to the measurement and calculation ending point, press "Set" key to confirm.
- I Measurement and calculation results will display in the window (M mode time interval s):
 Time XXX s

(I)NOTE(I)

Press "Measure" key again any time to select desired starting point or ending point during the process of measurement and calculation.

9.4.3 Depth slope measurement & calculation

- I Under M mode, continuously press "Measure" key 3 times and a window will pop up displaying "M Depth Slope" at the left of the screen.
- I Scroll the trackball to the measurement and calculation starting point, press "Set" key to confirm.
- I Scroll the trackball to the measurement and calculation ending point, press "Set" key to confirm.
- I Measurement and calculation results will display in the window (M mode time interval: s; slope: cm/s):

Time XXX s
Slope XXX cm/s

(I)NOTE(I)

u Press "Measure" key again any time to select desired starting point or ending point during the process of measurement and calculation.

9.4.4 %stenosis measurement & calculation

- I Under M mode, Press "Measure" key, turn encoder 1 (refer to Figure 4-1 and Table 4-1) or scroll the trackball, highlighting "Generic" then press "Set" key to activate %stenosis measurement & calculation.
- I %stenosis can be measured by calculating vascular diameter or area. Measurement and calculation formula are as follows:

% Stenosis = (D1-D2)/D1; (D1, D2 are the diameter distances measured)

% Stenosis = (A1-A2)/A1; (A1, A2 are the section areas measured)

- I Distance, area measurement and calculation methods can be referred to Chapter 9.3.1-9.3.3.
- I Measurement and calculation result displays as follows (%stenosis):

% Stenosis XXX XXX

9.4.5 Ratio measurement & calculation

Under M mode, Press "Measure" key, turn encoder 1 (refer to Figure 4-1 and Table 4-1) or scroll the trackball, highlighting "Generic" then press "Set" key to activate A/B Ratio

measurement & calculation.

I A/B ratio can be obtained by measuring and calculating distance, time or slope. Calculation formula are as follows:

A/B Ratio = D1/D1; (D1, D2 are the distances measured)

A/B Ratio = T1/T2; (T1, T2 are the time intervals measured)

A/B Ratio = V1/V2 (V1, V2 are the slopes measured)

- I Distance, time and slope measurement methods can be referred to Chapter 9.4.1-9.4.3.
- I Measurement result displays as follows (A/B Ratio):

A/B Ratio XXX XXX

9.4.6 Heart rate measurement & calculation

- I Under M mode, Press "Measure" key, turn encoder 1 (refer to Figure 4-1 and Table 4-1) or scroll the trackball, highlighting "Generic" then press "Set" key to activate Heart Rate measurement & calculation.
- I Heart rate can be obtained by measuring and calculating heart beat TA Max/Min time interval.
- I Please refer to Chapter 9.4.2 for time interval measurement and calculation methods.
- I Measurement and calculation result displays as follows (Heart rate: beats/minute):
 Heart Rate XXX

9.5 PW mode measurement & calculation

- I Under PW mode, speed, TA Max/Min/Mean, slope/time interval, and time interval can be measured and calculated by pressing "Measure" key.
- I Under PW mode, %stenosis, A/B ratio, PI, RI, S/D(PS/ED), D/S(ED/PS), Max PG, Mean PG, SV, and heart rate can be measured and calculated through the "Measure" menu.

9.5.1 Speed measurement & calculation

- I Under PW mode, press "measure" key once to activate **Speed** measurement and calculation.
- I Scroll the trackball to the measurement and calculation point, press "Set" key to confirm.
- I Measurement and calculation results will display in the window (Speed: cm/s): Speed XXX cm

9.5.2 TA Max/Min/Mean measurement & calculation

- I Under PW mode, continuously press "Measure" key twice and a window will pop up displaying "TA Max/Min/Mean" at the left of the screen.
- I TA Max/Min/Mean can be measured and calculated by applying manual trace or auto trace method which can be switched by turning and pressing encoder 3 (please refer to Figure 4-1 and Table 4-1).
- In the case of manual trace method, scroll the trackball to the starting point and ending point for measurement and calculation, press "Set" key to confirm.
- In the case of auto trace method, the system will automatically track the waveform trace (marked in yellow in the screen), scroll the trackball to the starting point and ending point for measurement and calculation, press "Set" key to confirm.
- I Measurement and calculation results will display in the window (TA Max/Min/Mean speed: cm/s, PI, RI):

VMIN XXX cm/s
VMAX XXX cm/s
VMEAN XXX cm/s
PI XXX

RI XXX

9.5.3 Slope/time interval measurement & calculation

- I Under PW mode, continuously press "Measure" key 3 times and a window will pop up displaying "Slope/Time Interval" at the left of the screen.
- I Scroll the trackball to the measurement and calculation starting point, press "Set" key to confirm.
- I Scroll the trackball to the measurement and calculation ending point, press "Set" key to confirm.
- Measurement and calculation results will display in the window (Time interval: s; Slope: cm/s²):

Time XXX s
Slope XXX cm/s

9.5.4 Time interval measurement & calculation

- I Under PW mode, continuously press "Measure" key 4 times and a window will pop up displaying "Time Interval" at the left of the screen.
- Scroll the trackball to the measurement and calculation starting point, press "Set" key to confirm.

- I Scroll the trackball to the measurement and calculation ending point, press "Set" key to confirm.
- I Measurement and calculation results will display in the window (Time interval: s):

 Time XXX s



Press "Measure" key again any time to select desired starting point or ending point during the process of measurement and calculation.

9.5.5 %stenosis measurement & calculation

- I Under PW mode, Press "Measure" key, turn encoder 1 (refer to Figure 4-1 and Table 4-1) or scroll the trackball, highlighting "Generic" then press "Set" key to activate %stenosis measurement & calculation.
- 1 %stenosis can be measured by calculating vascular diameter or area. Measurement and calculation formula are as follows:

```
% Stenosis = (D1-D2)/D1; (D1, D2 are the diameter distances measured)
% Stenosis = (A1-A2)/A1; (A1, A2 are the section areas measured)
```

- I Distance, area measurement and calculation methods can be referred to Chapter 9.3.1-9.3.3.
- I Measurement and calculation result displays as follows (%stenosis):% Stenosis XXX XXX

9.5.6 Ratio measurement & calculation

- I Under PW mode, Press "Measure" key, turn encoder 1 (refer to Figure 4-1 and Table 4-1) or scroll the trackball, highlighting "Generic" then press "Set" key to activate A/B Ratio measurement & calculation.
- A/B ratio can be measured calculating distance, time or slope. Calculation formula are as follows:

```
A/B Ratio = V1/V1; (D1, D2 are the speeds measured)
A/B Ratio = T1/T2; (T1, T2 are the time intervals measured)
A/B Ratio = Acc1/Acc2 (Acc1, Acc2 are the slopes measured)
```

- I Distance, time and slope measurement methods can be referred to Chapter 9.5.1-9.5.3.
- I Measurement and calculation result displays as follows (A/B Ratio):

A/B Ratio XXX XXX

9.5.7 PI measurement & calculation

- I Under PW mode, Press "Measure" key, turn encoder 1 (refer to Figure 4-1 and Table 4-1) or scroll the trackball, highlighting "Generic" then press "Set" key to activate PI measurement & calculation.
- I PI can be measured at the same time calculating TA Max/Min/Mean. Also it can be separately measured and calculated by applying manual trace or auto trace method. Please refer to Chapter 9.5.2.
- I Measurement and calculation result displays as follows (PI):

PI XXX

9.5.8 RI measurement & calculation

- Under PW mode, Press "Measure" key, turn encoder 1 (refer to Figure 4-1 and Table 4-1) or scroll the trackball, highlighting "Generic" then press "Set" key to activate RI measurement & calculation.
- I RI can be measured the time calculating TA Max/Min/Mean. Also it can be separately measured and calculated by applying manual trace or auto trace method. Please refer to Chapter 9.5.2.
- I Measurement and calculation result displays as follows (RI):

RI XXX

9.5.9 PS/ED, ED/PS measurement & calculation

- Under PW mode, Press "Measure" key, turn encoder 1 (refer to Figure 4-1 and Table 4-1) or scroll the trackball, highlighting "Generic" then press "Set" key to activate PS/EC, ED/PS measurement & calculation.
- PS/EC, ED/PS can be measured by applying manual trace or auto trace method to set PS and ED. Please refer to Chapter 9.5.2.
- I Measurement and calculation results display as follows (PS, ED, S/D, D/S):

S/D XXX

PS XXX cm/s

ED XXX cm/s

D/S XXX

ED XXX cm/s

PS XXX cm/s

9.5.10 Max PG measurement & calculation

Under PW mode, Press "Measure" key, turn encoder 1 (refer to Figure 4-1 and Table 4-1) or scroll the trackball, highlighting "Generic" then press "Set" key to activate Max PG

measurement & calculation.

- I Scroll the trackball to the speed to be measured and calculated and press "Set" key to confirm.
- I The calculation formula is as follows:

```
Max PG = 4x(Vmax/100)^2
```

Measurement and calculation results display as follows (Max PG mmHg)
 Max PG XXX mmHg

9.5.11 Mean PG measurement & calculation

- Under PW mode, Press "Measure" key, turn encoder 1 (refer to Figure 4-1 and Table 4-1) or scroll the trackball, highlighting "Generic" then press "Set" key to activate Mean PG measurement & calculation.
- Mean PG can be measured by calculating mean speed applying manual trace or auto trace method. Please refer to Chapter 9.5.2.
- I The calculation formula is as follows: $Mean PG = 4x(Vmean/100)^2$
- Measurement and calculation results display as follows (Mean PG mmHg)
 Mean PG XXX mmHg

9.5.12 Heart rate measurement & calculation

- Under PW mode, Press "Measure" key, turn encoder 1 (refer to Figure 4-1 and Table 4-1) or scroll the trackball, highlighting "Generic" then press "Set" key to activate Heart Rate measurement & calculation.
- I Heart rate can be measured by calculating heart beat TA Max/Min time interval.
- I Please refer to Chapter 9.4.2 for time interval measurement and calculation methods.
- I Measurement and calculation result displays as follows (Heart rate: beats/minute):
 Heart Rate XXX

Chapter 10 System Setting & Update

10.1 System setting

Press "System" key to activate system setting function (refer to Table 4-2) as Figure 10-1.

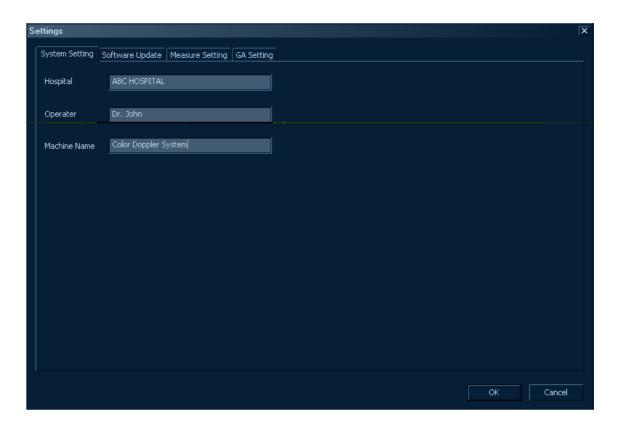


Figure 10-1 System setting interface

- Hospital name, doctor name, system name, measurement & calculation formula, etc can be set.
- I After setting, scroll the trackball to "OK" then press "Set" key to confirm and the information will prompt in the screen. Please refer Chapter 4.2 for more details.
- I For general measurement and calculation settings, please refer to Chapter 9.2.1.
- For professional settings, such as obstetric settings, please refer to the Instruction Manual for Advanced Application.

10.2 System update

Copy the upgrading software to any USB flash.

Insert the USB flash to the system USB port.

Press "System" key to activate system setting function (refer to Table 4-2) as Figure 10-2.

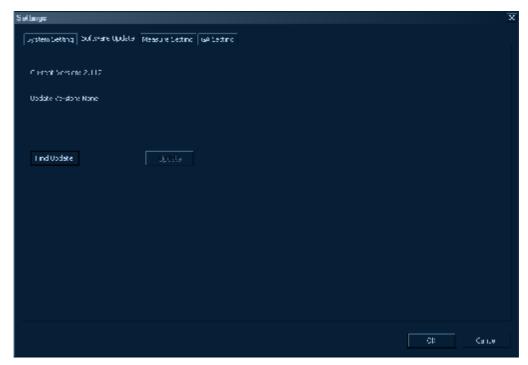


Figure 10-2 System upgrading interface

- I System current version displays in the interface.
- I Scroll the trackball to "Find Update" and press "Set" key.
- I The system will automatically read out the update software package from the USB flash and display version information in "Update Version" as Figure 10-3.

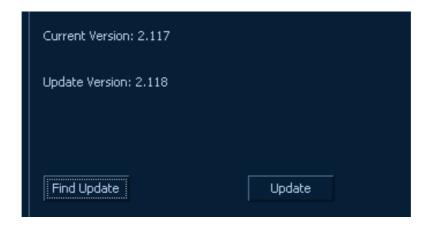


Figure 10-3 Update software version

- I Scroll the trackball to "Update" and press "Set" key.
- I The system will ask if the operator is sure want to update. Scroll the trackball to "OK" and press "Set" key to confirm if yes, as in Figure 10-4.

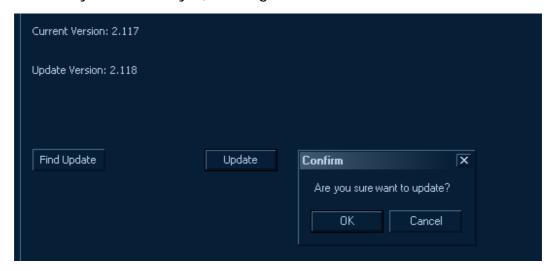


Figure 10-4 Update confirmation

I Scroll the trackball to "Next" and press "Set" key to continue as Figure 10-5.

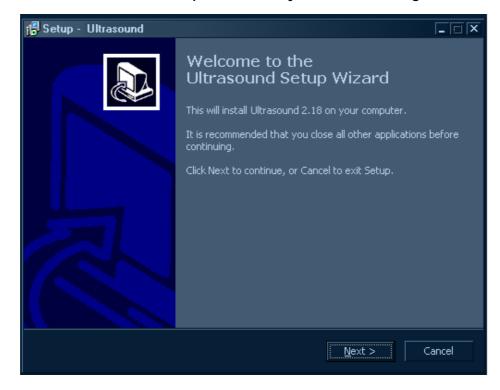


Figure 10-5 Update wizard

Ready to Install
Setup is now ready to begin installing Ultrasound on your computer.

Click Install to continue with the installation.

I Scroll the trackball to "Install" and press "Set" key to continue as Figure 10-6.

Figure 10-6 Update installation

< Back

Install

Cancel

After system update is finished, the system will ask if you'd like to restart the system now. scroll the trackball to "Yes, restart the computer now" first, then to "Finish" and press "Set" key as Figure 10-7.

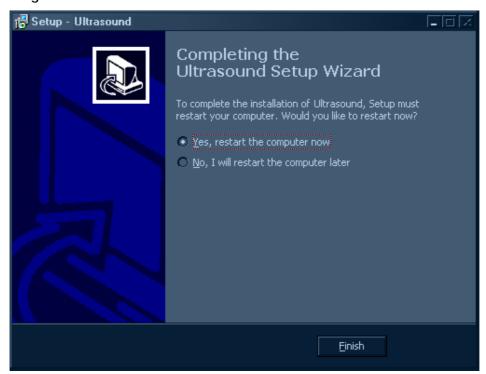


Figure 10-8 Restart the system

(I)NOTE(I)

- u System update takes around 1-2 minutes. Please wait with patience.
- u Application of an external mouse is much faster than scrolling the trackball and pressing "Set" key.

≜WARNING

Update should be carried out under the instruction of the manufacturer's service engineer.