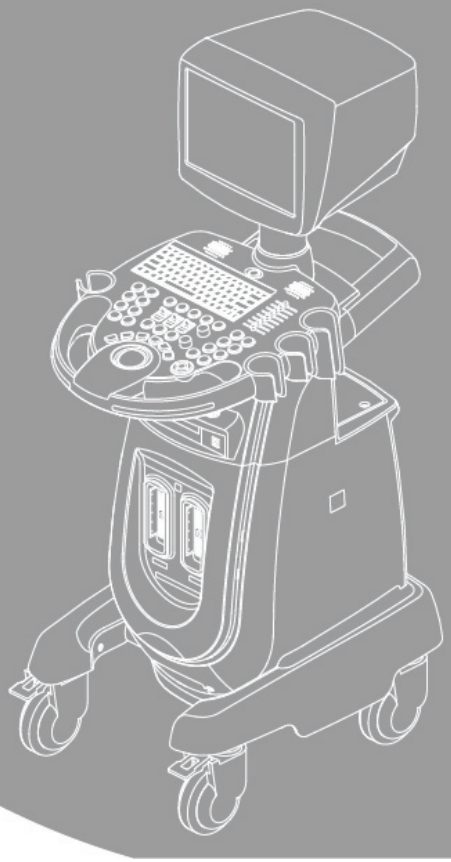
SONOACE X4



Operation Manual

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WARRANTY

MEDISON provides the following warranty to the purchaser of this system. This warranty is valid for a period of one year from the date of installation and covers all problems caused by faulty workmanship or faulty material. MEDISON will, as sole and exclusive remedy and at no charge, replace any such defective unit returned to MEDISON within the designated warranty period.

The warranty does not cover damages and loss caused by outside factors including, but not limited to fire, flood, storm, tidal wave, lightening, earthquake, theft, abnormal conditions of operation, and intentional destruction of the equipment. Damage caused by equipment relocation is not covered.

The warranty is void in cases where the equipment has been damaged as a result of an accident, misuse, abuse, dropping, or when attempts to modify or alter any part or assembly of the equipment have taken place.

Parts with cosmetic defects or deterioration will not be replaced.

Replacement of batteries, training materials, and supplies are not covered.

MEDISON will not be responsible for incidental or consequential damages of any kind arising from or connected with the use of the equipment.

MEDISON will not be responsible for any loss, damage, or injury resulting from a delay in services rendered under the warranty.

This limited warranty is in lieu of all other warranties expressed or implied, including warranties of merchant ability or fitness for any particular use. No representative or other person is authorized to represent or assume for MEDISON any warranty liability beyond that set forth herein.

Defective equipment shipped from you to MEDISON must be packed in the replacement cartons. Shipping and insurance costs are the responsibility of the customer. To return defective material to MEDISON, contact the MEDISON Customer Service Department.

MEDISON or a local distributor will make available, upon request, circuit diagrams, component parts lists, descriptions, calibration instructions and other information which will assist your appropriately qualified technical personnel to repair those parts of the equipment which are designated by MEDISON as repairable.

CAUTION : United States federal law restricts this device to sale by or on the order of a physician.

MEDISON

MANUFACTURED BY MEDISON CO., LTD
1003, Daechi-dong, Gangnam-Gu, SEOUL, 135-280 KOREA

MEDISON Customer Service Department
TEL : 82-2-2194-1234 FAX : 82-2-2194-1071 International World Wide Web: www. medison. com

EC Representative
SonoAce Deutschland GmbH Elbestrasse 10, 45768 Marl, Germany
TEL : 49-2365-924-3810 FAX : 49-2365-924-3830

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SONOACE X4

M342-E20100-00

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PROPRIETRAY INFORMATION AND SOFTWARE LICENSE

The Customer shall keep confidential all proprietary information furnished or disclosed to the Customer by MEDISON, unless such information has become part of the public domain through no fault of the Customer. The Customer shall not use such proprietary information, without the prior written consent of MEDISON, for any purpose other than the maintenance, repair or operation of the goods.

MEDISON's systems contain MEDISON's proprietary software in machine-readable form. MEDISON retains all its rights, title and interest in the software except that purchase of this product includes a license to use the machine-readable software contained in it. The Customer shall not copy, trace, disassemble or modify the software. Transfer of this product by the Customer shall constitute a transfer of this license that shall not be otherwise transferable. Upon cancellation or termination of this contract or return of the goods for reasons other than repair or modification, the Customer shall return to MEDISON all such proprietary information.

Safety Requirements

*** Classification:**

Type of protection against electrical shock: Class I

Degree of protection against electrical shock (Patient connection): Type BF equipment

Degree of protection against harmful ingress of water: Ordinary equipment

Degree of safety of application in the presence of a flammable anesthetic material with air or with oxygen or nitrous oxide: Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

Mode of operation: Continuous operation

*** Electromechanical safety standards met:**

IEC/EN 60601-1 Medical Electrical Equipment, Part 1, General Requirements for Safety.

IEC/EN 60601-1-1 Safety requirements for medical electrical systems.

IEC/EN 60601-1-2 Electromagnetic compatibility -Requirements and tests.

IEC/EN 60601-2-37 Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment.

IEC 61157 Declaration of acoustic output parameters.

ISO 10993-1 Biological evaluation of medical devices.

UL 2601-1 Medical Electrical Equipment, Part 1, General Requirements for Safety.

CSA 22.2, 601.1 Medical Electrical Equipment, Part 1, General Requirements for Safety.

*** Declarations:**

This is CSA symbol for Canada and United States of America

CE 0123 This is manufacturer's declaration of product compliance with applicable EEC directive(s) and the European notified body.

CE This is manufacturer's declaration of product compliance with applicable EEC directive(s).

READ THIS FIRST

How to Use Your Manual

This manual addresses the reader who is familiar with ultrasound techniques. Only medical doctors or persons supervised by medical doctors should use this system. Sonography training and clinical procedures are not included here. This manual is not intended to be used as training material for the principles of ultrasound, anatomy, scanning techniques, or applications. You should be familiar with all of these areas before attempting to use this manual or your ultrasound system.

This manual does not include diagnosis results or opinions. Also, check the measurement reference for each application's result measurement before the final diagnosis.

It is useless to make constant or complex adjustments to the equipment controls. The system has been preset at the factory to produce an optimum image in the majority of patients. User adjustments are not usually required. If the user wishes to change image settings, the variables may be set as desired. Optimal images are obtained with little difficulty.

We are not responsible for errors that occur when the system is run on a user's PC.

Please keep this operation manual close to the product as a reference when using the system.

For safe use of this product, you should read 'Chapter1. Safety' in this manual, prior to starting to use this system.

NOTE	Some features are not available in some countries. The features with options, and specifications that this manual present can be changed without notice. Government approval is still pending in some nations.

Conventions Used in This Manual

DANGER	Describes precautions necessary to prevent user hazards of great urgency. Ignoring a DANGER warning will risk life-threatening injury.
WARNING	Used to indicate the presence of a hazard that can cause serious personal injury, or substantial property damage.
CAUTION	Indicates the presence of a hazard that can cause equipment damage.
NOTE	A piece of information useful for installing, operating and maintaining a system. Not related to any hazard.

System Upgrades and Manual Set Updates

MEDISON Ultrasound is committed to innovation and continued improvement. Upgrades may be announced that consist of hardware or software improvements. Updated manuals will accompany those system upgrades.

Verify that this version of the manual is correct for the system version. If not, please contact the Customer Service Department.

If You Need Assistance

If you need any assistance with the equipment, please contact the MEDISON Customer Service Department or one of their worldwide customer service representatives, immediately.

Chapter 1

Safety

Safety Signs

Please read this chapter before using the MEDISON ultrasound system. It is relevant to the ultrasound system, the probes, the recording devices, and any of the optional equipment.

SONOACE X4 is intended for use by, or by the order of, and under the supervision of, a licensed physician who is qualified for direct use of the medical device.

Safety Symbols

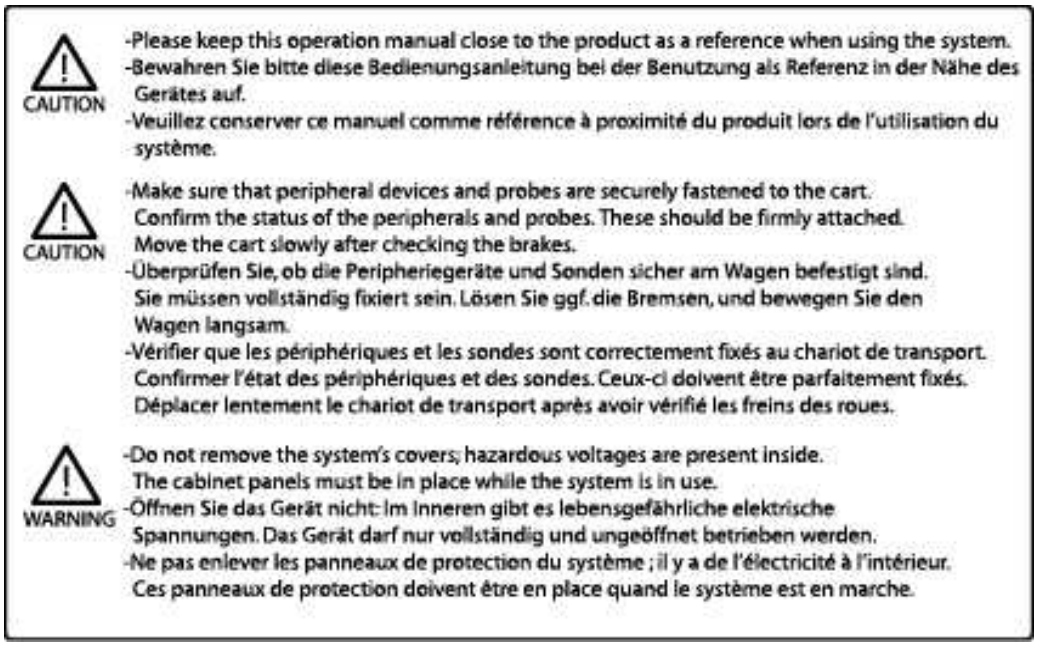
The International Electro Technical Commission (IEC) has established a set of symbols for medical electronic equipment, which classify a connection or warn of potential hazards. The classifications and symbols are shown below.

Symbols	Description
V~	AC (alternating current) voltage source
	Indicates a caution for risk of electric shock.
	Isolated patient connection (Type BF applied part).
	Power switch (Supplies/cuts the power for product)
	OFF (Cuts the power to a part of the product)
	ON (Supplies power to a part of the product)
	Refer to the User Manual.
	Identifies an equipotential ground.
	Indicates dangerous voltages over 1000V AC or over 1500V DC.

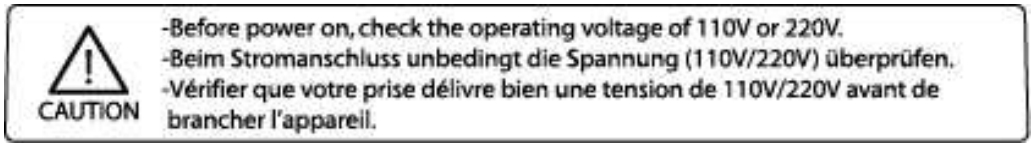
	Identifies the point where the system safety ground is fastened to the chassis. Protective earth connected to conductive parts of Class I equipment for safety purposes.
	VGA output port or Parallel port.
	ECG port.
	Left and right Audio / Video input
	Remote print output
	Foot switch connector
	ECG connector
	USB connector
	Protection against the effects of immersion.
	Protection against dripping water.
	Probe connector

Labels

To protect the system, you may see ‘Warning’ or ‘Caution’ marked on the surface of the product.



[Label 1. Marked on the back side of the product]



[Label 2. Marked below OUTLET]

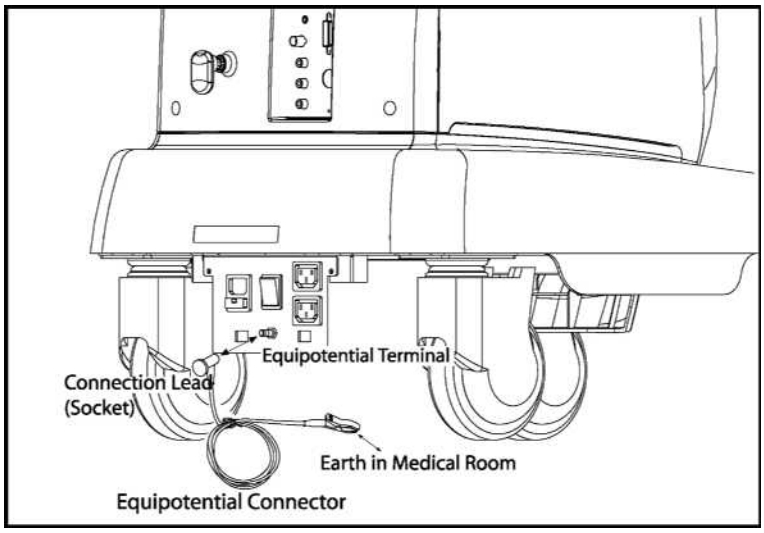
Electrical Safety

This equipment has been verified as a Class I device with Type BF applied parts.

CAUTION	■ As for US requirement, the LEAKAGE CURRENT might be measured from a center-tapped circuit when the equipment connects in the United States to 240V supply system. ■ **To help assure grounding reliability, connect to a "hospital grade" or "hospital only" grounded power outlet.**

Prevention of Electric Shock

In a hospital, dangerous currents are due to the potential differences between connected equipment and touchable conducting parts found in medical rooms. The solution to the problem is consistent equipotential bonding. Medical equipment is connected with connecting leads made up of angled sockets to the equipotential bonding network in medical rooms.



[Figure 1.1 Equipotential bonding]

Additional equipment connected to medical electrical equipment must comply with the respective IEC or ISO standards (e.g. IEC 60950 for data processing equipment). Furthermore all configurations shall comply with the requirements for medical electrical systems (see IEC 60601-1-1 or clause 16 of the 3 Ed. of IEC 60601-1, respectively). Anybody connecting additional equipment to medical electrical equipment configures a medical system and is therefore responsible that the system complies with the requirements for medical electrical systems. Attention is drawn to the fact that local laws take priority over the above mentioned requirements. If in doubt, consult your local representative or the technical service department.

WARNING

- Electric shock may exist result if this system, including and all of its externally mounted recording and monitoring devices, is not properly grounded.
- Do not remove the covers on the system; hazardous voltages are present inside. Cabinet panels must be in place while the system is in use. All internal adjustments and replacements must be made by a qualified MEDISON Customer Service Department.
- Check the face, housing, and cable before use. Do not use, if the face is cracked, chipped, or torn, the housing is damaged, or if the cable is abraded.
- Always disconnect the system from the wall outlet prior to cleaning the system.
- All patient contact devices, such as probes and ECG leads, must be removed from the patient prior to application of a high voltage defibrillation pulse.
- The use of flammable anesthetic gas or oxidizing gases (N20) should be avoided.

CAUTION

- The system has been designed for 100-120VAC and 200-240VAC; you should select the input voltage of monitor, printer and VCR. Prior to connecting an OEM power cord, verify that the voltage indicated on the power cord matches the voltage rating of the OEM device.
- An isolation transformer protects the system from power surges. The isolation transformer continues to operate when the system is in standby.
- Do not immerse the cable in liquids. Cables are not waterproof.
- The operator does not contact the parts (SIP/SOP) and the patient simultaneously

ECG-Related Information

WARNING

- This device is not intended to provide a primary ECG monitoring function, and therefore does not have means of indicating an inoperative electrocardiograph.
- Do not use ECG electrodes of HF surgical equipment. Any malfunctions in the HF surgical equipment may result in burns to the patient.
- Do not use ECG electrodes during cardiac pacemaker procedures or other electrical stimulators.
- Do not use ECG leads and electrodes in an operating room.

ESD

Electrostatic discharge (ESD), commonly referred to as a static shock, is a naturally occurring phenomenon. ESD is most prevalent during conditions of low humidity, which can be caused by heating or air conditioning. During low humidity conditions, electrical charges naturally build up on individuals, creating static electricity. An ESD occurs when an individual with an electrical energy build-up comes in contact with conductive objects such as metal doorknobs, file cabinets, computer equipment, and even other individuals. The static shock or ESD is a discharge of the electrical energy build-up from a charged individual to a lesser or non-charged individual or object.

The ESD caution symbol is on the probe connector and the rear panel.

[Figure 1. 2 ESD symbol]

CAUTION	■ The level of electrical energy discharged from a system user or patient to an ultrasound system can be significant enough to cause damage to the system or probes. ■ The following precautions can help to reduce ESD: - Anti-static spray on carpets or linoleum - Anti-static mats - A ground wire connection between the system and the patient table or bed.

EMI

Although this system has been manufactured in compliance with existing EMI(Electromagnetic Interference) requirements, use of this system in the presence of an electromagnetic field can cause momentary degradation of the ultrasound image.

If this occurs often, MEDISON suggests a review of the environment in which the system is being used, to identify possible sources of radiated emissions. These emissions could be from other electrical devices used within the same room or an adjacent room. Communication devices such as cellular phones and pagers can cause these emissions. The existence of radios, TVs, or microwave transmission equipment nearby can also cause interference.

CAUTION	In cases where EMI is causing disturbances, it may be necessary to relocate this system.

EMC

The testing for EMC(Electromagnetic Compatibility) of this system has been performed according to the international standard for EMC with medical devices (IEC60601-1-2). This IEC standard was adopted in Europe as the European norm (EN60601-1-2).

Guidance and manufacturer's declaration - electromagnetic emission

This product is intended for use in the electromagnetic environment specified below. The customer or the user of this product should assure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment -guidance
RF Emission CISPR 11	Group 1	The Ultrasound System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emission CISPR 11	Class A	The Ultrasound System is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply network that supplies building used for domestic purpose.
Harmonic Emission IEC 61000-3-2	Class A	
Flicker Emission IEC 61000-3-3	Complies	

Approved Cables, Transducers and Accessories for EMC

Approved Cable for Electromagnetic Compliance

Cables connected to this product may affect its emissions; Use only the cable types and lengths listed below table.

Cable	Type	Length
VGA	Shielded	Normal
Parallel	Shielded	Normal
RS232C	Shielded	Normal
USB	Shielded	Normal
LAN(RJ45)	Twisted pair	Any
S-Video	Shielded	Normal
Foot Switch	Shielded	2.5m
B/W Printer	Unshielded Coaxial	Normal
MIC	Unshielded	Any
Printer Remote	Unshielded	Any
Audio R.L	Shielded	Normal
VHS	Shielded	Normal
ECG AUX input	Shielded	< 3m

Approved Transducer for Electromagnetic Compliance

The image transducer used with this product may affect its emission. The transducer listed in 'Chapter 8. Probes' when used with this product, have been tested to comply with the group1 class A emission as required by International Standard CISPR 11.

Approved Accessories for Electromagnetic Compliance

Accessories used with this product may effect its emissions.

CAUTION	When connecting other customer-supplied accessories to the system, such as a remote printer or VCR, it is the user's responsibility to ensure the electromagnetic compatibility of the system. Use only CISPR 11 or CISPR 22, CLASS B compliant devices.

WARNING	The use of cables, transducers, and accessories other than those specified may result in increased emission or decreased Immunity of the Ultrasound System

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment -guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6KV Contact ±8KV air	±6KV Contact ±8KV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2KV for power supply lines ±1KV for input/output lines	±2KV for power supply lines ±1KV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1KV differential mode ±2KV common mode	±1KV differential mode ±2KV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5cycle 40% U_T (60% dip in U_T) for 5 cycle 70% U_T (30% dip in U_T) for 25 cycle <5% U_T (<95% dip in U_T) for 5 s	<5% U_T (>95% dip in U_T) for 0.5cycle 40% U_T (60% dip in U_T) for 5 cycle 70% U_T (30% dip in U_T) for 25 cycle <5% U_T (<95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of this product requires continued operation during power mains interruptions, it is recommended that this product be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80MHz	0.01V	Portable and mobile RF communications equipment should be used no closer to any part of the Ultrasound System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = [\frac{3,5}{V_1}]\sqrt{P}$ $d = [\frac{3,5}{E_1}]\sqrt{P}$ 80MHz to 800MHZ $d = [\frac{7}{E_1}]\sqrt{P}$ 800MHz to 2.5GHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5GHz	3V/m	where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as deter-mined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol : 

NOTE 1) At 80MHz and 800MHz, the higher frequency range applies.
NOTE 2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Ultrasound System is used exceeds the applicable RF compliance level above, the Ultrasound System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Ultrasound System or using a shielded location with a higher RF shielding effectiveness and filter attenuation.

[b] Over the frequency range 150kHz to 80MHz, field strengths should be less than $[V_1]$ V/m.

Recommended separation distances between portable and mobile RF communications equipment and the SONOACE X4

This product is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of this product can help Prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and this product as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter [W]	Separation distance according to frequency of transmitter [m]		
	150kHz to 80MHz $d = [\frac{3,5}{V_1}]\sqrt{P}$	80MHz to 800MHz $d = [\frac{3,5}{E_1}]\sqrt{P}$	800MHz to 2.5GHz $d = [\frac{7}{E_1}]\sqrt{P}$
	V_1=0.01Vrms	E_1=3 V/m	E_1=3V/m
0.01	35.00	0.11	0.23
0.1	110.68	0.36	0.73
1	350.00	1.16	2.33
10	1106.80	3.68	7.37
100	3500.00	11.66	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *p* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1) At 80MHz and 800MHz, the separation distance for the higher frequency range applies.
NOTE 2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Electromagnetic environment – guidance

The Ultrasound System must be used only in a shielded location with a minimum RF shielding effectiveness and, for each cable that enters the shielded location. Field strengths outside the shielded location from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than 3V/m.
It is essential that the actual shielding effectiveness and filter attenuation of the shielded location be verified to assure that they meet the minimum specification.

CAUTION	If the system is connected to other customer-supplied equipment, such as a local area network (LAN) or a remote printer, Medison cannot guarantee that the remote equipment will work correctly in the presence of electromagnetic phenomena.

Avoiding Electromagnetic Interference

A medical device can either generate or receive electromagnetic interference. The EMC

standards describe tests for both emitted and received interference.

Medison Ultrasound Systems do not generate interference in excess of the referenced standards.

An Ultrasound System is designed to receive signals at radio frequency and is therefore susceptible to interference generated by RF energy sources. Examples of other source of interference are medical device, information technology products, and radio and television transmission towers. Tracing the source of radiated interference can be a difficult task. Customers should consider the following in an attempt to locate the source:

- Is the interference intermittent or constant?
- Does the interference show up only with one transducers operating at the same frequency or with several transducer?
- Do two different transducer operating at the same frequency have the same problem?
- Is the interference present if the system is moved to a different location in the facility?

The answers to these questions will help determine if the problem reside with the system or the scanning environment. After you answer the question, contact your local MEDISON customer service department.

Mechanical Safety

Moving the Equipment

When you move the equipment, you should use the handle at the backside of the console. The monitor can be separated and easily removed from the unit if necessary.
The adjustable wheels under the console facilitate easy transporting of the product.
The components are installed securely and can withstand considerable shock, but excessive shock may cause system failure. On rare occasions a component may become disconnected inside the system. If the system operates abnormally after repositioning, please contact the MEDISON Customer Service Department.

WARNING	The system can weigh approximately 101kg (202lb), depending upon configuration, and could cause injury should it topple over.

The Brakes

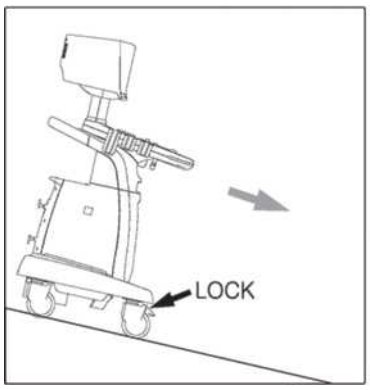
The brakes are on the front wheels of the console. Press the brakes with your feet to lock or release them.
You can use the brakes to control the movement of the product such as by preventing its movement while scanning.

Precautions on Ramps

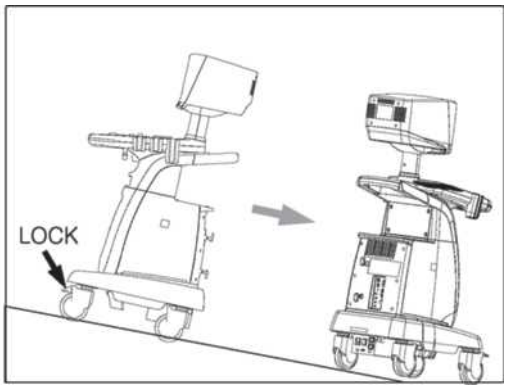
Always make sure that the control panel is facing the direction of movement.

WARNING	Be aware of the castors, especially when moving the system. MEDISON recommends that you exercise caution when moving the product up or down ramps.

When moving the product down a ramp or resting it temporarily on a ramp, the product may tilt over even with the brakes on depending on the direction of the product. Do not rest the product on ramps.



[Good example]



[Bad example]

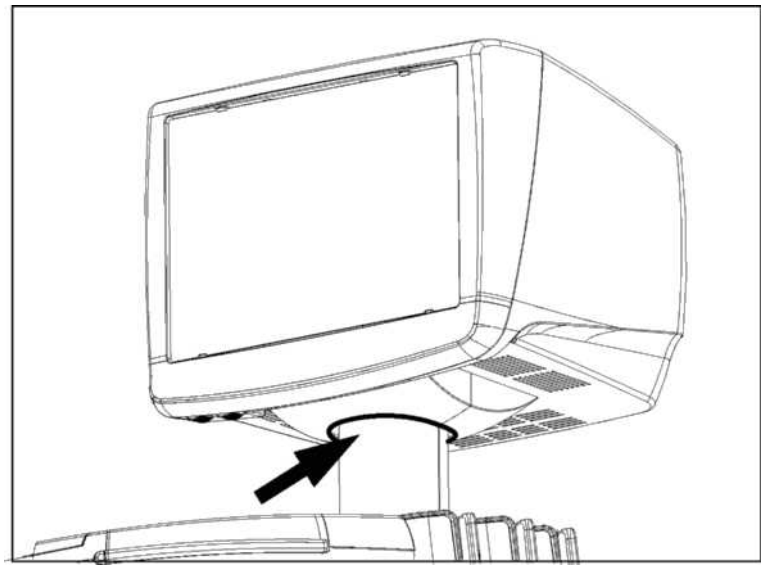
Safety Note

CAUTION	■ Never attempt to modify the product in any way. ■ Check the operational safety when using the product after a prolonged break in service. ■ Make sure that other objects, such as metal pieces, do not enter the system. ■ Do not block the ventilation slots. ■ To prevent damage to the power cord, be sure to grip the plug head – not the cord – when unplugging. ■ Excessive bending or twisting of cables on patient-applied parts may cause failure or intermittent operation of the system. ■ Improper cleaning or sterilization of a patient-applied part may cause permanent damage.

Please refer to “Chapter 7. Maintenance” for detailed information on protecting, cleaning and disinfecting the equipment.

Safety Note for Monitor

When adjusting the position of the monitor, be careful not to get your fingers caught in between the monitor and the arm.



[Figure 1. 3 Safety Note for Monitor]

Biological Safety

Verify the alignment of the biopsy guide before use. See the “Chapter 8. Probes” section of this manual.

WARNING	■ Ultrasound waves may have damaging effects on cells and, therefore, may be harmful to the patient. If there is no medical benefit, minimize the exposure time and maintain the ultrasound wave output level at low. Please refer to the ALARA principle. ■ Do not use the system if an error message appears on the video display indicating that a hazardous condition exists. Note the error code, turn off the power to the system, and call your local MEDISON Customer Service Department. ■ Do not use a system that exhibits erratic or inconsistent updating. Discontinuities in the scanning sequence are indicative of a hardware failure that should be corrected before use. ■ The system limits the maximum contact temperature to 43 degree Celsius, and the ultrasonic waves output observes American FDA regulations.

ALARA Principle

Guidance for the use of diagnostic ultrasound is defined by the “as low as reasonably achievable” (ALARA) principle. The decision as to what is reasonable has been left to the judgment and insight of qualified personnel. No set of rules can be formulated that would be sufficiently complete to dictate the correct response for every circumstance. By keeping ultrasound exposure as low as possible, while obtaining diagnostic images, users can minimize ultrasonic bioeffects.

Since the threshold for diagnostic ultrasound bioeffects is undetermined, it is the sonographer’s responsibility to control the total energy transmitted into the patient. The sonographer must reconcile exposure time with diagnostic image quality. To ensure diagnostic image quality and limit exposure time, the ultrasound system provides controls that can be manipulated during the exam to optimize the results of the exam.

The ability of the user to abide by the ALARA principle is important. Advances in diagnostic ultrasound not only in the technology but also in the applications of the technology, have resulted in the need for more and better information to guide the user. The output indices are designed to provide that important information

There are a number of variables, which affect the way in which the output display indices can be used to implement the ALARA principle. These variables include mass, body size, location of the bone relative to the focal point, attenuation in the body, and ultrasound exposure time. Exposure time is an especially useful variable, because the user controls it. The ability to limit the index values over time support the ALARA principle.

Applying ALARA

The system-imaging mode used depends upon the information needed. 2D-mode and M-mode imaging provide anatomical information, while Doppler imaging provide information about blood flow. Scanned modes, like 2D-mode disperse or scatter the ultrasonic energy over an area, while an unscanned mode, like M-mode or Doppler, concentrates ultrasonic energy. Understanding the nature of the imaging mode being used allows the sonographer to apply the ALARA principle with informed judgment. The probe frequency, system set-up values, scanning techniques, and operator experience aid the sonographer in meeting the definition of the ALARA principle.

The decision as to the amount of acoustic output is, in the final analysis, up to the system operator. This decision must be based on the following factors: type of patient, type of exam, patient history, ease or difficulty of obtaining diagnostically useful information, and the potential localized heating of the patient due to probe surface temperatures. Prudent use of the system occurs when patient exposure is limited to the lowest index reading for the shortest amount of time necessary to achieve acceptable diagnostic results.

Although a high index reading does not mean that a bioeffect is actually occurring, a high index reading should be taken seriously. Every effort should be made to reduce the possible effects of a high index reading. Limiting exposure time is an effective way to accomplish this goal.

There are several system controls that the operator can use to adjust the image quality and limit the acoustic intensity. These controls are related to the techniques that an operator might use to implement ALARA. These controls can be divided into three categories: direct, indirect, and receiver control.

Direct Controls

Application selection and the output intensity control directly affect acoustic intensity. There are different ranges of allowable intensity or output based on your selection. Selecting the correct range of acoustic intensity for the application is one of the first things required during any exam. For example, peripheral vascular intensity levels are not recommended for fetal exams. Some systems automatically select the proper range for a particular procedure, while others require manual selection. Ultimately, the user bears the responsibility for proper clinical use. The MEDISON system provides both automatic and user-definable settings.

Output has direct impact on acoustic intensity. Once the application has been established, the output control can be used to increase or decrease the intensity output. The output control allows you to select intensity levels less than the defined maximum. Prudent use dictates that you select the lowest output intensity consistent with good image quality.

Indirect Controls

The indirect controls are those that have an indirect effect on acoustic intensity. These controls affect imaging mode, pulse repetition frequency, focus depth, pulse length, and probe selection.

The choice of imaging mode determines the nature of the ultrasound beam. 2D-mode is a scanning mode, Doppler is a stationary or unscanned mode. A stationary ultrasound beam concentrates energy on a single location. A moving or scanned ultrasound beam disperses the energy over a wide area and the beam is

only concentrated on a given area for a fraction of the time necessary in unscanned mode.

Pulse repetition frequency or rate refers to the number of ultrasound bursts of energy over a specific period of time. The higher the pulse repetition frequency, the more pulses of energy in a given period of time. Several controls affect pulse repetition frequency: focal depth, display depth, sample volume depth, number of focal zones, and sector width controls.

Focus of the ultrasound beam affects the image resolution. To maintain or increase resolution at a different focus requires a variation in output over the focal zone. This variation of output is a function of system optimization. Different exams require different focal depths. Setting the focus to the proper depth improves the resolution of the structure of interest.

Pulse length is the time during which the ultrasonic burst is turned on. The longer the pulse, the greater the time-average intensity value. The greater the time-average intensity, the greater the likelihood of temperature increase and cavitations. Pulse length or burst length or pulse duration is the output pulse duration in pulsed Doppler. Increasing the Doppler sample volume increases the pulse length.

Probe selection affects intensity indirectly. Tissue attenuation changes with frequency. The higher the probe operating frequency, the greater the attenuation of the ultrasonic energy. Higher probe operating frequencies require higher output intensity to scan at a deeper depth. To scan deeper at the same output intensity, a lower probe frequency is required. Using more gain and output beyond a point, without corresponding increases in image quality, can mean that a lower frequency probe is needed.

▌Receiver Controls

Receiver controls are used by the operator to improve image quality. These controls have no effect on output. Receiver controls only affect how the ultrasound echo is received. These controls include gain, TGC, dynamic range, and image processing. The important thing to remember, relative to output, is that receiver controls should be optimized before increasing output. For example; before increasing output, optimize gain to improve image quality.

Additional Considerations

Ensure that scanning time is kept to a minimum, and ensure that only medically required scanning is performed. Never compromise quality by rushing through an exam. A poor exam will require a follow-up, which ultimately increases the time. Diagnostic ultrasound is an important tool in medicine, and, like any tool, should be used efficiently and effectively.

Output Display Features

The system output display comprises two basic indices: a mechanical index and a thermal index. The thermal index consists of the following indices: soft tissue (TIs) and bone (TIb). One of these three thermal indices will be displayed at all times. Which one depends upon the system preset or user choice, depending upon the application at hand.

The mechanical index is continuously displayed over the range of 0.0 to 1.9, in increments of 0.1.

The thermal index consists of the three indices, and only one of these is displayed at any one time. Each probe application has a default selection that is appropriate for that combination. The TIb or TIs is continuously displayed over the range of 0.0 to maximum output, based on the probe and application, in increments of 0.1.

The application-specific nature of the default setting is also an important factor of index behavior. A default setting is a system control state which is preset by the manufacturer or the operator. The system has default index settings for the probe application. The default settings are invoked automatically by the ultrasound system when power is turned on, new patient data is entered into the system database, or a change in application takes place.

The decision as to which of the three thermal indices to display should be based on the following criteria:

Appropriate index for the application: TIs is used for imaging soft tissue; and TIb for a focus at or near bone.

Some factors might create artificially high or low thermal index readings e.g. presence of fluid or bone, or the flow of blood. A highly attenuating tissue path, for example, will cause the potential for local zone heating to be less than the thermal index displays.

Scanned modes versus unscanned modes of operation affect the thermal index. For scanned modes, heating tends to be near the surface; for unscanned modes, the potential for heating tends to be deeper in the focal zone.

Always limit ultrasound exposure time. Do not rush the exam. Ensure that the indices are kept to a minimum and that exposure time is limited without compromising diagnostic sensitivity.

▌Mechanical Index (MI) Display

Mechanical bioeffects are threshold phenomena that occur when a certain level of output is exceeded. The threshold level varies, however, with the type of tissue. The potential for mechanical bioeffects varies with peak pressure and ultrasound frequency. The MI accounts for these two factors. The higher the MI value, the greater the likelihood of mechanical bioeffects occurring but there is no specific MI value that means that a mechanical effect will actually occur. The MI should be used as a guide for implementing the ALARA principle.

▌Thermal Index (TI) Display

The TI informs the user about the potential for temperature increase occuring at the body surface, within body tissue, or at the point of focus of the ultrasound beam on bone. The TI is an estimate of the temperature increase in specific body tissues. The actual amount of any temperature rise is influenced by factors such as tissue type, vascularity, and mode of operation etc. The TI should be used as a guide for implementing the ALARA principle.

The bone thermal index (TIb) informs the user about potential heating at or near the focus after the ultrasound beam has passed through soft tissue or fluid, for example, at or near second or third trimester fetal bone.

The cranial bone thermal index (TIc) informs the user about the potential heating of bone at or near the

surface, for example, cranial bone.

The soft tissue thermal index (TIs) informs the user about the potential for heating within soft homogeneous tissue.

You can select either TIs or TIb using the TIs/TIb selection on the Miscellaneous system setups. TIc is displayed when you select a trans-cranial application.

Mechanical and Thermal indices Display Precision and Accuracy

The Mechanical and Thermal Indices on the system are precise to 0.1 units.

The MI and TI display accuracy estimates for the system are given in the Acoustic Output Tables manual. These accuracy estimates are based on the variability range of probes and systems, inherent acoustic output modeling errors and measurement variability, as described below.

The displayed values should be interpreted as relative information to help the system operator achieve the ALARA principle through prudent use of the system. The values should not be interpreted as actual physical values investigated tissue or organs. The initial data that is used to support the output display is derived from laboratory measurements based on the AIUM measurement standard. The measurements are then put into algorithms for calculating the displayed output values.

Many of the assumptions used in the process of measurement and calculation are conservative in nature. Over-estimation of actual in situ exposure, for the vast majority of tissue paths, is built into the measurement and calculation process. For example:

The measured water tank values are de-rated using a conservative, industry standard, attenuation coefficient of 0.3dB/cm-MHz.

Conservative values for tissue characteristics were selected for use in the TI models. Conservative values for tissue or bone absorption rates, blood perfusion rates, blood heat capacity, and tissue thermal conductivity were selected.

Steady state temperature rise is assumed in the industry standard TI models, and the assumption is made that the ultrasound probe is held steady in one position long enough for steady state to be reached.
A number of factors are considered when estimating the accuracy of display values: hardware variations, algorithm accuracy estimation and measurement variability. Variability among probes and systems is a significant factor. Probe variability results from piezoelectric crystal efficiencies, process-related impedance differences, and sensitive lens focusing parameter variations. Differences in the system pulse voltage control and efficiencies are also a contributor to variability. There are inherent uncertainties in the algorithms used for estimating acoustic output values over the range of possible system operating conditions and pulse voltages. Inaccuracies in laboratory measurements are related to differences in hydrophone calibration and performance, positioning, alignment and digitization tolerances, and variability among test operators.

The conservative assumptions of the output estimation algorithms of linear propagation, at all depths, through a 0.3dB/cm-MHz attenuated medium are not taken into account in calculation of the accuracy estimate displayed. Neither linear propagation, nor uniform attenuation at the 0.3dB/cm-MHz rate, occur

in water tank measurements or in most tissue paths in the body. In the body, different tissues and organs have dissimilar attenuation characteristics. In water, there is almost no attenuation. In the body, and particularly in water tank measurements, non-linear propagation and saturation losses occur as pulse voltages increase.

The display accuracy estimates take into account the variability ranges of probes and systems, inherent acoustic output modeling errors, and measurement variability. Display accuracy estimates are not based on errors in, or caused by measuring according to, the AIUM measurement standards. They are also independent of the effects of non-linear loss on the measured values.

Control Effects

Control affecting the indices

As various system controls are adjusted, the TI and MI values may change. This will be most apparent as the power control is adjusted; however, other system controls will affect the on-screen output values.

Power

Power controls the system acoustic output. Two real-time output values are on the screen: a TI and a MI. They change as the system responds to Power adjustments.

In combined modes, such as simultaneous M mode and PW Doppler, the individual modes each add to the total TI. One mode will be the dominant contributor to this total. The displayed MI will be from the mode with the largest peak pressure.

2D-mode Controls

2D-mode size

Narrowing the sector angle may increase the frame rate. This action will increase the TI. Pulse voltage may be automatically adjusted down with software controls to keep the TI below the system maximums. A decrease in pulse voltage will decrease MI.

Zoom

Increasing the zoom magnification may increase frame rate. This action will increase the TI. The number of focal zones may also increase automatically to improve resolution. This action may change MI since the peak intensity can occur at a different depth.

Persistence

A lower persistence will decrease the TI. Pulse voltage may be automatically increased. An increase in pulse voltage will increase MI.

Focal no.

More focal zones may change both the TI and MI by changing frame rate or focal depth automatically. Lower frame rates decrease the TI. MI displayed will correspond to the zone with the largest peak intensity.

Focus

Changing the focal depth will change the MI. Generally, higher MI values will occur when the focal depth is near the natural focus of the transducer.

M-mode and Doppler Controls

Speed

M-mode and Doppler sweep speed adjustments will not affect the MI. When M-mode sweep speed changes, TI changes.

Simultaneous and Update Methods

Use of combination modes affects both the TI and MI through the combination of pulse types. During simultaneous mode, the TI is additive. During auto-update and duplex, the TI will display the dominant pulse type. The displayed MI will be from the mode with the largest peak pressure.

Sample Volume Depth

When Doppler sample volume depth is increased the Doppler PRF may automatically decrease. A decrease in PRF will decrease the TI. The system may also automatically decrease the pulse voltage to remain below the system maximum. A decrease in pulse voltage will decrease MI.

Doppler, M-mode and Imaging Controls

When a new imaging mode is selected, both the TI and the MI will change to default settings. Each mode has a corresponding pulse repetition frequency and maximum intensity point. In combined or simultaneous modes, the TI is the sum of the contribution from the modes enabled and MI is the MI for the focal zone and mode with the largest derated intensity. If a mode is turned off and then reselected, the system will return to the previously selected settings.

Probe

Each probe model available has unique specifications for contact area, beam shape, and center frequency. Defaults are initialized when you select a probe. MEDISON factory defaults vary with probe, application, and selected mode. Defaults have been chosen below the FDA limits for intended use.

Depth

An increase in 2D-mode depth will automatically decrease the 2D-mode frame rate. This would decrease the TI. The system may also automatically choose a deeper 2D-mode focal depth. A change of focal depth may change the MI. The MI displayed is that of the zone with the largest peak intensity.

Application

Acoustic output defaults are set when you select an application. MEDISON factory defaults vary with probe, application, and mode. Defaults have been chosen below the FDA limits for intended use.

Related Guidance Documents

For more information about ultrasonic bioeffects and related topics refer to the following;
AIUM Report, January 28, 1993, “Bioeffects and Safety of Diagnostic Ultrasound”
Bioeffects Considerations for the Safety of Diagnostic Ultrasound, *J Ultrasound Med.*, Sept. 1998: Vol. 7, No. 9 Supplement
Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment. (AIUM, NEMA. 1998)
Acoustic Output Labeling Standard for Diagnostic Ultrasound Equipment (AIUM, 1998)
Second Edition of the AIUM Output Display Standard Brochure, Dated March 10, 1994. (A copy of this document is shipped with each system.)
Information for Manufacturer Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers. FDA. September 1997. FDA.
Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic

Ultrasound Equipment. (Revision 1, AIUM, NEMA. 1998)
WFUMB. Symposium on Safety of Ultrasound in Medicine: Conclusions and Recommendations on Thermal and Non-Thermal Mechanisms for Biological Effects of Ultrasound, *Ultrasound in Medicine and Biology*, 1998: Vol. 24, Supplement1.

Acoustic Output and Measurement

Since the first usage of diagnostic ultrasound, the possible human biological effects (bioeffects) of ultrasound exposure have been studied by various scientific and medical institutions. In October 1987, the American Institute of Ultrasound in Medicine(AIUM) ratified a report prepared by its Bioeffects Committee (Bioeffects Considerations for the Safety of Diagnostic Ultrasound, J Ultrasound Med., Sept. 1988: Vol.7, No.9 Supplement), sometimes referred to as the Stowe Report, which reviewed available data on possible effects of ultrasound exposure. Another report "Bioeffects and Safety of Diagnostic Ultrasound," dated January 28, 1993 provides more up to date information.

The acoustic output for this system has been measured and calculated in accordance with the December 1985 "510(K) Guide for Measuring and Reporting Acoustic Output of Diagnostic Ultrasound Medical Devices," except that the hydrophone meets the requirements of "Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment" (NEMA UD 2-1992)

In Situ, Derated, and Water Value Intensities

All intensity parameters are measured in water. Since water does not absorb acoustic energy, these water measurements represent a worst case value. Biological tissue does absorb acoustic energy. The true value of the intensity at any point depends on the amount and type of tissue and the frequency of the ultrasound that passes through the tissue. The intensity value in the tissue, *In Situ*, has been estimated using the following formula:

In Situ = Water [$e^{-(0.23alf)}$]
where: *In Situ* = *In Situ* Intensity Value
Water = Water Value Intensity
e = 2.7183
a = Attenuation Factor

Tissue	a(dB/cm-MHz)
Brain	.53
Heart	.66
Kidney	.79
Liver	.43
Muscle	.55

l = skin line to measurement depth (cm)
f = Center frequency of the transducer/system/mode combination(MHz)

Since the ultrasonic path during an examination is likely to pass through varying lengths and types of tissue, it is difficult to estimate the true *In Situ* intensity. An attenuation factor of 0.3 is used for general reporting purpose; therefore, the *In Situ* value which is commonly reported uses the formula:

In Situ (*derated*) = Water [$e^{-(0.069lf)}$]

Since this value is not the true *In Situ* intensity, the term "derated" is used.
The maximum derated and the maximum water values do not always occur at the same operating condition; therefore, the reported maximum water and derated values may not be related to the *In Situ* (derated) formula. Take for example a multi-zone array transducer that has maximum water value intensities in its deepest zone: the same transducer may have its largest derated intensity in one if its shallowest focal zones.

Acoustic Output and Measurement

The terms and symbols used in the acoustic output tables are defined in the following paragraphs.

ISPTA.3 The derated spatial-peak temporal-average intensity (milliwatts per square centimeter).

ISPPA.3 The **derated spatial-peak pulse-average intensity** (watts per square centimeter). The value of IPA.3 at the position of global maximum MI (IPA.3@MI) may be reported instead of ISPPA.3 if the global maximum MI is reported.

MI The **Mechanical Index**. The value of MI at the position of ISPPA.3, (MI@ISPPA.3) may be reported instead of MI (global maximum value) if ISPPA.3 is □190W/cm^2

Pr.3 The **derated peak rarefactional pressure** (megapascals) associated with the transmit pattern giving rise to the reported MI value.

WO The **ultrasonic power** (milliwatts). For the operating condition giving rise to ISPTA.3, WO is the total time-average power;. For operating conditions subject to reporting under ISPPA.3, WO is the **ultrasonic power** associated with the transmit pattern giving rise to the value reported under ISPPA.3

Fc The **center frequency** (MHz). For MI and ISPPA.3, Fc is the **center frequency** associated with the transmit pattern giving rise to the global maximum value of the respective parameter. For ISPTA.3, for combined modes involving beam types of unequal **center frequency**, Fc is defined as the overall range of center frequencies of the respective transmit patterns.

ZSP The axial distance at which the reported parameter is measured (centimeters).

x-6,y-6 are respectively the in-plane (azimuth) and out-of-plane (elevation) -6□ dimensions in the x-y plane where ZSP is found (centimeters).

PD The **pulse duration** (microseconds) associated with the transmit pattern giving rise to the reported value of the respective parameter.

PRF The **pulse repetition frequency** (Hz) associated with the transmit pattern giving rise to the reported value of the respective parameter.

EBD The **entrance beam dimensions** for the azimuth and elevation planes (centimeters).

EDS The **entrance dimensions of the scan** for the azimuth and elevation planes (centimeters).

Acoustic Measurement Precision and Uncertainty

The Acoustic Measurement Precision and Acoustic Measurement Uncertainty are described below.

Quantity	Precision	Total Uncertainty
PII.3 (derated pulse intensity integral)	3.2 %	+21 % to - 24 %
Wo (acoustic power)	6.2 %	+/- 19 %
Pr.3 (derated rarefaction pressure)	5.4 %	+/- 15 %
Fc (center frequency)	< 1 %	+/- 4.5 %

Systematic Uncertainties.

For the pulse intensity integral, derated rarefaction pressure Pr.3, center frequency and pulse duration, the analysis includes considerations of the effects on accuracy of:
Hydrophone calibration drift or errors.
Hydrophone / Amp frequency response.
Spatial averaging.
Alignment errors.
Voltage measurement accuracy, including.

- Oscilloscope vertical accuracy.
- Oscilloscope offset accuracy.
- Oscilloscope clock accuracy.
- Oscilloscope Digitization rates.
- Noise.

The systematic uncertainties Acoustic power measurements using a Radiation Force are measured through the use of calibrated NIST acoustic power sources.
We also refer to a September 1993 analysis done by a working group of the IEC technical committee 87 and prepared by K. Beissner, as a first supplement to IEC publication 1161.

The document includes analysis and discussion of the sources of error/measurement effects due to:
Balance system calibration.
Absorbing (or reflecting) target suspension mechanisms.
Linearity of the balance system.
Extrapolation to the moment of switching the ultrasonic transducer (compensation for ringing and thermal drift).
Target imperfections.
Absorbing (reflecting) target geometry and finite target size.
Target misalignment.
Ultrasonic transducer misalignment.
Water temperature.
Ultrasonic attenuation and acoustic streaming.
Coupling or shielding foil properties.
Plane-wave assumption.
Environmental influences.
Excitation voltage measurement.
Ultrasonic transducer temperature.
Effects due to nonlinear propagation and saturation loss.
The overall findings of the analysis give a rough Acoustic Power accuracy figure of +/- 10% for the frequency range of 1 - 10 MHz.

Environmental Protection

CAUTION	■ The console and peripherals could be sent back to manufacturers for recycling or proper disposal after their useful lives. ■ Disposal of waste shall be disposed in accordance with national laws. ■ The waste sheaths are to be disposed of safely and national regulations must be observed.

Waste Electrical and Electronic Equipment

This symbol is applied in the European Union and other European countries.

This symbol on the product indicates that this product shall not be treated as household waste. Instead it shall be handed over to the applicable collection point for the recycling of electrical and electronic equipment. By ensuring this product is disposed of correctly, you will help prevent potential negative consequences for the environment and human health, which could otherwise be caused by inappropriate waste handling of this product. The recycling of materials will help to conserve natural resources. For more detailed information about recycling of this product, please contact your local city office, your electrical and electronic waste disposal service or the shop where you purchased the product.

Chapter 2

Introduction And Installation

What is SONOACE X4?

The **SONOACE X4** is a high-resolution ultrasound scanner with high penetration and a variety of measurement functions.

Features and Advantages of SONOACE X4

- High-end Digital Beam Forming – The SONOACE X4 utilizes the newly developed Digital Beam forming technology.
- A variety of applications – The SONOACE X4 is optimized for use in a variety of ultrasound departments, including abdomen, obstetrics, gynecology, vascular, cardiac and urology applications.
- Various diagnostic Modes - 2D Mode, M Mode, PW Spectral Doppler Mode (optional), etc.
- 3D images can be obtained.
- Measurement and Report Functions – Besides the basic distance, area, circumference and volume measurement functions, the SONOACE X4 also provides application-specific measurement functions. The report function collates measurement data.
- Review of Scanned Images – The SONOACE X4 displays Cine images of 512 frames and loop images of 4096 lines.
- SonoView - This is a total ultrasound image management system, which allows a user to archive, view and exchange documents.
- DICOM (Digital Imaging and Communication in Medicine) Function - This is used to archive, transmit and print DICOM images through a network.
- Peripheral/Accessory Connection – A variety of peripheral devices including VCRs and printers can be easily connected to the SONOACE X4.

Specifications

Physical Dimensions	Height: 1330mm (with monitor) Width: 450mm Depth: 700mm Weight: More than 63kg
Imaging modes	2D real-time Dual 2D real-time 2D/M-mode Pulsed-wave Doppler 3D-mode Simultaneous
Gray Scale	256 (8 bits)
Focusing	Dynamic transmit focusing, maximum of eight points (four points simultaneo-usly selectable) Digital dynamic receive focusing (continuous)
Probes	**Curved Linear Array** C2-4ES C2-5ET C3-7ED C3-7EP C4-9ED **Linear Array** HL5-9ED HL5-12ED L5-9EC L5-9EE L5-12/50EP **Endocavity Curved Linear Array** EC4-9ED EC4-9ES

Probe connections	2 probe connectors, 3 probe connectors for option.
Monitor	12 inch B/W monitor
Rear Panel Input Connections	VHS and Audio ECG Keyboard Patient monitor video and 9V dc power B/W printer video and remote control VGA monitor Parallel port USB 2.0 2port Foot Switch
Front Panel Input Connections	USB 2.0 2port
Image Storage	Cine memory (maximum 512 frames) Cine memory (maximum 4096 Lines)
Application	General, Gynecology, Abdomen, OB, Renal, Urology, Vascular, Small Part, Fetal Heart, Breast, Musculoskeletal, Cardiac, Neonatal, Pediatric
Electrical Parameters	100-120V/200-240VAC, 8/5A, 50/60Hz
Automatic Calculation and Quantification	Obstetrics Gynecology Cardiology Fetal Echo Vascular Urology * Refer the Chapter 5 for additional information
Signal processing (Pre-processing)	TGC control Mode-independent gain control Acoustic power control (adjustable) Dynamic aperture Dynamic apodization Dynamic range control (adjustable) Image view area control M-mode sweep speed control HD Zoom

Signal processing (Post-processing)	Frame average Gamma-scale windowing Image orientation (left/right and up/down) White on black/black on white
Measurement	Trackball operation of multiple cursors 2D: Linear measurements and area measurements using elliptical approximation or trace M-mode: Continuous readout of distance, time, and slope rate Doppler: Velocity and trace
Auxiliary	Black-and white printer Line printer VCR Monitor Foot switch
Pressure Limits	Operating: 700hPa to 1060hPa Storage: 700hPa to 1060hPa
Humidity Limits	Operating: 30% to 75% Storage & Shipping: 20% to 90%
Temperature Limits	Operating: 10 ^{O}C ~ 35^{O}C Storage & Shipping: -25^{O}C ~ 60^{O}C

Product Configuration and Installation

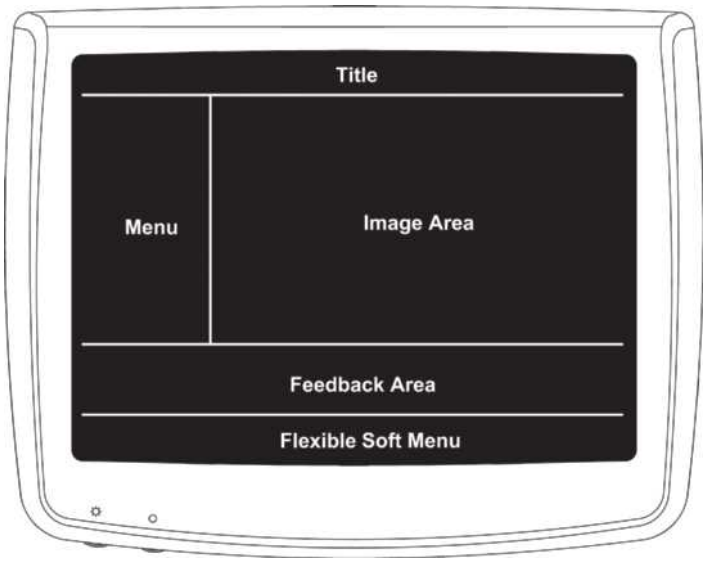
The SONOACE X4 consists of the monitor, the control panel, the console, the peripheral devices, and the probes.

Monitor

The monitor of this system displays ultrasound images and additional information. This monitor is connected to the main body through a central pivot, allowing it to be tilted to the optimal viewing angle.

Monitor Display

The monitor displays ultrasound images, operation menus and a variety of other information. The screen is divided into five sections: Title, Image, Menu, Feedback, and Flexible Soft Menu sections.



[Figure 2.1 Monitor Display]

Title

This section displays the Logo, Patient Name, Hospital Name, Application, Frame Rate & Depth, Probe Information, Acoustic Output Information and Date & Time.

[Figure 2.2 Title]

Image Area

The ultrasound image, image information, annotation, and measurement information are displayed in the image area.

[Figure 2.3 Image Area]

Menu

The menu is divided into 3 kinds: Image adjustment menu, Measurement menu, and Utility menu. Use **Menu** dial-button to select an item from the menu.

[Figure 2.4 Menu –2D, OB, Utility]

Feedback Area

This feedback area provides a variety of information necessary for system use e.g. current system status and Body Markers.

[Figure 2.5 Body Marker Feedback]

Flexible Soft Menu

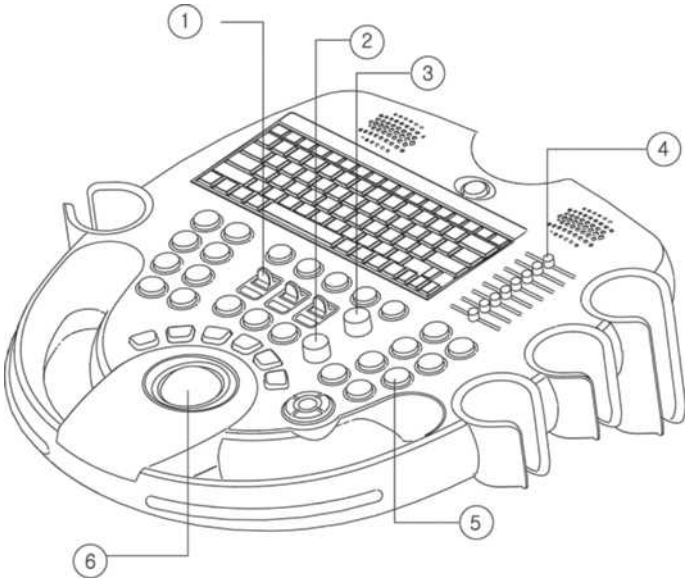
The Flexible Soft Menu is displayed on the screen at all times. The items shown on the monitor vary, depending on the status of the system.

[Figure 2.6 Flexible Soft Menu]

Control Panel

The control panel can be used for controlling the system. It consists of the following four sections:

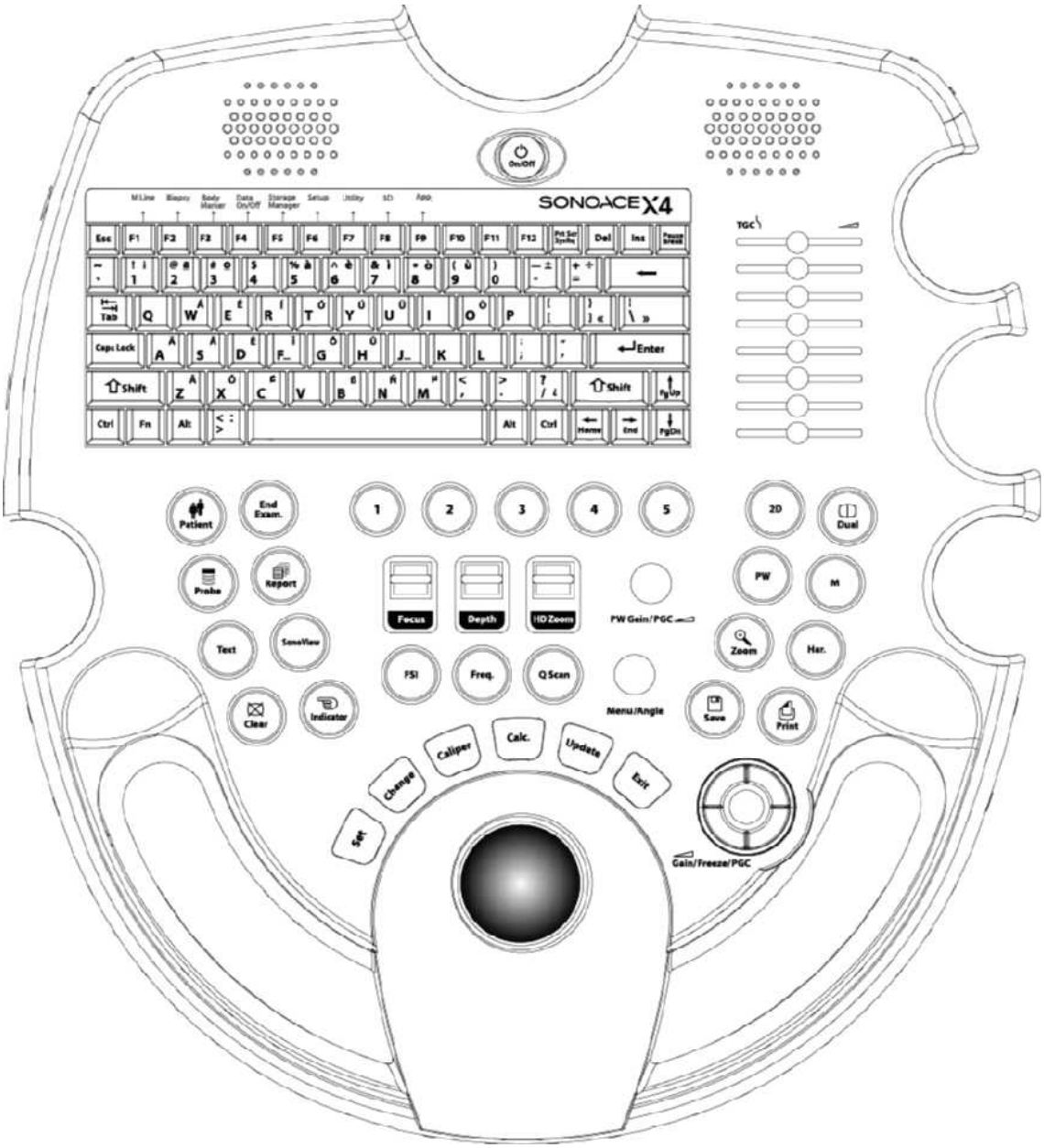
- Function keys for scanning and menu control, located on the center of the control panel.
- Function keys for annotation and measurements, on the left side of the control panel.
- Menu selection buttons, located on the right side of the control panel.
- An alpha-numeric keyboard, located at the top of the control panel.



[Figure 2.7 Control Panel]

The user can manipulate the control panel using ① Slide, ② Button, ③Trackball, ④ Dial-Button, ⑤ Dial, and ⑥ Up/Down Switch. The dial-button can be used both as a dial and a button.

Control Panel Map



[Figure 2.8 Control Panel]

Power On/Off

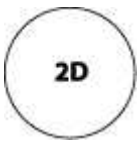
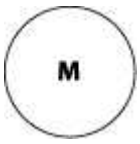
	On/Off	This is used toTurn the system on/off. Press the button for about 1 second to turn the product On for use, and press and hold down the button for 2 seconds to turn the product Off after use. Once turned Off, the system needs a 5-second interval before restarting by pressing the button.

Starting and Finishing Exam

	Probe	This is used to change another probe. If you use Two-probe connector (optional), this is used to appear a window to select/change probes and applications.
	Patient	This is used to appear a window for patient selection and information entry.
	End Exam	This is used to finish the exam of the currently selected patient and reset the related data.

Selecting Diagnosis mode and Gain Control

NOTE	For further information on each Mode, refer to 'Chapter 4. Diagnosis Modes'.

	2D	This is used to view two-dimensional anatomy images in the direction of scanning in real time. Pressing this button while in 2D mode does not turn it off. However, pressing the **2D** button will return the system to 2D Mode from other image modes.
	M	This is used to turn M Mode on. The M Mode is used to observe the motion patterns of objects occurring over time along a single vector. Press this button again to turn M Mode off.
	PW (Optional)	This is used to turn PW Spectral Doppler Mode on. This mode is used to show vascular or cardiac blood flow. 2D Mode can be used simultaneously. Press this button again to turn PW Spectral Doppler Mode off.

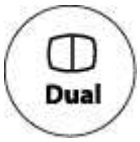
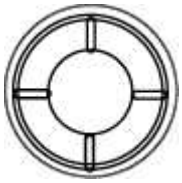
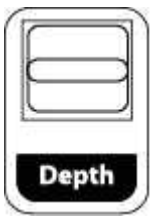
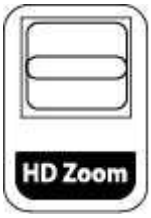
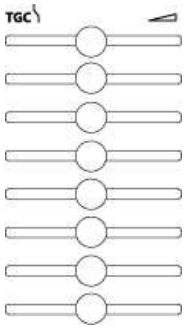
	Dual	This is used to turn Dual Mode on. Dual Mode is used to compare two 2D images. Use the **Set** button **Dual** button or **Update** button to change the activated image in Dual Mode. Press **2D** button to turn Dual Mode off.
	Harmonic	This is used to turn Harmonic Imaging on. Press this button again to turn the mode off. This button is only activated with the specific probe.
	Gain/ Freeze/ PGC	This adjusts 2D Gain, 2D Post Gain or activates the Freeze function. - 2D Gain function – Use the dial in 2D mode to adjust Gain. - Freeze function – Press the button while scanning to stop the video scanning. LED of this button in frozen state is displayed as blue and Cine, Save, Echo Print, and Measurements are available. Press this button again, LED is displayed as green. - 2D PGC(Post Gain Control) function - Changes the post curve in the frozen state to provide effects similar to changing Gain, TGC, DR, etc.
	PW Gain/ PGC	This adjusts PW Spectral Doppler Gain, PW Post Gain.

Image Adjustment

	Focus	This switch is used to focus on the area of interest. Raise/ lower the switch to raise/lower the focusing point.
	Depth	This switch is used to adjust the scanning depth of the image. Raise/ lower the switch to decrease/ increase the scanning depth of an image.

	HD Zoom	Raising this switch causes a Zoom box to appear. Modify the size of Zoom box with the **Change** button and **Trackball**, and press **Set** button to apply it to the image. Press **Exit** button or adjust **Depth** switch to exit. The position of the magnified area can be adjusted with the **Trackball**.
	Zoom	This is used to perform the Read Zoom function. Adjust the size/position of a 2D image with **Change** button and the **Trackball**. Roll the **Trackball** upwards to view the lower portion of the image, and vice versa. To observe the right/left portion of the image, move the **Trackball** to the left/right. Press **Exit** button or **Zoom** button to exit Zoom mode.
	FSI	This is used to synthesize the images obtained with frequencies of different characteristics. Shallow observation depths yield higher resolution and deep observation depths yield higher penetration.
	Frequency	This is used to change the frequency of a probe supporting multi-frequency. Press it to change the frequency setting. If the frequency of the currently selected probe is a ‘General’ one, it displays as ‘GEN’, and the higher and lower frequencies are displayed as ‘RES’ and ‘PEN’, respectively.
	Quick Scan	This is used to adjust Gain, TGC, etc. automatically to optimize Contrast and Brightness. The ‘Q’ mark is displayed on the top of the image. Press this button again to exit.
	Menu/ Angle	**Menu** function - Press dial button to activate the available menu item of current scan mode. Rotate the dial button to the right/left to move up/down a menu. **Angle** function - Adjust the angle of sample volume in PW Spectral Doppler Mode. It is also used to adjust the Indicator angle or the Probe angle of Body Marker.

TGC (Time Gain Control)

	TGC(Time Gain Control)	Eight slides are used to adjust TGC (Time Gain Compensation) values.

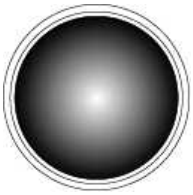
CAUTION	Care should be taken when adjusting TGC values. Too large difference in the gain value settings of two adjacent slides may lead to inaccurate image generation.

Measurement and Annotation

	Caliper	This is used to measure distance, volume, circumference, and area. Press the button repeatedly to cycle through all the available measurement methods.
	Calculator	This is used to appear a different measurement menu, depending on the examination subject and diagnosis mode. The examination subject changes each time the button is pressed. Select an appropriate item to perform the measurement.
	Indicator	This button is used to appear an arrow marker. It points the parts of the displayed image.
	Text	This button is used to enter comments or text on the displayed image.
	Clear	This button is used to erase the text, Indicator, Body Marker, and measurement data from the displayed image.

NOTE	For more information about Measurement, refer to `Chapter 5 Measurements and Calculations'. For more information about annotation, refer to `Chapter 6 Image Managements'.

Trackball and its related control

	Trackball	This is used to move the cursor on the display and to scroll through CINE images.
	Change	This is used to change the current **Trackball** function. It is used during measurements to alter the position of the last point. It is also used to adjust the position of the text cursor.
	Exit	This is used to exit the current mode and return to initial settings.
	Set	This is used in conjunction with the **Trackball** to set a specific item or value.
	Update	This button is used to perform options specific to the current diagnosis mode. In Dual Mode, for example, it is used to change the activated image. Pressing it once causes the scanned image to appear in the right-hand portion of the screen. Pressing it again freezes the right image and activates the left image. In PW Spectral Doppler Mode it is also used to hold a 2D image and activate it again. When this is pressed again after one measurement is finished, another cursor appears.

SonoView and Report

	SonoView	When this is pressed on the keyboard, SonoView, the Image Filing program, is activated.
	Report	When this is pressed on the keyboard, a report program containing measurement results from the current diagnosis mode appears.

NOTE	For more information about SonoView, refer to `Chapter 6 Image Managements' and for more information about Report, refer to `Chapter 5 Measurements and Calculations'.

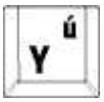
Save and Print

	Save	This is used to save a currently displayed image or measurement report in the system database. The user can manage the saved image and report with SonoView.
	Echo Print	This is used to print out the current image via an Echo printer.

Alphanumeric Keyboard

[Figure 2.9 Alphanumeric keyboards]

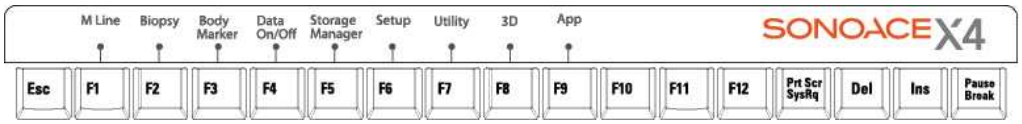
The alphanumeric keyboards are used to type in text. Some function keys are related to measurement.

	Y Key	Press the Y key during biopsy to show guidelines on the screen.
	Z Key	Press this button in HD Zoom mode to hide the Zoom Navigation Box. Press it again to show the box.

Flexible Soft Buttons

	These buttons activate the corresponding Flexible Soft Menu at the bottom of the screen.

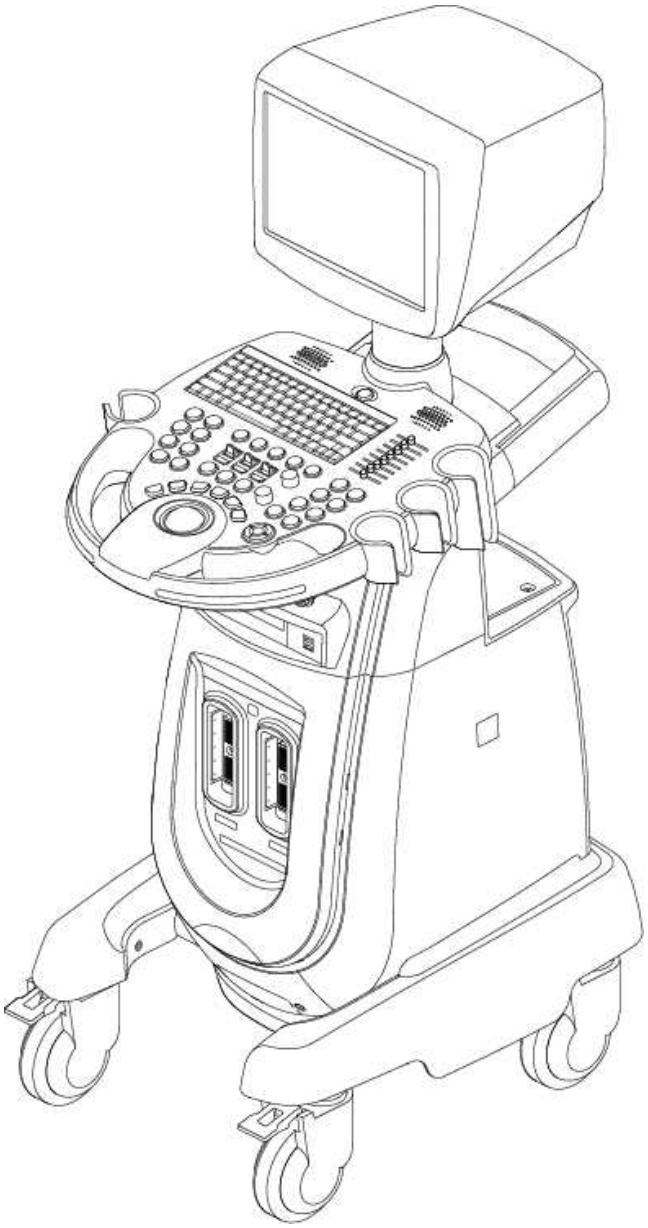
Function Buttons



[F1] M Line	This is used to display M line or hide.
[F2] Biopsy	This is used to start the biopsy.
[F3] Body Marker	This button is used to appear a Body Marker list.
[F4] Data on / off	This button is used to display information of image on the upper right side of screen or hide.
[F5] Storage Manager	This button is used to appear the Storage Manager window, where saving, transmission, backup and other functions are available.
[F6] Setup	This button is used to appear the Setup window for setting system parameters.
[F7] Utility	This button is used to appear the utility menu.
[F8] 3D	This is used to start 3D Mode.
[F9] Application	This is used to appear a window to select/change probes and applications.

Console

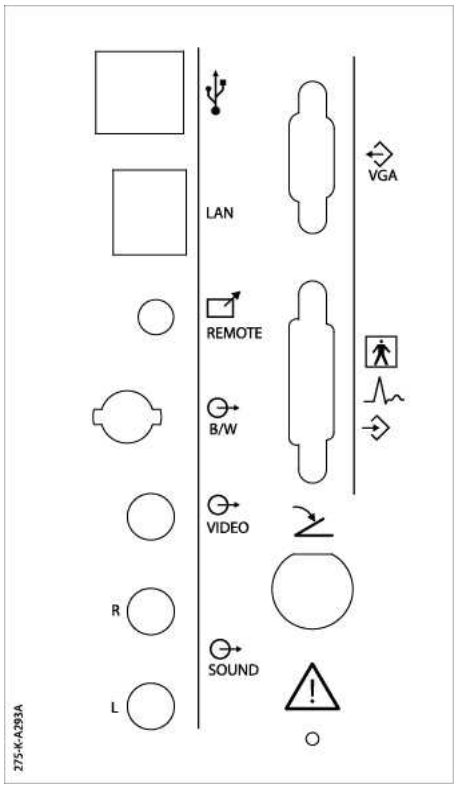
The console consists of two parts – the inner unit and the outer unit. The inner section is responsible for ultrasound image generation. The outer section is designed to support the use of other devices and includes monitor and probe connection sockets, the probe holder, storage devices like HDDs, storage space for peripheral devices and the system power switch.



[Figure 2.10 Console]

Rear Panel

A monitor, printer, VCR, etc. are connected via the rear panel at the back of the system.



[Figure 2.11 Rear Panel]

VGA (Output)

The VGA signal is sent to the monitor.

LAN (Input/Output)

DICOM can be connected via the LAN port. Patient information is transferred to another server via the DICOM network.

Audio (Output)

The input/output of Audio signals is possible.

VHS (Output)

Connect the VCR using the VHS method.

Printer (Output)

Echo printer connection.

Printer Remote (Output)

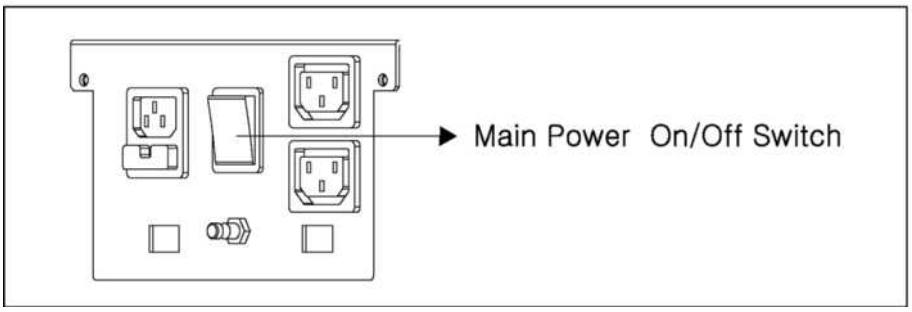
Remote Echo printer connection.

ECG Connector

ECG Module connection.

Main Power On/Off Switch

The main power on/off switch locates under the rear panel. Powers the product On/Off.



[Figure 2.12 Main Power On/Off Switch]

Probe Holder

A probe holder is mounted at the right/left side of the control panel.

Peripherals

Peripheral devices are those that are connected to the main body e.g. VCR, Echo Printer, Foot Switch, etc.

USB

It is possible to connect devices (e.g.: storage devices, USB printers) via the USB connector located at the upper left of the product.

CAUTION	Only connect/disconnect USB devices when the system is turned off. Connection/disconnection of USB devices during power-on may lead to malfunction of the system and USB devices.

- **USB Storage Devices**

  A variety of storage devices can be connected to the SONOACE X4 via the USB port, enabling backup & restore of SonoView or Measure Package data.

  The storage devices support the USB MO Driver, USB CDRW Driver, and Flash Memory media.

  - SonoView supports: USB MO Driver, USB CDRW Driver, Flash Memory media
  - Measure Package supports: USB MO Driver, Flash Memory media

  MEDISON recommends these Flash Memory media;

  - IOMEGA Mini Drive
  - SANDISK Cruzer Mini USB Flash Drive
  - RiDATA EZdrive USB 2.0
  - Imation iFLASH USB 2.0
  - Imation Blue 1GB
  - Transcend Zet Flash

CAUTION	The USB MO Driver should not be used with other USB storage devices.

- **USB Inkjet Printer**

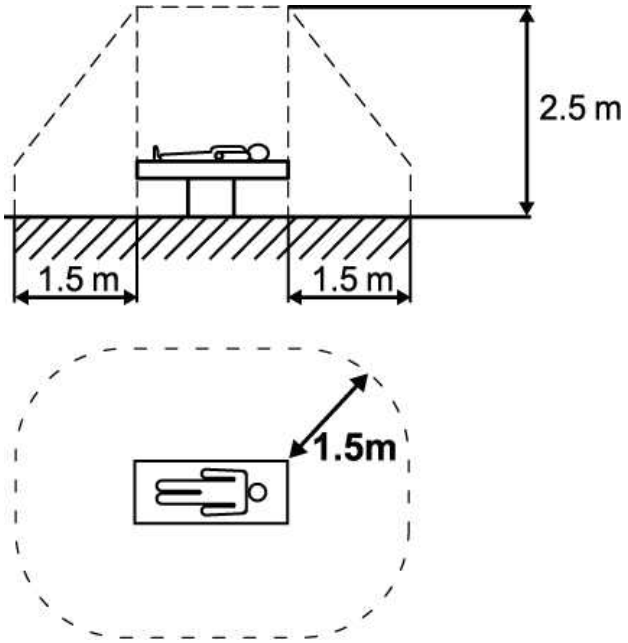
  The SONOACE X4 supports a Post-script compatible printer. It can be connected to the USB port.

  This system supports HP DeskJet 880C, HP DeskJet 895C, HP LaserJet 1200, HP DeskJet 6122, HP DeskJet 5550, HPDeskJet5650, HP DeskJet 6540,

HPDeskJet5940, HP DeskJet 6840, HPDeskJet6940, HPDeskJet6980, HP LaserJet 1320, HP LaserJet 2420, HP Color LaserJet 3600, HP Laserjet P2015, HP Business Inkjet 1200series, HP OfficeJet Pro K550, and HP Officejet 5780.

CAUTION	Contact MEDISON Customer Service Center for inquiries about printer driver installation.

Do not place an inkjet printer inside the patient environment.



[Figure 2.13 The patient environment]

- **USB to RS-232C Serial Cable**

The system uses the function of Open Line Transfer for report transfer. Connect the USB to RS-232C Serial Cable to the USB port.

MEDISON recommends the following USB to RS-232C Serial Cable;
- USB to Serial (RS-232C) Converter with FTDI Chipset (FTDI FT232BM Compatible)

NOTE	For more information about the Open Line Transfer, refer to `Chapter 5. Measurements and Calculations'.

Foot switch Connector

The footswitch connector is located at the rear panel.

Probe

Probes are devices that generate ultrasound waves and process reflected wave data for the purpose of image formation.

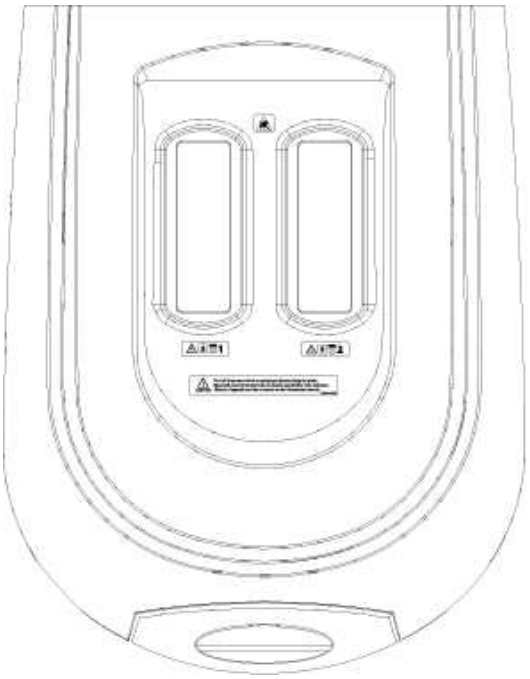
NOTE	For more information, refer to `Chapter 8 Probes'.

Connecting probes

Be sure to connect or disconnect probes when the power is off to ensure the safety of the system and the probes.

1. Connect probes to the probe ports on the front panel of the system. A maximum of two probes (three probes optional) can be connected at one time.
2. Turn the connector-locking handle clockwise after inserting the probe into the probe port.

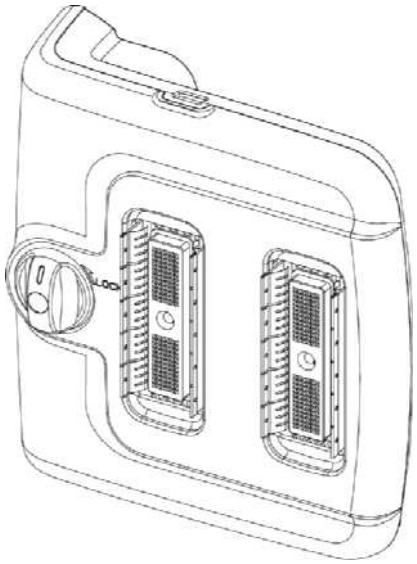
When the system is powered on, the probe last in use is automatically activated.



[Figure 2.14 Probe Connector]

※How to connect Two-probe connector (Optional)

You can connect a maximum of three probes with this two probe connectors.



[Figure 2.15 Two-probe connector]

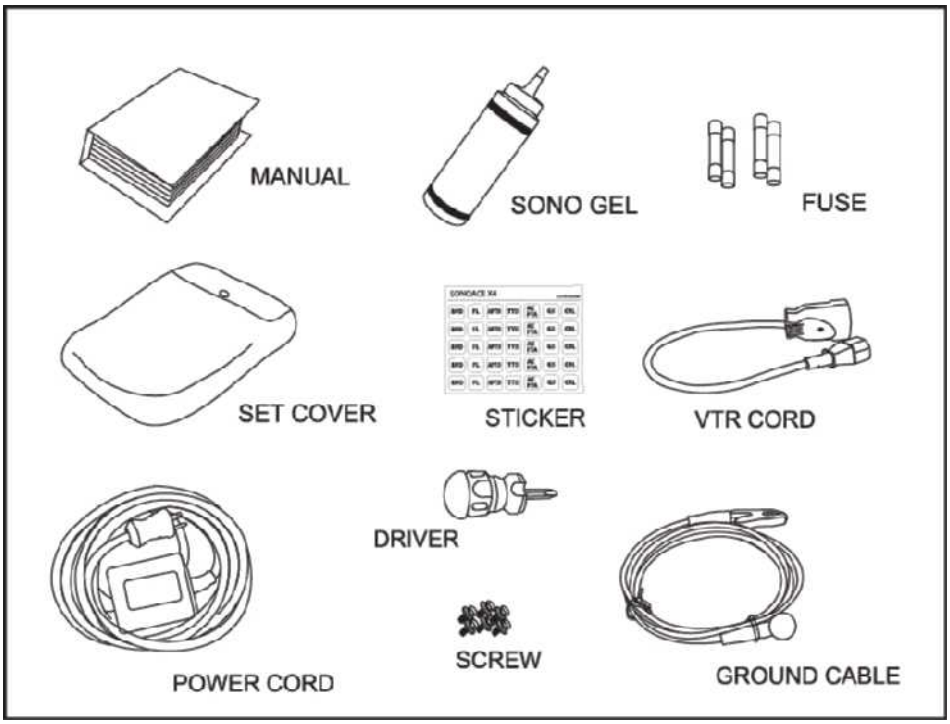
1. Please turn off the power button off before connecting the Two-probe connector to the system.
2. Insert the Two-probe connector to the right side of probe connector on the console of the system.
3. Lock the connector by turning the knob clockwise.
4. Connect the USB port of the Two-probe connector and the console with the USB cable.

To disconnect the Two-probe connector from the system, disconnect USB cable and probes. And then, turn the knob counter-clockwise.

Accessory

This system provides a box including accessories.

CAUTION	**Main cord set, separately certified according to the relevant standards, is to be used when supplied to EU and USA/CAN.**



[Figure 2.16 Accessories]

NOTE	Accessories can be different according to the country.

Options

The SONOACE X4 has the following optional functions:

- Freehand 3D
- SONOVIEW
- DICOM
- Pulse Wave Doppler

For further information, please refer to the relevant chapters in this manual.

Chapter 3

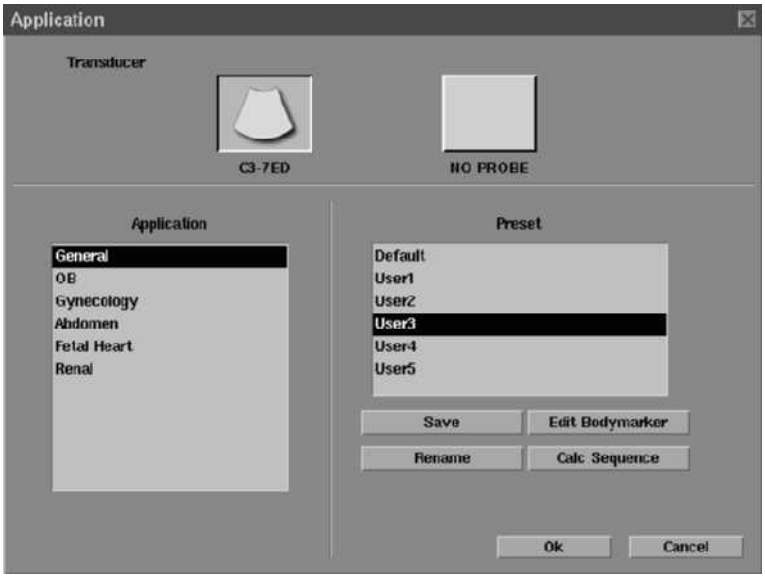
Setting

Selecting Probe / Application

Before scanning, select a probe and an application. Refer to `Chapter 8 Probes' for more information about the probes available for this system.

On the control panel, press the **[F9] Application** button to bring up the Application window on the screen. This window can be used to select or change applications and probes, and to edit probe preset.

NOTE	To switch to another probe without using Application window, press **Probe** button on the control panel.



[Figure 3.1 Application]

Probe /Application Selection

1. Select a probe and an application using the **Trackball** and **Set** button.
2. After selecting them, click **Ok** in the Application Window. To cancel the selection, press **Cancel**.

Application Change

1. After checking the currently selected probe, select an application using the **Trackball** and **Set** button.

2. After selecting it, click **Ok** in the Application Window. To cancel the selection, press **Cancel**.

Probe Setting Change

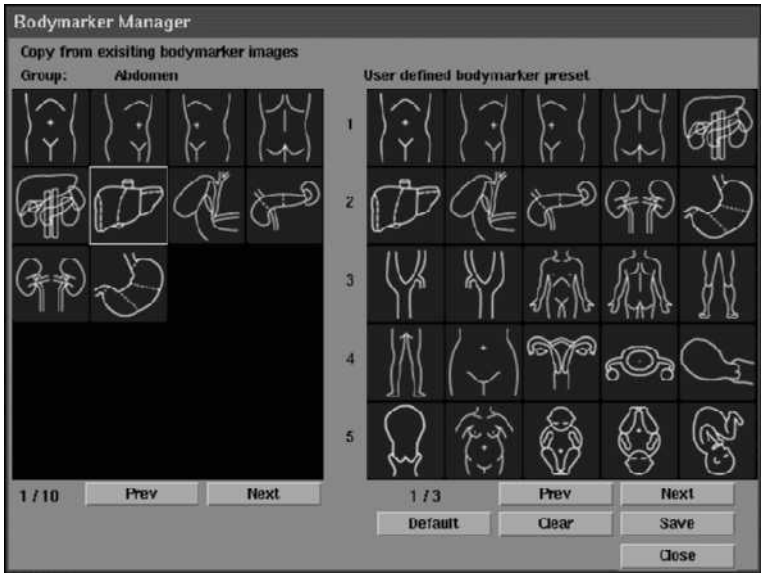
While the probe settings are preset with the optimal values for each application, the user may change the preset values using the following method.

1. After checking the currently selected probe/application, change the probe setting using the **Trackball** and **Set** button. Click **Save** to save the changed values.
2. Click **Ok** in the Application Window. To cancel the selection, press **Cancel**.
3. Change the names of the user-definable settings other than 'Default' values using the **Rename**.

To change the probe setting values, see 'Utility'.

Editing Bodymarker

Press **Edit Bodymarker** in the application window to bring up the bodymarker manager. Select some bodymarkers to use in the system or change the order of bodymarkers.



[Figure 3.2 Bodymarker Manager]

'Group' shows system supporting bodymarkers with the application. Use **Prev** or **Next** to display Bodymarkers of other applications.

'User defined Bodymarker preset' shows selected bodymarekrs.

Add Bodymarkers

Select a bodymarker on 'Group' using the **Trackball**. Press **Set** button to add to the 'User defined Bodymarker preset'.

Delete Bodymarkers

Select a bodymarker on 'User defined Bodymarker preset' using the **Trackball**. Press **Set** button to delete.

Change the order of Bodymarkers

Select a bodymarker on 'User defined Bodymarker preset' using the **Trackball**. Press **Set** button to delete. With pressing the **Exit** button on the control panel, move the position using the **Trackball**. Release the **Exit** button to finish changing the order.

Back to default Bodymarker

Press the **Default** on 'User defined Bodymarker preset' to back to default Bodymarker.

Delete all Bodymarkers

Press the **Delete** on 'User defined Bodymarker preset' to delete all bodymarkers. It deletes bodymarkers only in 'User defined Bodymarker preset'.

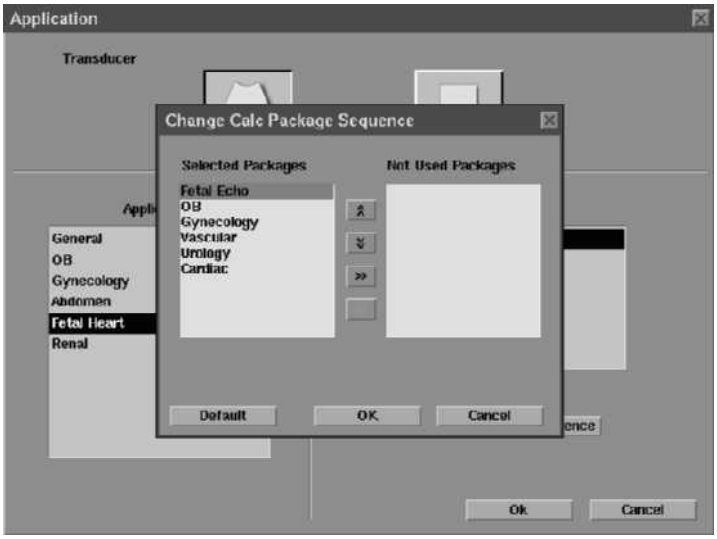
Save Bodymarkers

Press the **Save** on 'User defined Bodymarker preset' to save current setting. When you press the **Bodymarker** button on the control panel during using the system, this setting will be displayed.

NOTE	Refer to `Chapter 6 Image managements' for more information about displaying Bodymarker.

Calc Sequence

To change the order and content of the Calculation Package of each application, click the **Calc Sequence**. If you want to return to the initial settings, click **Default** in the window.



[Figure 3.3 Calc Package Sequence Change]

Probe Frequency Change

To change Probe Frequency in scanning, press **Frequency** on the control panel. The probe frequency setting is displayed in the Probe Information Display Area:

GEN : General frequency	RES : High frequency	PEN: Low frequency

Entering Patient Data

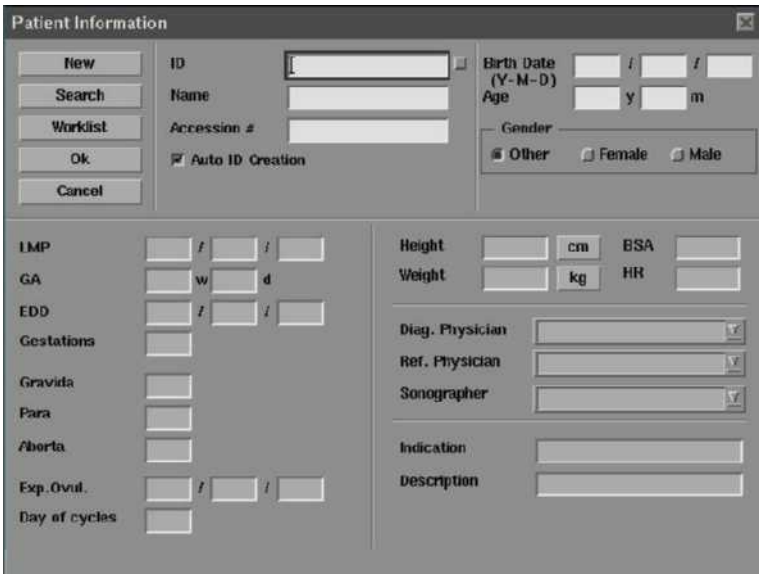
Be sure that the patient information has been correctly entered before scanning.

The patient information includes basic information such as patient ID, patient name, birth date, gender as well as other application specific data.

NOTE	Patient ID and name are mandatory information when registering a new patient.

All patient data are classified according to the patient ID. If the ID is not entered, the **Ok** is not activated. (Extra information can be entered when needed.)

Press **Patient** on the control panel, and the Patient Information window shown below appears. You can register and modify patient information.



[Figure 3.4 the Patient Information]

Registering a New Patient

1. After clicking the **New**, enter the patient name, ID and other information using the **Trackball**, **Set** button and keyboard.
   - While **Auto ID Creation** is checked, click the **New**. A new Patient ID is automatically provided by the system.
   - When an existing ID is entered, the **ID** field icon changes to .
2. After entering patient information correctly, click **Ok**. Or click **Cancel** or **X** to cancel.

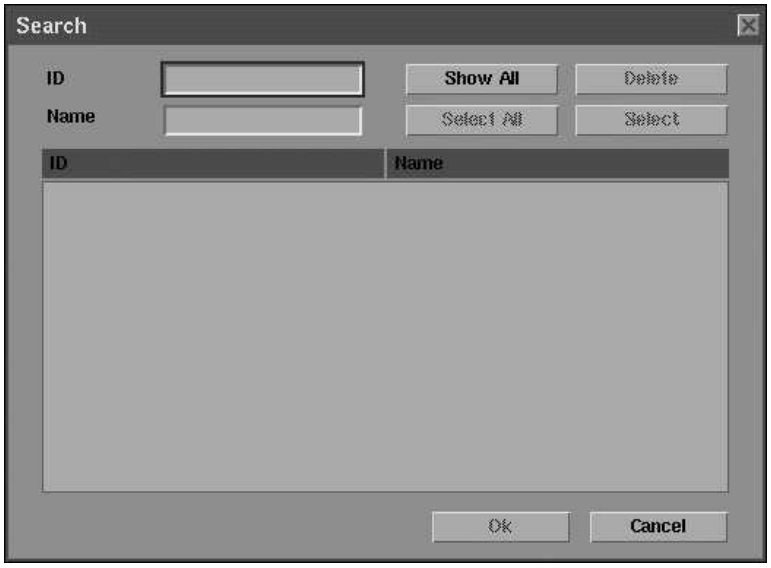
Finding Patient Information

Finding Patient Information using ID

Enter the Patient ID to change his or her information.

Finding Patient Information using the Search Function

1. Click **Search** in the Patient Information window, and the Search window shown below appears.



[Figure 3.5 Patient Search]

2. Type in patient ID or name, and the list of registered patients appears.
   - If there is no ID or name that satisfies the search key, the **Select** and **Ok** are not activated.
   - To display all registered ID, click **Show All**. To select all ID on the list, click **Select All**.
   - To delete the ID and its all information, select the patient and click **Delete**.
3. After selecting ID, press Select or Ok to display information of the selected patient. To stop the search or close the current search dialog box, click **Cancel** or **X**.

WARNING	If a patient ID is deleted, all data and images stored in SonoView are erased.

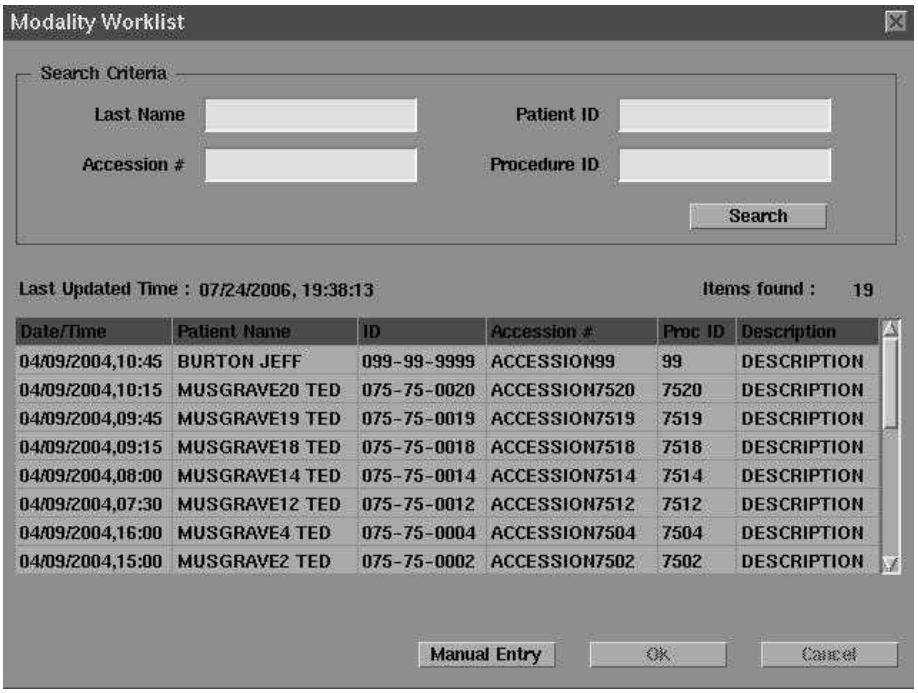
Finding Patient Information using Worklist

The system connects to the hospital's DICOM Modality Worklist server and obtains information on scheduled patients and examinations. Searching a patient by Worklist allows you to enter the patient information automatically.

NOTE	Use the **DICOM** tab in the Settings screen to select the Worklist server. For more information, see "DICOM Settings."

1. Press **Worklist** in the Patient Information screen and the Modality Worklist window will appear. (If "Open MWL on Patient Key" is selected under the DICOM server settings, pressing the **Patient** button opens the Modality Worklist window first.)
2. Select Worklist Server, enter one or more search conditions in "Search Criteria", and then press **Search** button. A list of scheduled patients that match the search conditions will appear.
3. Select a patient and press **OK**. The patient information will appear.
4. Press the **X** button on the window to quit searching patients and close the Modality Worklist window. If you wish to enter patient information directly without using Worklist data, press **Manual Entry**.

NOTE	ID, Name, Accession #, Birth, Age, or Gender cannot be changed when entering patient information by using Worklist.



[Figure 3.6 Modality Worklist]

Modifying Patient Information

To modify information in the Patient Information window:

1. Modify the information using the **Trackball**, **Set** button and keyboard.
2. After modifying patient information correctly, click **Ok**. To cancel editing, click **Cancel** or **X**.

NOTE	For more details on patient backup, see the 'Information Management' section in 'Chapter 6. Image Managements'.

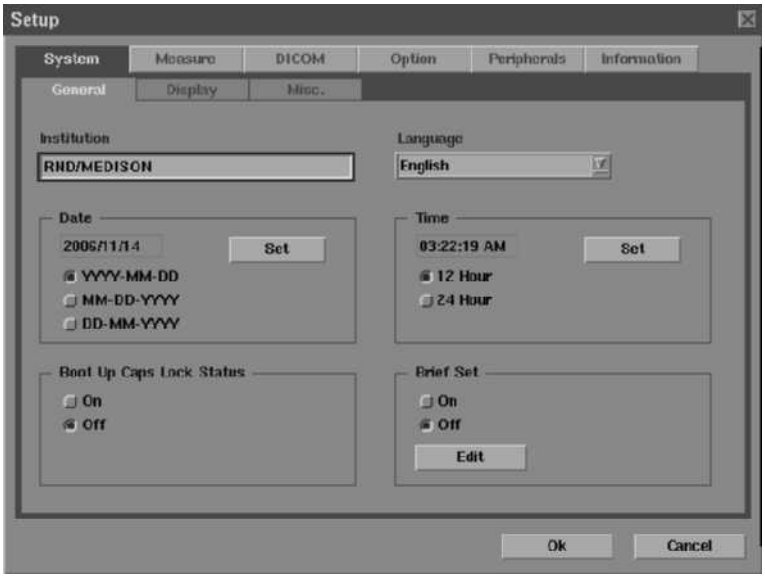
Setting System

This mode is used for system settings. It does not affect image output. The setup may be modified depending on specific needs or preferences.

1. Press the **[F6] SetUp** button on the keyboard. Setup window is appeared.
2. Select **System** in the Setup menu.
3. Set the specific system values according to each item on the screen.
4. Press **Ok** to finish the setup. To close the screen, press **Cancel** or **X.**

General

Select the **General** tab in the **System** menu.



[Figure 3.7 System Setup – General]

■ **Institution**

Enter the name of the hospital/institution.

■ **Language**

This sets the language to be used. English, Deutsch, Français, Italiano, Español, Russian, and Simplified Chinese are available. To display the screen in the selected language, reboot the system after completing setup.
The input setup of key button is automatically updated.

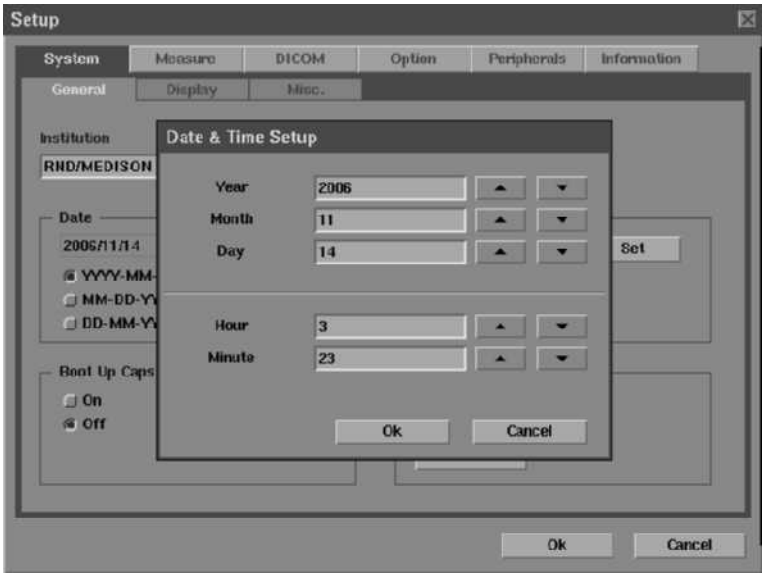
■ **Date**

Set the date and its format.

■ **Time**

Set the time and its format.

※ How to set the date and time.



[Figure 3.8 System Setup – Date/Time]

1. Click **Set** in the **Title** tab of System menu.
2. Set the Date/Time using the **Trackball** and **Set** button.
3. After finishing setup correctly, click **Ok**. To cancel setup, click **Cancel**.

■ **Boot up caps lock status**

This menu sets the initial status of Caps Lock after system boot-up. Its default value is 'Off'. This Caps Lock enables capital letter entry without the need to press the **Shift** key.

■ **Brief Set**

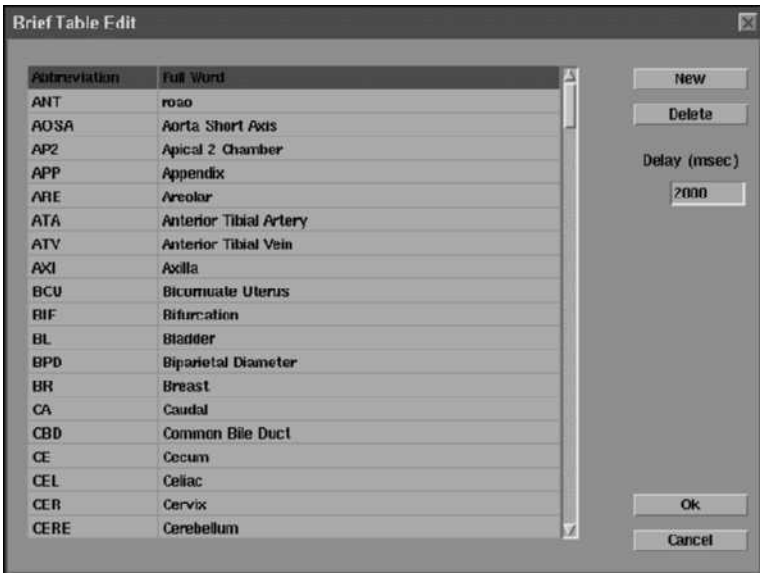
Select **Brief Set** to use the brief text function. Its default value is 'Off'.

Using the brief text function allows fast and easy input of text statements. For example, to enter the text 'Tumor', you only need to enter 'Tu' and the system will search the word from the abbreviation list and automatically enter the word 'Tumor'.

※ How to edit the Brief Set.

Press the **Edit** button on the screen. The Brief Table Edit table window will be appeared. To add a new abbreviation, click **New**, and to completely delete an existing abbreviation, click the entry to be deleted and then click **Delete**.

'Delay(msec)' sets seconds to input the full word after enter the abbreviation. The unit value is msec, and 1000msec is 1second.



[Figure 3.9 Brief Set Edit]

Display

To set the information about images and related data, select the **Display** tab in the **System** menu.

■ **Auto Freeze**

After the preset time span (Minute) of inactivity, the scan mode is automatically frozen.

■ **Screen Saver**

After the preset time span (Minute) of inactivity, the screen saver is automatically started.

■ **Post Map**

This sets the display of the Post Map in the Feedback section at the bottom of the screen.

■ **TGC Line**

This sets whether or not the TGC line is displayed. If 'Off' is selected, the TGC Line is not shown. If 'Off after 3 seconds' is selected, the TGC value appears when a TGC value is adjusted, but disappears after 3 seconds. If 'On' is selected, the TGC Line is always shown.

■ **TI (Thermal Index)Display**

The system sets TI values automatically. However, this menu allows the user to choose manually from one of the three TI parameters as desired: Default, TIs or TIb.

■ **HPRF Set**

Enable or disable High Pulse Repetition Frequency (HPRF) supported in the PW Spectral Doppler mode. If it is set to 'On,' HPRF is supported by default.

■ **Bodymarker After Freeze**

Determine whether the system will automatically switch to the Body Marker mode when the **Freeze** button is pressed. If it is set to 'On,' a Body Marker appears when the **Freeze** button is pressed during scanning. If it is set to 'Off,' a Body Marker appears when **[F3]** is pressed during scanning.

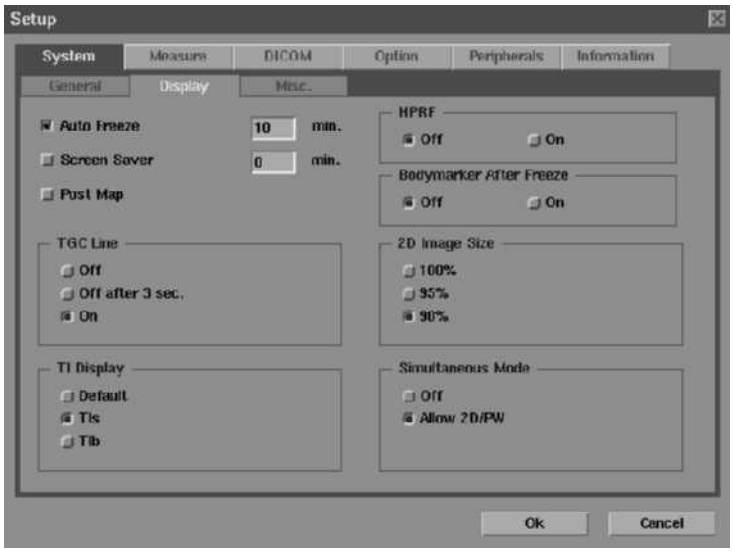
■ **2D Image Size**

The Image size can be set to 100%, 95% or 90%.

■ **Simultaneous Mode**

This menu determines whether or not simultaneous mode is enabled in PW Spectral Doppler Mode.

- 'Off': Select this if you do not wish use simultaneous mode.
- 'Allow 2D/PW: Select this if you wish to use simultaneous mode in 2D/ PW mode.



[Figure 3.10 System Setup – Display]

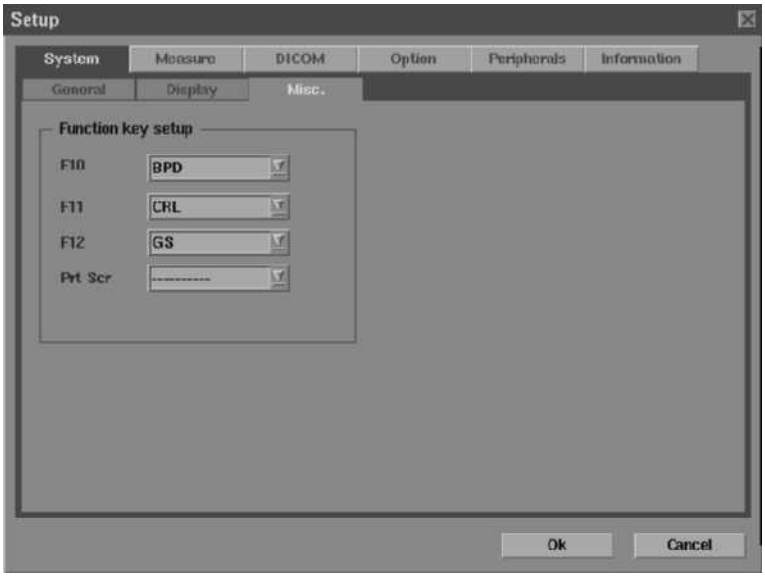
Miscellaneous

Select the **Misc.** tab in the **System** menu.

- **Function Key Setup**

  Assign commonly used obstetrics measurement items to the F10, F11, F12, Print Screen (Prt Scr) keys in the alphanumeric keyboard. You can use this feature to start a desired obstetrics measurement instantly while scanning.

  The measurement items that can be assigned are as follows: BPD, FL, APTD, TTD, AC/FTA, GS and CRL.



[Figure 3.11 System Setup – Display]

NOTE	Adhesive labels for obstetrics measurement items are included in the accessories box that comes with this product. You can place these adhesive labels above the function keys to help distinguish them.

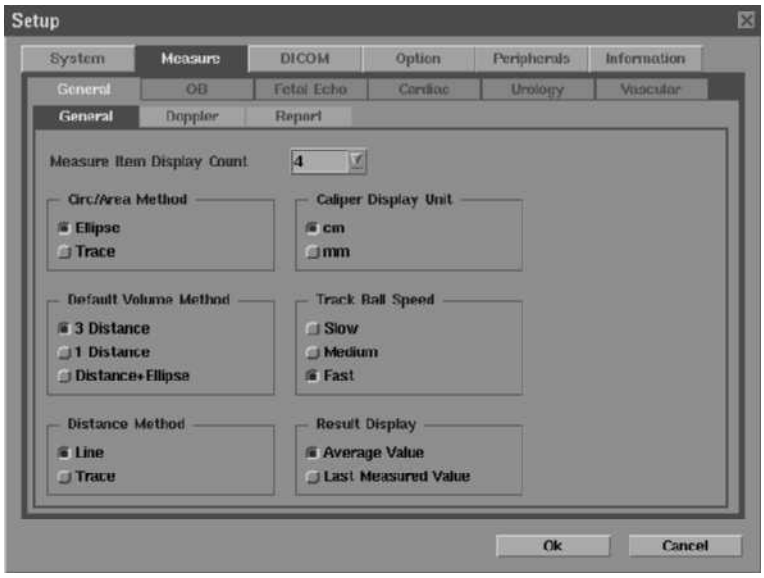
Setting Measurements

Select **Measure** in the Setup menu to set up measurement functions.

1. Press the **[F6] SetUp** button on the keyboard. Setup window is appeared.
2. Select **Measure** in the Setup menu.
3. Set the specific system values according to each item on the screen.
4. Press **Ok** to finish the setup. To close the screen, press **Cancel** or **X**.

General

Select the **General** tab in the **Measure** menu to set general measurement settings.



[Figure 3.12 Measurement Settings- General]

General

Select **General** tab.

■ Measure Item Display Count

Select the number of measurement items to be between 1 and 4. If you select 'Hide', measurement items are not displayed.

■ **Circ/Area Method**

Select either the ‘Ellipse’ or ‘Trace’ caliper to be the default tool for measurement.

■ **Default Volume Method**

Select either the ‘3 Distance’, ‘1 Distance’ or ‘Distance + Ellipse’ items to be used as the default tool in volume measurement.

■ **Distance Method**

Set either ‘Line’ or ‘Trace’ as the distance measurement method.

■ **Caliper Display Unit**

Set either ‘cm’ (centimeter) or ‘mm’ (millimeter) as the caliper display unit.

■ **Trackball Speed**

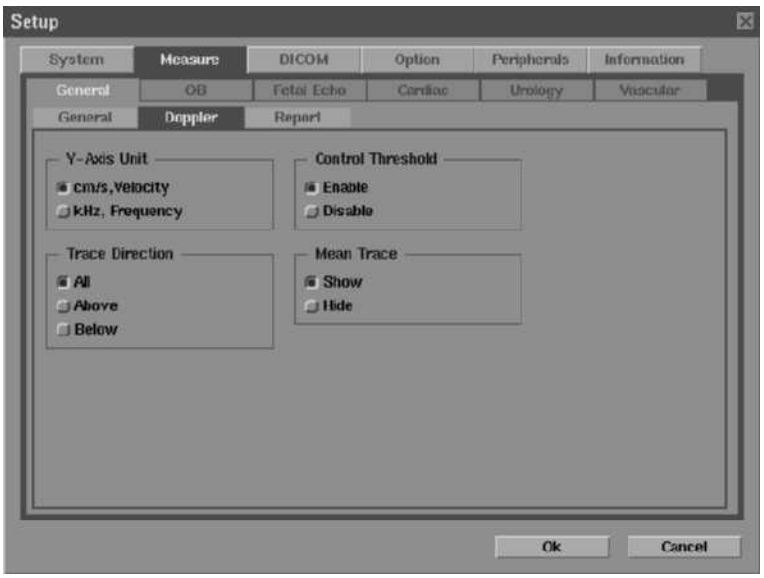
Set the Trackball speed to either ‘Fast’, ‘Medium’ or ‘Slow’.

■ **Result Display**

Set the output format of measurement results in the report. When ‘Average Value’ is selected, the report shows the average value of the last three measurement results. When ‘Last Measured Value’ is selected, the last measurement value is shown.

Doppler

Select the **Doppler** tab in the **General** tab.



[Figure 3.13 Measurement Settings- Doppler]

■ **Y-Axis Unit**

This sets the vertical (Y) axis unit in Spectral Doppler Mode.

■ **Trace Direction**

When Auto Trace and Limited Trace functions are used in Spectral Doppler Mode, this sets the range of the measurement values.

■ **Control Threshold**

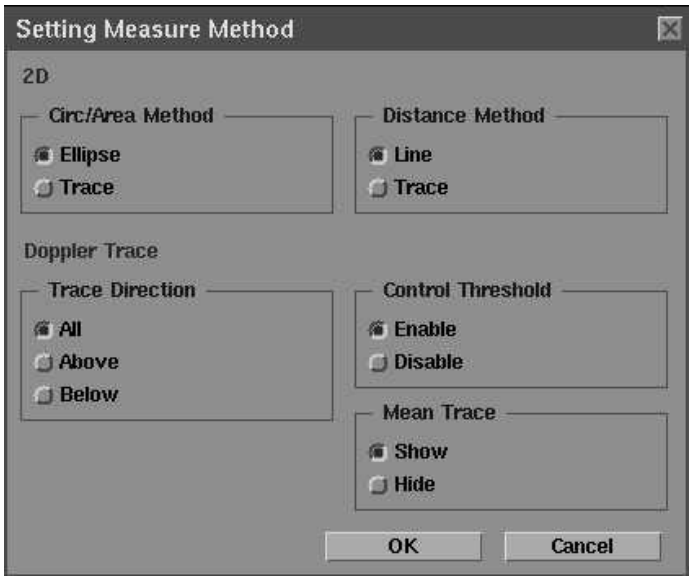
The trace threshold can be adjusted by rotating the **Menu** dial-button when tracing is not finished after Auto trace / Limited trace.

■ **Mean Trace**

This menu specifies the use of Mean Trace Line on the screen for Auto trace / Limited trace.

※ How to change Doppler setting during measurement

Press the space bar after pressing the **Calculator** button to bring up the Setting Measure Method window shown below.

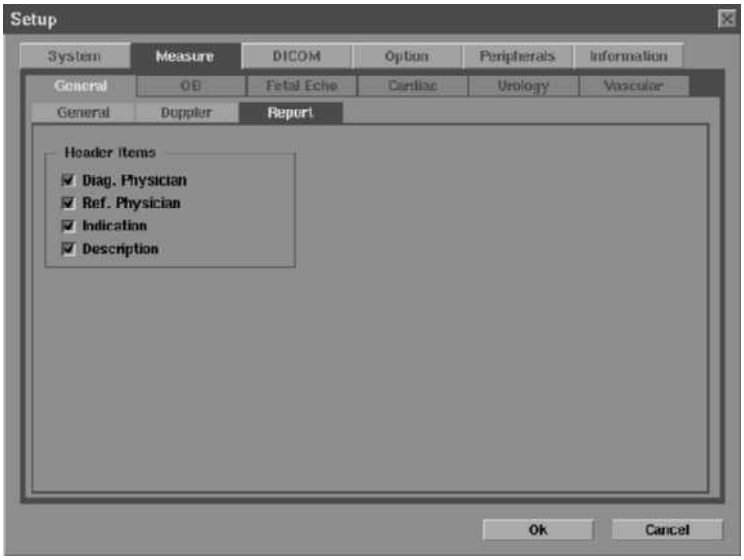


[Figure 3.14 Setting Measure method]

Report

Select the **Report** tab in the **General** tab.

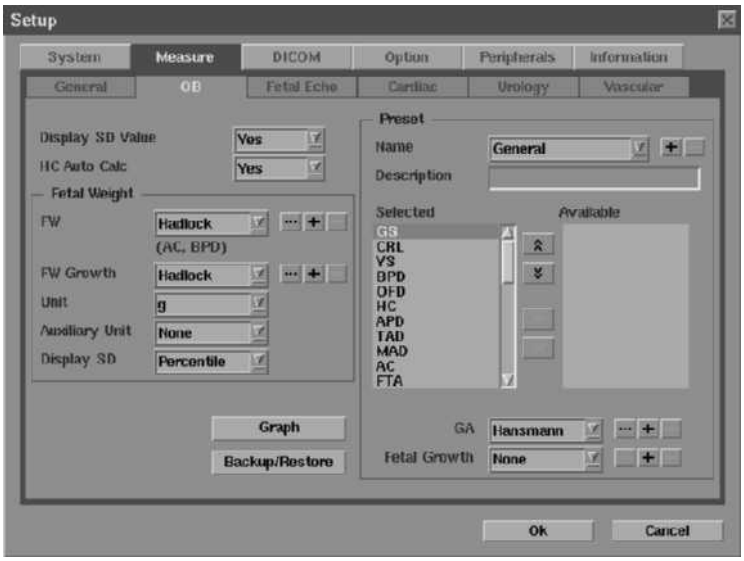
Select items to mark the header on the report. The header will be shown only the item has its data.



[Figure 3.15 Report Setting]

Obstetrics Measurement Setup

To set up obstetrics related measurement, select the **OB** tab in the **Measure** menu.



[Figure 3.16 Measurement Settings – Obstetrics]

■ Display SD Value

This menu sets whether SD (Standard Deviation) is displayed or not. If ‘Yes’ is selected, the SD value is shown on the screen and on the report. If ‘No’ is selected, it is not shown and its range value appears on the report.

■ **HC Auto Calc**

This menu is used to set the HC Auto Calculation. 'Yes' shows the HC value on the screen and in the report using the result of OFD and BPD calculation. 'No' will not show the HC value on the screen.

■ **Fetal Weight**

This menu is used to set the measurement items used for fetal examination. In the fetal weight and fetal weight growth fields, more measurement items can be added.

- Unit: This sets the unit of fetal weight measurement. You can choose from grams [g], ounces [oz], and pounds [lb].

- Auxiliary Unit: This sets the auxiliary unit of fetal weight measurement. Unit sets the available auxiliary unit. For instance, set the unit as Gram [g], available units are None, oz, lb, or lb+oz. If you select lb+oz as an auxiliary unit, the value will be shown like as xx lb yy oz.

- Display SD: This menu sets the SD information shown in the result display section: No, SD or Percentile. Both SD and Percentile appear in the report.

■ **Preset**

Measurement items used during exams are set.

Set a specific preset in the Name field. If 'General' is selected, all items can be used. If 'Fetal Biometry' is selected, only Fetal Biometry-related items can be used.

- User Preset

If the + beside the Name field is selected, a user can set a new preset.

Enter a title in the Preset Name field and a brief explanation in the Description field. Press **Ok**.

[Figure 3.17 New Preset window]

After a new preset is made, register items in the right-hand list to use in obstetrics measurement. When « is clicked, the items in the right list are moved to the left list to be used with the user preset. To delete the items from the left list, select them and click ».

To delete a user preset, select it and click . Because `General and Fetal Biometry' are system presets, cannot be deleted.

- Table and Equation

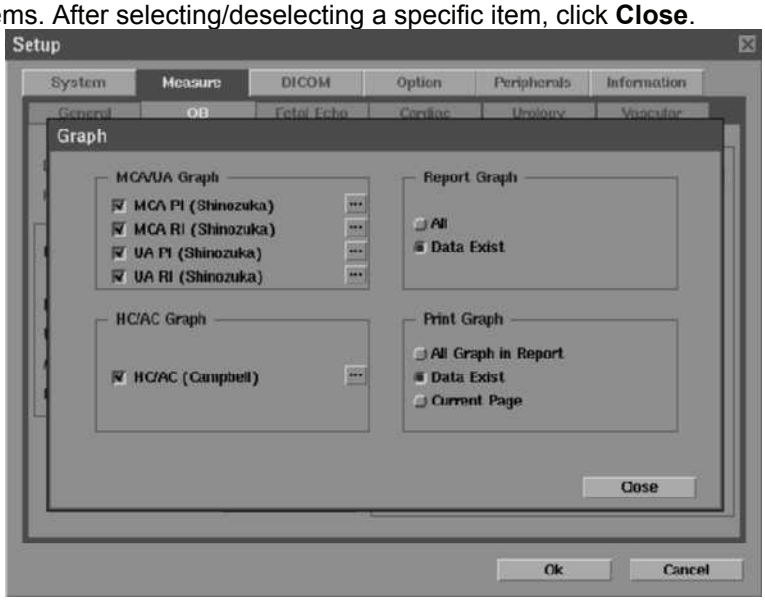
The measurement items used in the Preset menu are GA and Fetal Growth. The measurement values of GA and Fetal Growth are shown in table or equation form.

When is clicked, the contents of the GA or Fetal Growth's table and equation contents are shown. When is clicked, a user can set a specific value, and when is clicked, the table and equation set by the user are erased. However, the default values provided by the system are not erased.

For more information about each table and equation, refer to the Reference Manual.

■ Graph

The user can select graphs to mark on the OB report or print. Press **Graph** button and select items. After selecting/deselecting a specific item, click **Close**.



[Figure 3.18 Graph window]

- MCA/UA Graph

Select MCA/UA graphs (MCA PI, MCA RI, UA PI, and UA RI) to include in the OB report.

- HC/AC Graph

Include HC/AC ratio in the graph.

- Report Graph

Select graph to include in the report. 'All' displays all graphs, and 'Data Exist' displays only the graph has its data.

- Print Graph

Select graph to print. ‘All Graph in Report’ prints all graphs of the report, and ‘Data Exist’ prints only the graph has its data. ‘Current Page’ prints the current page of report.

■ Backup / Restore

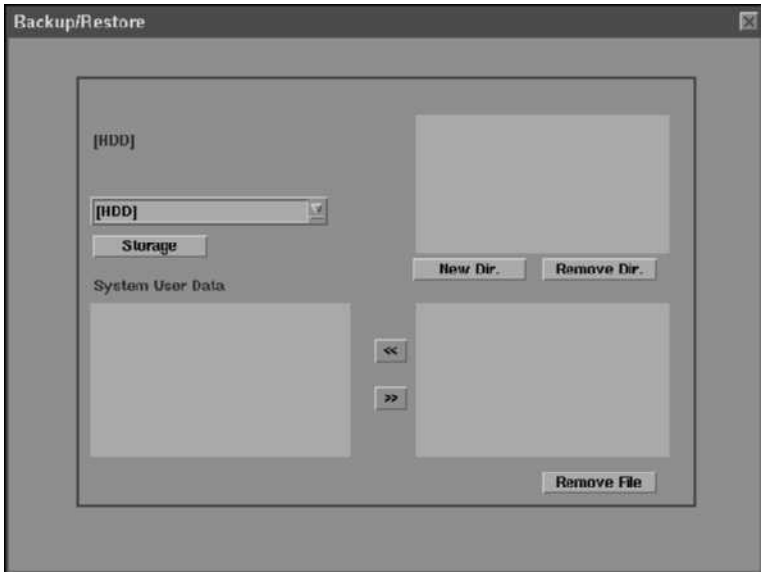
- **Backup**

If you want to back up a new user preset to Mo Media, Flash Memory or a HDD, press **Backup/Restore** on the screen. When the setting window is displayed, select the disk and directory. Directories can be created or deleted using the **New Dir.** or **Remove Dir.** Take care when deleting directories or files. Once a file or directory is erased, it cannot be restored.

During user-preset backup, all user reference tables/equations are backed up. Separate tables/equations backup is therefore not necessary.

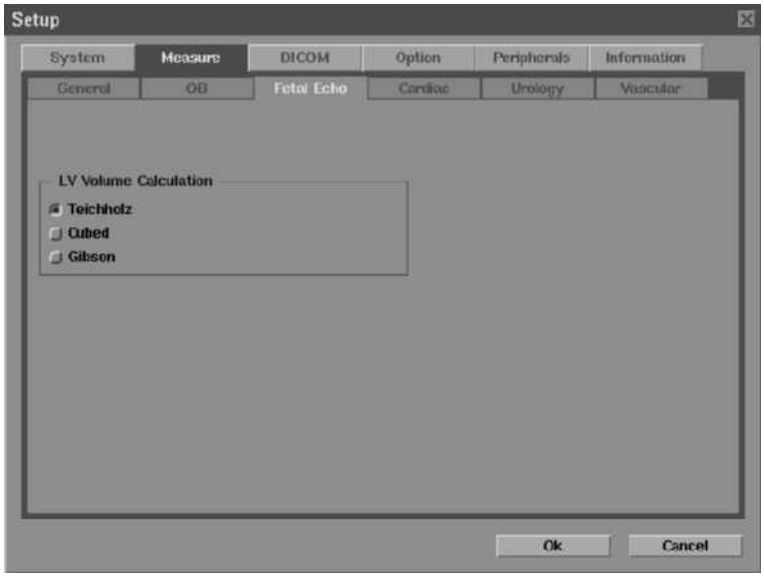
- **Restore**

To bring up the backed up user preset, click **Backup/Restore**. When the **Backup/Restore** screen appears, select the disk and directory which the user preset is to be restored to.



[Figure 3.19 Measurement Settings- Backup/Restore]

Fetal Echo Measurement Setup



[Figure 3.20 Measurement Setting– Fetal Echo]

During obstetric measurement, Fetal volume can be measured in M Mode. The calculation method is set in the 'LV Volume Calculation'.The options are the same as those in the cardiac package (Teichholz, Cubed, or Gibson).

Cardiac Measurement Setup

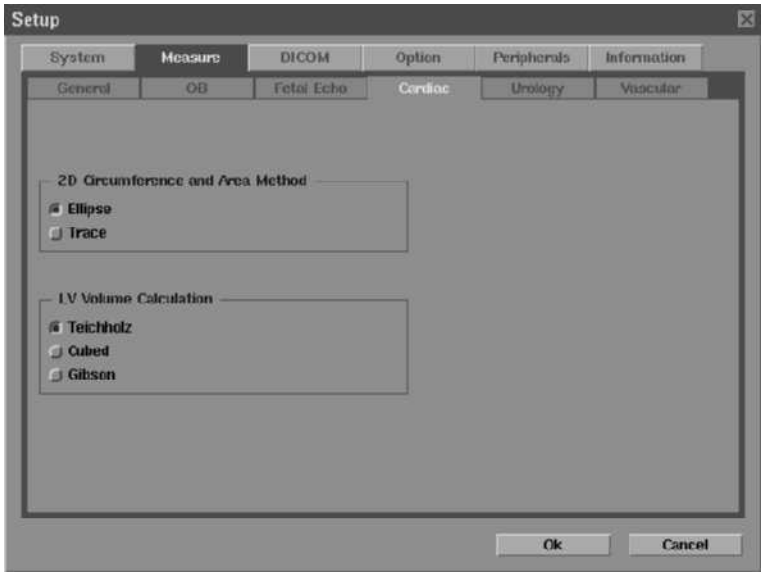
To set up cardiac measurement, select the **Cardiac** tab in the **Measure** menu.

■ **2D Circumference and Area Method**

Select either the 'Ellipse' or 'Trace' caliper to be the default tool for area measurement.

■ **LV Volume Calculation**

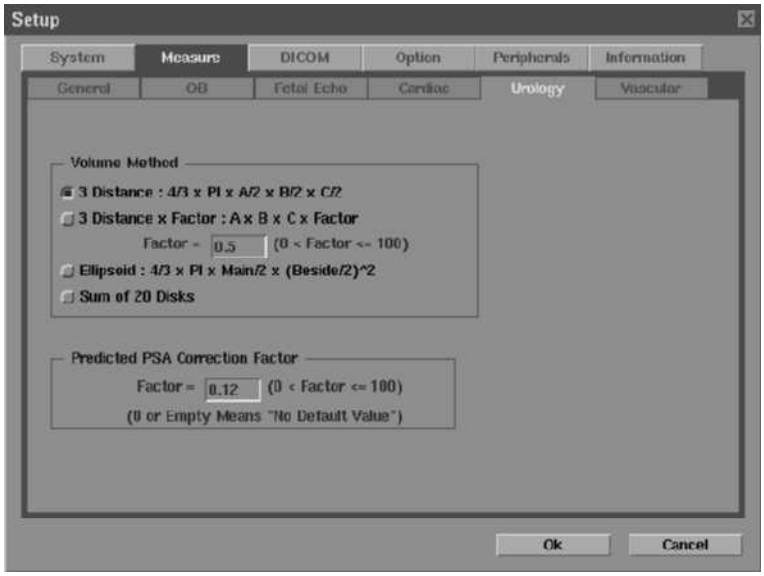
The LV Volume Calculation method is set with this menu.



[Figure 3.21 Measurement Setting window – Cardiac]

Urology Measurement Setup

To set up urology measurement, select the **Urology** tab in the **Measure** menu. This menu sets the formula used to calculate volume values during urology measurement.



[Figure 3.22 Measurement Setting window – Urology]

■ **Volume Method**

- 3 Distance: The volume value is calculated using three diameters in the longitudinal and transverse planes. (4 / 3 x 3.14 x A x B x C / 8)
- 3 Distance x Factor: The volume value is calculated using three diameters from the longitudinal plane and transversal plane and a factor (F) value entered by a user. (A x B x C x F)
- Ellipsoid: The volume value is calculated using the lengths of the Main axis and the beside axis. (4 / 3 x 3.14 x Main / 2 x (Beside / 2)^2)
- Sum of 20 Disks: The volume value is calculated by summing the areas in the 20-parallel planes. (d / 20 x (A1 + A2 + ... A20), d : the sum of distances between disks)

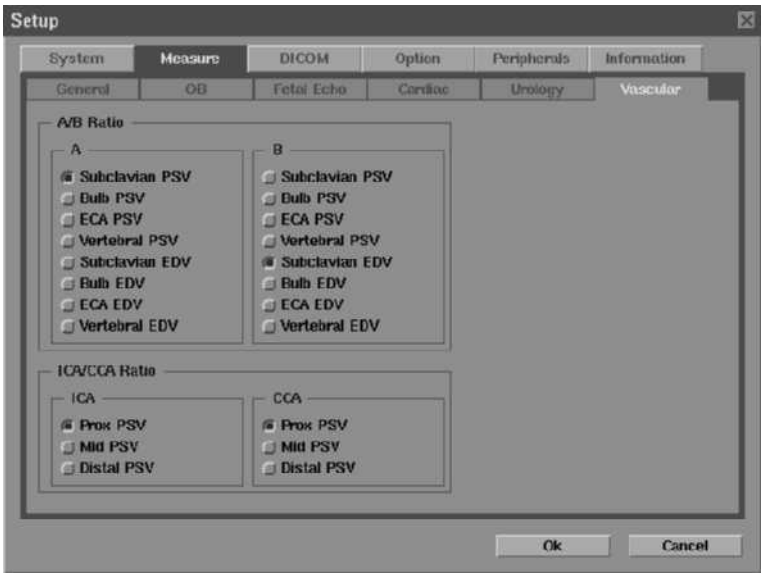
NOTE	3 Distances: A = 1st Dia. ; B = 2nd Dia. ; C = 3rd Dia. The default factor value (F) is '0.5'. If it is changed, a value between 0 and 100 (0 < factor <= 100) is recommended.

■ **Predicted PSA Correction Factor**

The Predicted PSA Correction Factor can be changed. The default value is 0.12.

Vascular Measurement Setup

Select the **Vascular** tab in the **Measure** menu. You can set the peak velocity used in the calculation of the 'A/B Ratio' and 'ICA/CCA Ratio'.

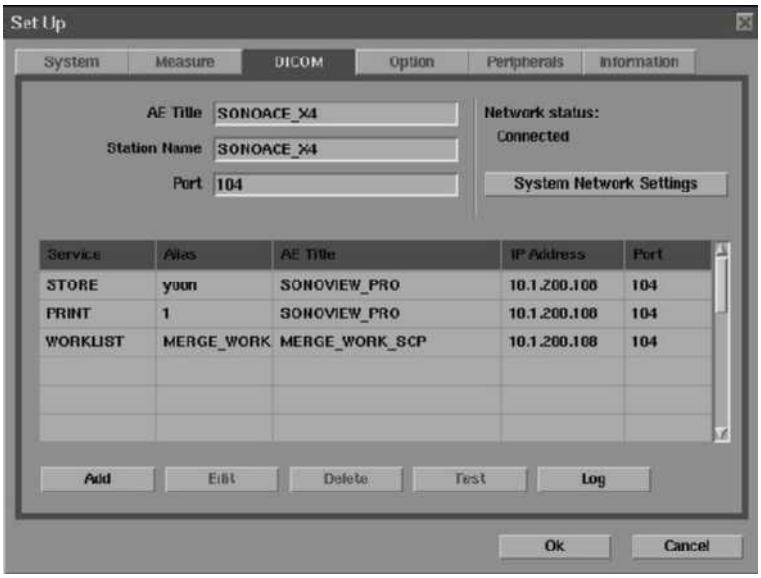


[Figure 3.23 Measurement Setting window – Vascular]

Setting DICOM (Optional)

Select the **DICOM** tab in the Setup menu. This function is used to set up the DICOM server and other DICOM-related functions.

NOTE	For more information, refer to the user manual of the corresponding server and the DICOM Conformance Statement.



[Figure 3.24 Setting DICOM]

Setting DICOM Information

Enter the DICOM information for the product in use. For automatic DICOM transmission, select 'Acquisition in Progress' after completing the fields. For automatic print out, select 'Print After Each image'.

- **AE Title**

  Enter the DICOM Application Entity title of the ultrasound system. This title uses to distinguish the ultrasound system in the network. (Ex. US, US2)

- **Station Name**

  Enter a name to differentiate pieces of ultrasound system. (Ex. SONOACE1, SONOACE2)

- **Port**

  Enter the Port Number of the server being used.

- **Network Status**

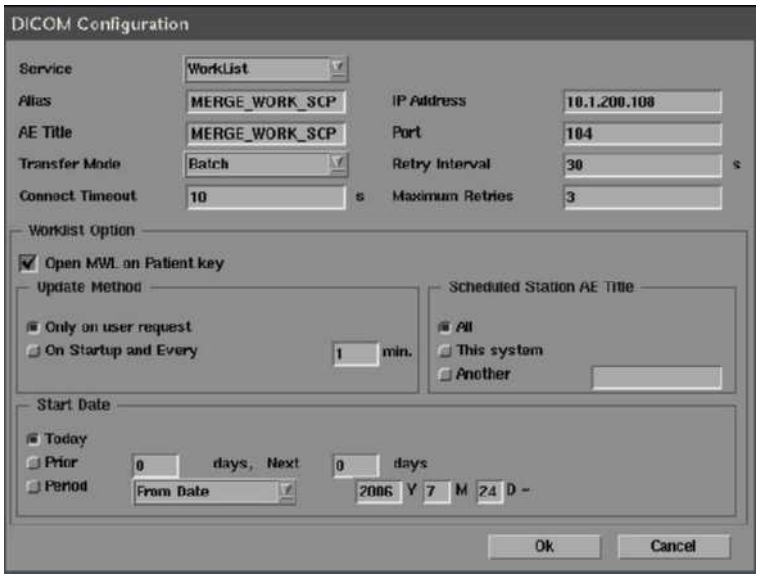
  Display the current status of the network.

Network Setup

To set the network like IP address, press **System Network Settings.** To set the IP value automatically, press 'Using Dynamic IP Configuration'. If you enter the wrong IP address, the network will not run.
To finish the network setup, press the **Apply**. To cancel setup, press the **Close**.

Adding or Changing the DICOM Server

Press **Add** to enter the information related to the DICOM Server.



[Figure 3.25 DICOM Configuration]

- **Service**

  Select the kind of server to use.

- **Alias**

  Enter the name of the server being used.

- **AE Title**

  Enter the AE title of the server being used.

- **Transfer Mode**

  Select any one of the three image transfer methods.

  - Batch: send all images when you click the **End Exam**.
  - Send As You Go: send the image whenever you press the **Save** button.
  - Manual: send the image manually only in the SonoView.

- **Connect Timeout**

  Set how many seconds the system will wait until get response.

- **IP Address**

  Enter the IP address of the server being used.

- **Port**

  Enter the Port Number of the server being used.

- **Retry Interval**

  Set how many seconds the system will wait if the transmission fails.

- **Maximum Retries**

  Set how many times the system will retry.

Worklist Server Settings

- **Open MWL on Patient key**

  Sets the screen that appears when pressing the **Patient** button on the control panel.

  If this function is selected, pressing the **Patient** button opens the Modality Worklist window. If not selected, pressing the **Patient** button opens the Patient Information screen.

- **Update Method**

  Sets the method for updating Worklist.

  - Only upon user request: Pressing **Search** in the Modality Worklist window updates Worklist.
  - On Startup and Every_ Min.: Worklist is updated at the system boot-up and then updated continually at a set interval. Note that Worklist is not updated while the Modality Worklist window is open.

- **Scheduled Station AE Title**

  Sets the range of AE Title to fetch from the hospital's Worklist server.

  - All: Obtains the list of patients saved under all AE Titles within the server.
  - This System: Obtains the list of patients for the AE Titles set under the DICOM tab.
  - Another: Obtains the list of patients for the AE Title directly entered by the user.

NOTE	This function is available only if when the Worklist server is configured.

- **Start Date**

  Set the range of dates to search.

  - Today: Obtains the list of patients for the current date.

  - Prior_days, Next_days: Obtains the list of patients for dates between n days prior to the current date and n days after the current date.

  - Period

    From Date: Enter a date and the system obtains the list of patients starting from the date entered up until the current date.

    To Date: Enter a date and the system obtains the list of patients starting from the current date up until the date entered.

    From Date To Date: Enter two separate dates and the system obtains the list of patients between the two dates entered.

Editing the DICOM Server Information

Press **Edit** in the setting DICOM window to edit the server information already entered.

Deleting DICOM Server

Press the **Delete** in the setting DICOM window to erase the current server information.

Testing DICOM Server

Press the **Test** in the setting DICOM window to check the connection between the system and the DICOM server.

DICOM Log

Press the **Log** in the setting DICOM window, and the screen will be changed. Set or copy the current DICOM log file.

DICOM log file is the history of all DICOM services performed so far on the product.

Press the **Close** to finish the DICOM log.

- **Log Settings**

  Set the DICOM Log.

- Delete archived log file after: set the number of days to wait before deleting the archived history. After that period, the log file will be deleted. However there is only one log file, it will not be deleted.
- Log File Maximum Size: set the maximum size of each history file archived. Set the unit as Kbytes.

■ **Explanation**

View the log setting.

■ **DICOM Log**

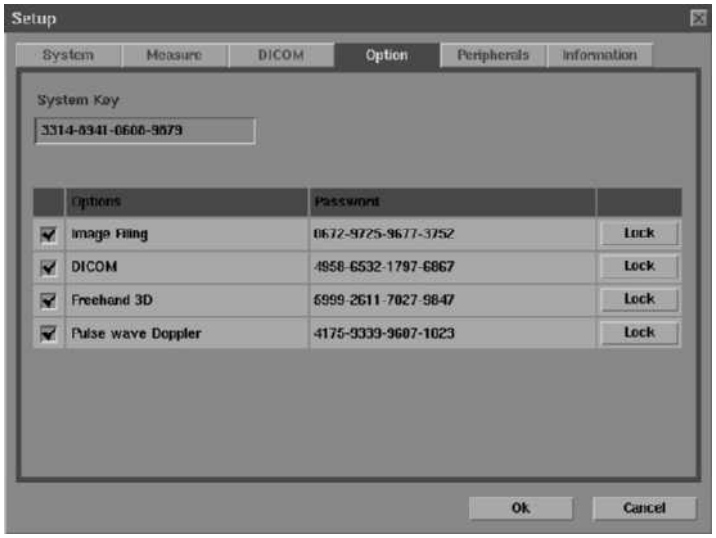
View, copy, or delete the DICOM log files.

- View Selected File: Select the log file from ‘Select log files to copy’ and press the **View selected file**.
- Copy Selected Files:
  1. Select the log files and set the storage file format on the ‘Copy to’.
  2. Set the ‘Delete files after copy’ whether to delete the log files saved in the hard disk of the system.
  3. Press the **Copy selected files**.
- Delete Selected Files: Select the log file and press the **Delete Selected Files**.

Setting Option

The S/W serial No information of the system is shown in this window. You can select/cancel S/W options. A user cannot modify options. Select the **Option** tab in the Setup menu.

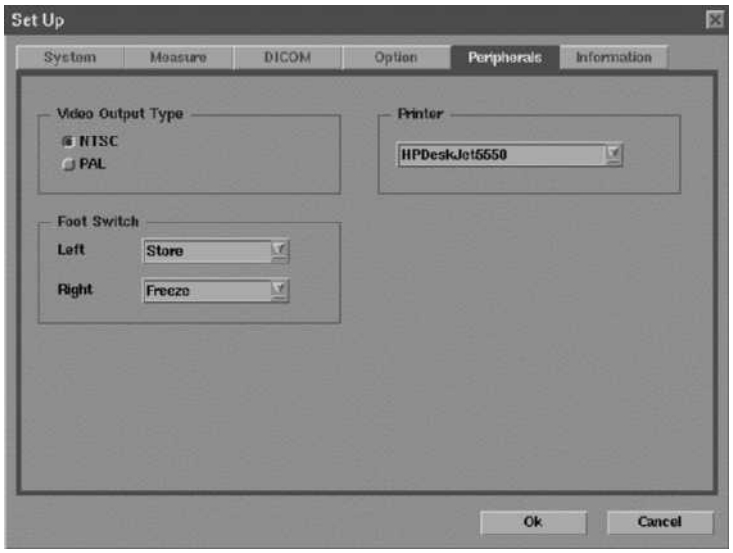
If the password you enter is not correct, the options are not activated. If the password is not correct, click **Cancel**.



[Figure 3.26 Setting Option]

Setting Peripheral Devices

The following describes how to set up the video output type, video input type, printer, foot switch and network. Select the **Peripherals** tab in the Setup menu.



[Figure 3.27 Peripherals Setting]

■ **Video Output Type**

Set the output type of the VCR Port as NTSC or PAL. The setting is applied immediately after setup.

■ **Foot Switch**

Assign functions to the left and right pedals of the foot switch. Four options are available: Dual, Store, Freeze and Update.

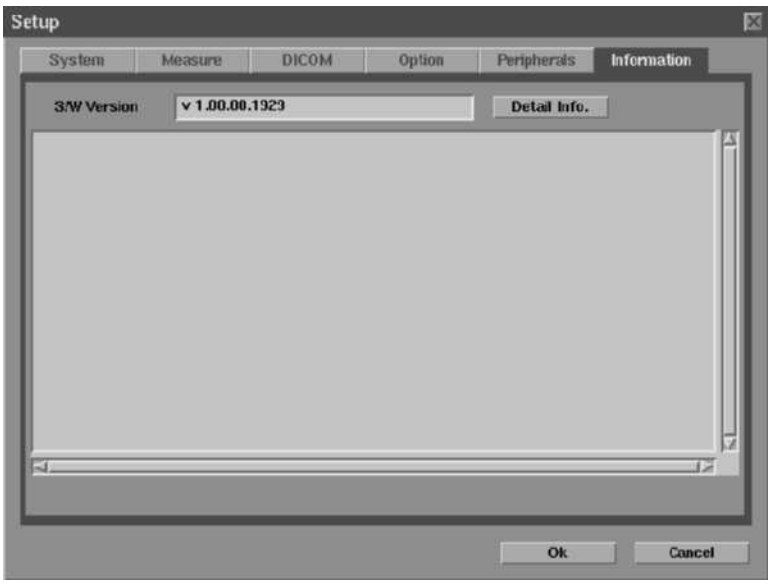
■ **Printer**

Select a printer to use. This system supports HP DeskJet 880C, HP DeskJet 895C, HP LaserJet 1200, HP DeskJet 6122, HP DeskJet 5550, HPDeskJet5650, HP DeskJet 6540, HPDeskJet5940, HP DeskJet 6840, HPDeskJet6940, HPDeskJet6980, HP LaserJet 1320, HP LaserJet 2420, HP Color LaserJet 3600, HP Laserjet P2015, HP Business Inkjet 1200series, HP OfficeJet Pro K550, and HP Officejet 5780. After connecting a USB printer to the USB port of the system, select the printer type on the screen and click **Ok**. The printer can then be used immediately.

The USB printer can only be used to print out Report and SonoView screens.

Information

The information menu displays information about the system S/W version. Select the **Information** tab in the Setup menu. Press the **Detail Info.** to view more detailed information.

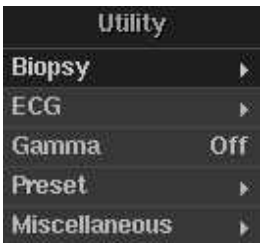


[Figure 3.28 Information]

* The S/W version of your system may be different from that in the figure above.

Utilities

Press **[F7] Utility** button on the keyboard. The **Utility** menu appears at the left side of the screen. You can select a menu with the **Menu** dial-button on the control panel.



[Figure 3.29 Utility menu]

Biopsy

The Biopsy function is designed to obtain cells of abnormal tissue via the Biopsy Needle.

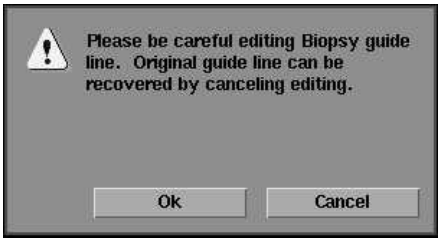
To change Biopsy Guideline settings, press **Utility** button on the control panel. If Biopsy Guideline is disabled you cannot mark guidelines on the screen.

NOTE	Prior to use Biopsy, edit the biopsy guideline first.

Editing Biopsy guide line

[Figure 3.30 Biopsy Edit]

1. Select **Edit** in the Biopsy menu. The message below appears on the screen.

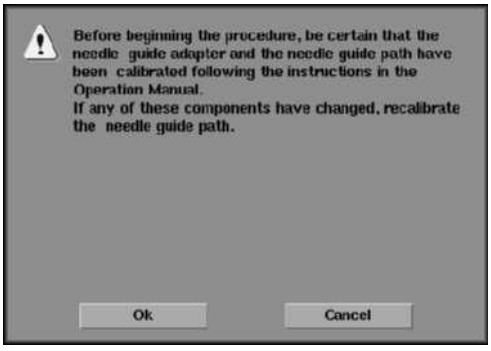


2. If you press the **Ok**, the Biopsy Edit screen appears. Press the **Cancel** to escape from the Biopsy menu.
3. After the Biopsy Edit screen appears, you can adjust the Biopsy Guide Line with the soft menu on the keyboard.
   - **Flexible soft button [1] Start**: Move the **Trackball** up and down to designate the starting point of the Biopsy Guide Line.
   - **Flexible soft button [2] Angle**: Move the **Trackball** right and left to decide the direction of Biopsy Guide Line movement.
   - **Flexible soft button [4] Save**: The following figure appears. Press [Ok] to save the edited Biopsy Guide Line.

   - **Flexible soft button [5] Cancel**: Cancels the current operation, and returns to the previous menu.
   - You can change the function of the **Trackball** to 'Start' or 'Angle' with the **Change** button on the control panel.

Displaying Biopsy guide line

1. Select **On** in the Biopsy menu. The message below appears.



2. To start biopsy click **Ok**. To cancel the current operation, press **Cancel.**

ECG

The ECG (echocardiogram) function allows viewing of the cardiac pulsation.

To turn on ECG, select **ECG** in the pop-up menu. The ECG setting menu appears.

[Figure 3.31 ECG]

- **ECG** : Set ECG On or Off.
- **Size** : Set the size of ECG. ‘Large’, ‘Normal’, or ‘Small’ is available.
- **Position** : Set the position of ECG from 0 to 300. When its number is large, ECG will be displayed in upper side of screen.
- **Trigger** : Set the Trigger interval or Off.
- **Trigger Time** : Set the Trigger time.

CAUTION	If the ECG is less then 30Hz, the Heart Rate (HR) is not displayed.

Dual ECG

Compare two cardiac images.

Press **Dual** button on the control panel. Use the **Set** button or **Dual** button to change the activated image in Dual Mode.

Gamma setting

Select **Gamma** and turn the **Menu** dial-button to select a value.

This function is used to set up contrast and brightness. You can choose from ‘off, Weak, Medium, and Hard’

- **Weak** : This function produces a bright image
- **Hard** : This function produces a dark image.

Preset

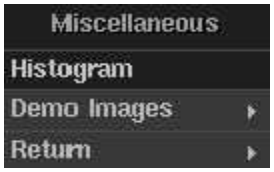
Preset allows the user to adjust Image Settings and select a Setting to apply to the system.
Select **Preset** in the utility menu.

[Figure 3.32 Preset]

- Setting: Use the **Menu** dial-button to make your selection. You can use the default Image Setting or choose from the User1 ~ User5 slots. If you select the value from User1 to User5, you can setup the image setting.
- Load: Select the desired Setting value and press **Load** to apply the value to the current screen.
- Save: After Image Setting, select the desired Setting value and press the **Save**.

Miscellaneous

Select **Miscellaneous** in the utility menu.



[Figure 3.33 Miscellaneous]

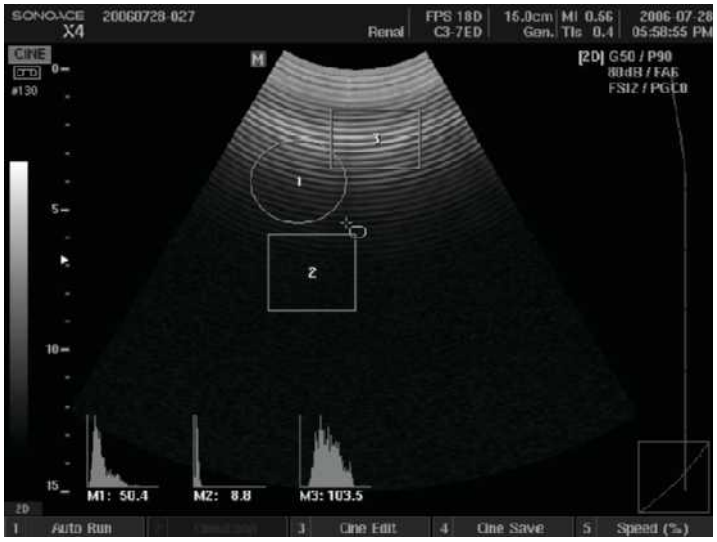
Histogram

Shows the brightness level of the selected area in a histogram.

Press **Histogram** to bring up the cursor to enable you to select an area.

Use the **Trackball** to move the cursor to a desired location and press the **Set** button to set the start point. Use the same method to set another point. The brightness histogram for the area between the two points will be displayed at the bottom of the screen. Press the **Change** button to change the shape of the selected area into an ellipse.

A maximum of 3 histograms can be displayed at a time. The value displayed represents the mathematical average of the brightness distribution. (The minimum value is 0 and the maximum value is 255.)



[Figure 3.34 Histogram]

Demo Images

This function displays DEMO images obtained from this system. Select **Demo Image** in the menu.

Each Demo image is displayed for 5 seconds, and you can adjust the display time by using the **Flexible Soft button [1] Slower** and **[2] Faster**. (Maximum 10 seconds. Minimum 1 second. 0,5 second increments).

If you press the **Flexible Soft button [3] Prev**, the image changes to the previous one. If you select the **Flexible Soft button [4]**] **Next**, it changes to the next one. Press the **Flexible Soft button [5] Play/Pause** to pause the image cycle; press it again to resume the cycle.

To end the Demo function, press **Exit** button on the control panel or **Esc** key on the keyboard.

[Figure 3.35 Demo Images]

Chapter 4

Diagnosis Modes

Diagnosis Mode Types and Control

Diagnosis Mode Types

This product supports a variety of diagnosis modes including Basic mode, Multi-Image Mode, and 3D mode.

- Basic Mode

  2D Mode, M Mode, and PW Spectral Doppler Mode(Optional).

- Combined Mode

  M Mode and PW Spectral Doppler Mode (Optional) can be added in 2D Mode. Two types of Combined Mode are supported.

- Multi-Image Mode

  In Dual Mode you can view two images side by side simultaneously and compare them.

- 3D Mode

  3D images can be obtained. Provides the Freehand 3D option, which allows viewing of three-dimensional images.

Changing Diagnosis Modes Format

The following section explains how to change the display format that is common to all diagnosis modes.

Changing Activated Image Position in Dual Mode

Use **Update** button or **Dual** button on the control panel.
For example, press **Update** button or **Dual** button in Dual-2D Mode. The image that is being scanned is frozen in the left section of the screen, and the right image becomes active.

Image Depth Control

Raise/lower the **Depth** switch to decrease/increase the scanning depth of an image. The maximum/minimum depth depends on the probe used.

Image Magnification(HD Zoom)

Use the **HD Zoom** switch on the control panel to save the magnified image. Raise the switch, and the HD Zoom Box appears. Use the **Change** button and trackball to set the position and size of the HD Zoom Box. Press the **Change** button to toggle between **Zm Pos.** and **Zm Size**; the selection will be indicated on the left side of the screen.

- Zoom Position: Press the **Change** button and the HD Zoom Box lines become solid lines. Use the trackball to move the box to the desired position.
- Zoom Size: Press the **Change** button and the HD Zoom Box lines become dotted lines. Use the trackball to change the size of the box.

After adjusting its position and size with the **Trackball**, press the **Set** button to enter HD Zoom Mode. You can view the position of the magnified area through the Zoom Navigation Box on the screen.

In HD Zoom mode, press the **Z** key on the keyboard to make the Zoom Navigation Box disappear and Zoom Position deactivate. Press **Z** key again, and the Zoom Navigation Box is shown again.

Adjust **Depth** switch or press **Exit** button to exit HD Zoom Mode.

Read Zoom

This function magnifies an image saved in the memory. Press the **Zoom** button on the control panel to start Read Zoom mode.

In HD Zoom mode, it is available to press the **Zoom** button on the control panel to start the Read Zoom mode. However, in Read Zoom mode, you cannot enter the HD Zoom mode with the **Zoom** button.

Diagnosis Modes Optimization

For optimizing images, the following functions are common to all modes.

Gain Control

Use the **Gain/Freeze/PGC**, or **PW Gain/PGC** dials on the control panel to adjust image brightness. If you rotate the **Gain** dial clockwise, its value increases, and vice versa.

TGC Control

Ultrasound penetration gets weaker with depth. Eight **TGC** slides are available for optimal image output. Adjust Gain according to depth.
Move the **TGC** slide to the right(+) to increase Gain (brightening the image) and vice versa.

FSI (Full Spectrum Imaging)

Use the **FSI** button on the control panel to switch.
When you press the button repeatedly, it changes its level from the FSI 1 to FSI 3. Synthesizes the images obtained with frequencies of different characteristics. Shallow observation depths yield higher resolution and deep observation depths yield higher penetration.

Frequency Change

Use the **Frequency** button on the control panel to obtain the optimal image by changing the frequency. The meanings of the frequencies are shown below.

The probe frequency setting is displayed in the Probe Information Display Area:

GEN : General frequency	**RES : High frequency**	**PEN: Low frequency**

Quick Scan

Automatically performs various processing steps including Gain and TGC to optimize the contrast and brightness of the images. This function can be accessed using the **Quick Scan** button on the control panel. Press the **Exit** button to quit the Quick Scan Mode.

PGC (Post Gain Control)

In the frozen state, use the [PW Gain/PGC] or [Gain/Freeze/PGC] dial. This changes the post curve in the frozen state to provide effects similar to changing Gain, TGC, DR, etc.

Focus Position Control

Raise/lower the **Focus** switch raise/lower the focusing point.

Harmonic Function

Press the **Harmonic** button on the control panel in 2D Mode. When the Harmonic function is used, ‘HGen.’, ‘HRes.’ and ‘HPen.’ are displayed in the probe information section.

The Harmonic function is only activated with the specific probe.

Power Control

Power is the intensity of the acoustic output.
Use the **Menu/Angle** dial-button on the control panel to set the **Power**, in the left menu. Its value ranges from 10 to 100.

Post Map Settings

Use the **Menu/Angle** dial-button on the control panel and press **2D Post**, **M Post** or **PW Post** on the menu to bring up the sub-menu. On this sub-menu, select an appropriate map from Type1~5, User1~3.
When select **User**, you can make your own Map.

※ User Post Map Edit

1. Press **Edit** in the menu. The User Post Map image and its Flexible Soft Menu appear on the screen.

[Figure 4.1 The Flexible soft menu of Post map]

- **Add**: Add a new point between the currently selected point and the adjacent point.
- **Delete** : Delete the currently selected point .
- **Save** : Save the map.
- **Cancel** : Cancel Map editing and return to the original map.
- **Apply** : Apply the Map setting to the image.

2. Each map point is selected with the **Change** button on the control panel, and you can set the shape of the map with the **Trackball** and **Set** button.

Select **Return** to escape this status.

Gamma Settings

Use the **Menu/Angle** dial-button on the control panel to press **Gamma** on the menu, and then select Off, Weak, Medium or Hard. Adjusts the contrast.

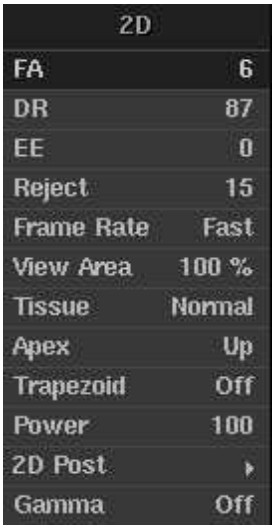
- Weak : make the image brightly.
- Medium : make the image medium bright.
- Hard : make the image darkly.

Basic Modes

2D Mode

This basic mode, also referred to as B Mode (Brightness mode), shows anatomy scan planes.

[Figure 4.2 2D Mode]



[Figure 4.3 2D Menu]

2D Mode Selection

Press the **2D** button on the control panel.

2D Mode is the default mode and the **2D** button is not a toggle button. Instead, it is used to return to basic 2D Mode when in other image modes.

Changing 2D Image Format

Changing Image Direction

- Changing Left/ Right Orientation (Horizontal Orientation Direction)
  Press the **Flexible Soft button [1] Direction**.
- Changing Up/down Orientation (Vertical Orientation. Apex)
  Select **Apex** in the 2D menu using the **Menu/Angle** dial-button.

Changing View Area

Select **View Area** in the menu using the **Menu/Angle** dial-button on the control panel.

[Figure 4.4 Flexible Soft Menu when changing View Area]

You can adjust View Area using the **Flexible soft button [3] Size +** and **[4] Size –** buttons in the Flexible Soft Menu.

Widening / narrowing the View Area, decreases/increases the frame rate (FPS). If you want to view other unseen parts, press the **Pos.L** and **Pos.R** buttons in Flexible Soft Menu to move the View Area to the right or left.

To apply changed view area and go to scan mode, press the **Flexible Soft button [5] Return**.

NOTE	During using a linear probe, flexible soft button [1] Pos.L, and [2] Pos.R are not available.

M Line Display

Pressing the **[F1] M Line** makes the M Line appear or disappear**.**

Indicates where the image for M Mode or PW Spectral Doppler Mode appears in the 2D image.

2D Image Optimization

Frame Average Control

Use the **Menu/Angle** dial-button on the control panel to press **FA** in the menu. Select a value.

The Frame Average function is used to average frames together on the screen, thereby reducing the speckles, which make diagnosis difficult. Setting the Frame Average value as high makes the display movements smoother but slower. (Though the actual frame rate doesn't drop.) Turn the function off in OB and cardiac examination where organs are highly active.

Dynamic Range Control

Use the **Menu/Angle** dial-button on the control panel to press **DR** in the left menu. Select a value.

This function is used to change the range of contrast by adjusting the ratio of minimum/maximum input signal value ratio. Increase/decrease Dynamic Range to smooth/roughen the image.

Edge Enhance Control

Use the **Menu/Angle** dial-button on the control panel to press **EE** in the menu. Select a value.

This function is used to view more accurate images of organ or tissue boundaries. Increase the Edge Enhance value to obtain clearer pictures of boundaries.

Reject Level Control

Use the **Menu/Angle** dial-button on the control panel to press **Reject** in the left menu. Select a value.

This function is used to eliminate noise or low level echoes for clearer signals.

Frame Rate Control

Use the **Menu/Angle** dial-button on the control panel to press **Frame Rate** in the left menu. Select Fast, Normal, or Slow.

The Frame Rate is the number of images generated per second. The Frame Rate should be set to Fast when viewing fast moving organs.

Tissue Property Control

Use the **Menu/Angle** dial-button on the control panel to select **Tissue** in the menu.

Select the desired ultrasound speed according to the patient's tissue type. The Tissue menu consists of Cystic, Adipose, Normal, and Solid.

Trapezoid Function

This function is used to view the trapezoid-shaped 2D image when using the Linear probe. Use the **Menu/Angle** dial-button on the control panel to select **Trapezoid** in the menu.

When adjusting image depth, some depth values do not support the Trapezoid function. Using **HD Zoom** switch makes the Trapezoid function off.

Density Control

Use the **Flexible soft button [2] Density**.

Increases the resolution by increasing the number of scan lines. Note that the frame rate falls in proportion to the number of scan lines.

Extended Resolution (Ext. Res.)

Use the **Flexible soft button [3] Ext. Res**.

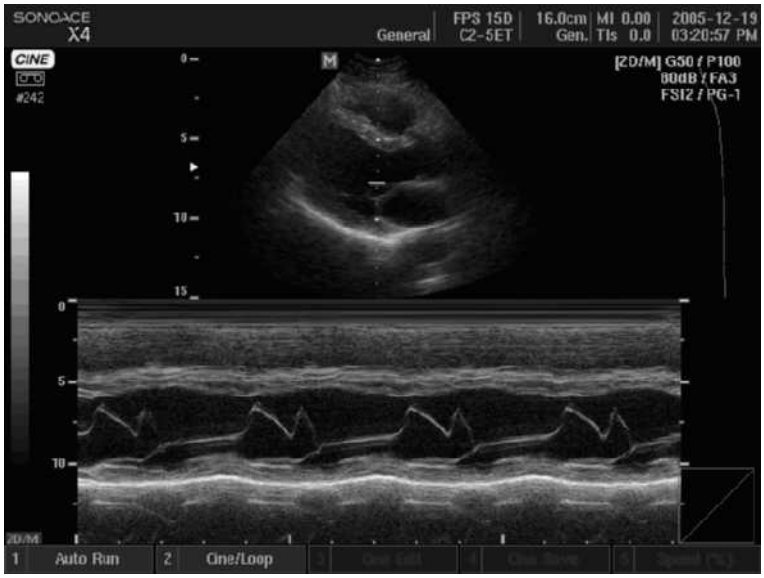
Increases the resolution by increasing the number of channels. Note that the frame rate falls in proportion to the number of channels.

Focus Number Control

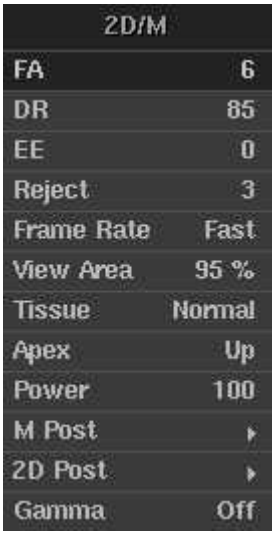
Press the **Flexible Soft button [4] Focus -,** or **[5] Focus +** to set the focus number.

M Mode

In M Mode, you can observe the motion patterns of an area of anatomy - along a 2D image reference line (M Line). This mode is especially useful for cardio-valvular observation.



[Figure 4.5 M Mode]



[Figure 4.6 M Mode Flexible Soft Menu]

M Mode Selection

Press the **M** button on the control panel. Press **M** button again. M Mode turns off and 2D Mode turns on.

Changing M Mode Format

Image Direction Change

Press the **Flexible soft button [1] Direction** to change the direction of the image.

M Line Control

Move the M Line to change the observation location. The M Line can be moved left and right by using the **Trackball** on the control panel.

M Image Size Change

To adjust the size (Large, Normal or Small) of the 2D image and the M image, select an M Mode image size with the **Flexible Soft button [5] M Size**.

Sweep Speed Control

Choose from 120Hz, 180Hz, 240Hz or 300Hz with the **Flexible soft button [3] Speed** button on the control panel.

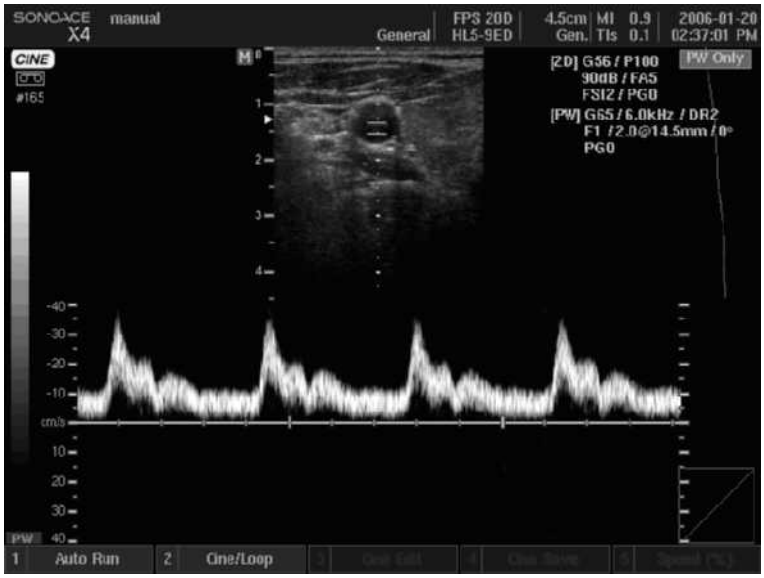
Loop Format Change

Select Top Down Format or Side-by-Side Format using the **Flexible Soft button [4] Loop Format**. Top Down Format sets the 2D image and M image at the top and bottom of the screen. Side-by-Side Format sets the images side by side.

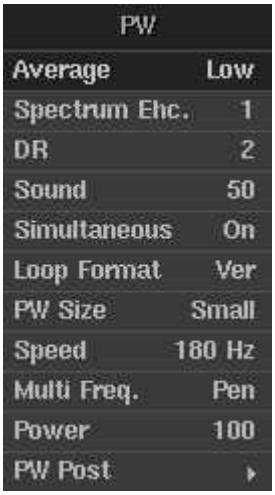
NOTE	Refer to `2D Mode' for more information about other items in the menu.

PW Spectral Doppler Mode (Optional)

PW (Pulsed Wave) Spectral Doppler Mode gives information on the speed/direction of blood flow at a specific site in the form of a spectral trace and audio signal. Since the pulse is transmitted being divided according to time, distance (depth) information can be obtained. The mode is suitable for measuring relatively slow blood flow such as that in abdominal and peripheral vessels. The 2D Mode image is shown simultaneously allowing the marking and adjustment of specific sites within blood vessels.



[Figure 4.7 PW Spectral Doppler Mode]



[Figure 4.8 PW Spectral Doppler Mode menu]

PW Spectral Doppler Mode Selection

Press the **PW** button on the control panel. Press **PW** button again to enter 2D Mode.

PW Spectral Doppler Mode Screen

On the PW Spectral Doppler Mode image, the horizontal axis represents time, and the vertical axis represents speed (or frequency).

Sample Volume

When Sample Volume is on the blood flow of 2D image, it represents Doppler Spectrum. Its position is moved with the **Trackball** and displayed in the xx.x@yy.y mm format. The format means that the Sample Volume of 'xx.x' mm size is located at a depth of 'yy.y' mm.

For example, 2.0@16.7 mm means that the Sample Volume of 2.0mm size is located at a depth of 16.7mm.

PW Spectral Doppler Mode Format Change

Changing Active Image

In Dual Mode, the control functions and screen menu configuration differ depending on the active image. To change the Flexible soft menu of currently activated mode, press the **Set** or **Update** button.

For example, you can change the currently active image in PW Spectral Doppler Mode → 2D Mode by pressing the **Set** or **Update** button if 2D Mode is activated in 2D/PW Mode.

However, these buttons are inactive in Freeze mode.

Changing Flexible Soft Menu/Angle

Use the keyboard space bar to move from Combined Mode to Flexible Soft Menu.

In 2D/PW Mode, for example, you can change Flexible Soft Menu in PW Sepctral Doppler Mode by pressing the space bar.

Freezing 2D Image in PW Spectral Doppler Mode

When 2D and PW Spectral Doppler images are showing simultaneously, press **Set** button on the control panel to freeze the 2D image for closer observation of Doppler images. Press **Set** button again to reactivate the image.

When Simultaneous Mode is off, the current image mode is shown as **PW Only,** or **2D Only** in the upper right portion of the screen. Activation of Simultaneous Mode is set in the **Display** tab in the Setup window. If you set 'Simultaneous Mode' is 'Off', the item 'Simultaneous' on the PW Spectral Doppler mode will not be activated.

Changing PW Spectral Doppler Image Size

Select **PW Size** in the menu(Large, Normal, or Small) using the **Menu/Angle** dial-button on the control panel.

To adjust the image position, the 2D image is shown together. The size of the 2D image and PW Spectral Doppler image can be changed. This function is activated in Simultaneous mode is on.

Activating Simultaneous Mode

The PW Spectral Doppler image and 2D image can be displayed simultaneously or separately.

Select **Simultaneous** in the menu using the **Menu/Angle** dial-button on the control panel. If Simultaneous is selected again when this mode is already on, the mode is deactivated.

Activate the Simultaneous Mode option by setting Simultaneous Mode as ‘Allow 2D/PW’ in the **Misc.** tab in the Setup window.

NB. Simultaneous Mode decreases Doppler PRF, thus decreasing the measurable speed range.

Scale (PRF) Control

Press the **Flexible soft button [1] Scale** and use **Menu/Angle** dial-button. Rotating the **Menu/Angle** dial clockwise makes the PRF (Pulse Repetition Frequency) increase so that the speed range of blood flow is widened, and vice versa.

Doppler Baseline Control

Press the **Flexible soft button [2] Baseline** and use **Menu/Angle** dial-button. Rotating the **Menu/Angle** dial clockwise makes the baseline up, and vice versa.

Doppler Axis Invert

Press the **Flexible soft button [4] Invert** button on the control panel. The ‘+ velocity value’ and ‘- velocity value’, shown at the Doppler axis, change positions.

Loop Format Change

Select **Loop Format** in the menu using the **Menu/Angle** dial-button on the control panel. ‘Hor’ means Top Down Format, in which 2D image is set above the PW Spectral Doppler image, and ‘Ver’ means Side by Side Format, in which the two images are set side-by-side.

PW Spectral Doppler Image Optimization

Sample Volume Position Control

Use the **Trackball** on the control panel.

Sample Volume Size Control

Adjust the Sample Volume size by pressing the **Change** button and using the **Trackball** on the control panel. Press **Change** button again to return to the Sample Volume Position Control screen. The icon showing the two **Trackball** functions (SV Pos/SV Size) is shown for a second and disappears.

Sample Volume Angle Control

Press the **Flexible soft button [5] Angle**, and the flexible soft menu will be changed. To control the angle with 60° from -60° ~ +60° , use the **Flexible soft button [3]~[5]**, or press **Menu/Angle** dial-button. To control the angle with 1° from -80° ~ +80° , use **Menu/Angle** dial-button.

Controlling sample volume angle makes speed measurement exactly.

Doppler Sound Volume Control

Select **Sound** in the menu using the **Menu/Angle** dial-button on the control panel.

Wall Filter Control

Select **Filter** in the menu using the **Menu/Angle** dial-button on the control panel. Select a value.
Wall filter is an electrical filter used to eliminate low-frequency Doppler signals caused by the motions of vessel walls. Eliminate Doppler signals whose frequencies are lower than the Cutoff Frequency by adjusting the Cutoff Frequency.

Steer Function

Pressing the **Flexible soft button [3] Steer** button on the control panel steers the M Line to the left, center and right - in that order.

When Linear probe is selected, this function adjusts the ultrasound beam angle to prevent the loss of information caused by the ultrasound beam angle.

Average Control

The Average Control is used to increase spectrum quality.
Select **Average** in the menu using the **Menu/Angle** dial-button on the control panel. Select the Average value (Low, Middle or High).

Spectrum Enhancement

Use the **Menu/Angle** dial-button on the control panel to press **Spectrum Ehc.** on the menu. Select the value.

Compensates for spectral Doppler spectrum signals with low gains for better display. This is available in the Loop Only Mode and Simultaneous function.

PW Multi Frequency

Improves the Doppler images according to the observation depths. Use the **Menu/Angle** dial-button on the control panel to press **Multi Freq.** on the menu. Select Pen or Gen.

HPRF (High PRF) Function

This function measures blood flow whose speed exceeds specified limits at a specified depth. It increases as three times than the original scale. However it has the upper limits along the depth.

- **HPRF Activation**

  To activate HPRF, increase the Scale values at the required depth. The Phantom Gate appears over the sample volume in D Line. Once HPRF is activated, the PRF doesn't increase even if the scale values are raised.

- HPRF Exit

To exit HPRF, decrease Scale values by one notch while HPRF is activated. The maximum PRF values in PW Spectral Doppler Mode are shown.

- Sample Volume Position Control

To move the Sample Volume position in the PW Only status, the system calculates PRF values and the Phantom Gate position, and updates them on the PW Spectral Doppler image. Exit HPRF when HPRF cannot be activated.

When Sample Volume is moved in the 2D Only status, the PRF values don't change.

NOTE	HPRF is not activated in Simultaneous Mode. It is also not activated if [PRF*2] exceeds 23KHz.

[Figure 4.9 HPRF]

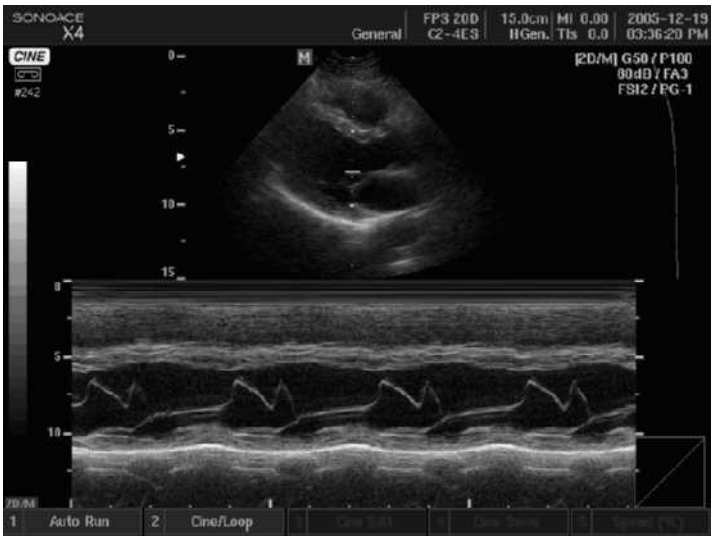
CAUTION	■ The Phantom Gate position can be located outside the 2D image area in Zoom Mode. ■ Ensure that the Sample Volume and Phantom Gate are not positioned over the area to be measured. If more than two SVs are located in the vessels, all Doppler components will appear in the spectrum, causing noise.

NOTE	Refer to `2D Mode' for more information about other items in the menu.

Combined Modes

2D/M Mode

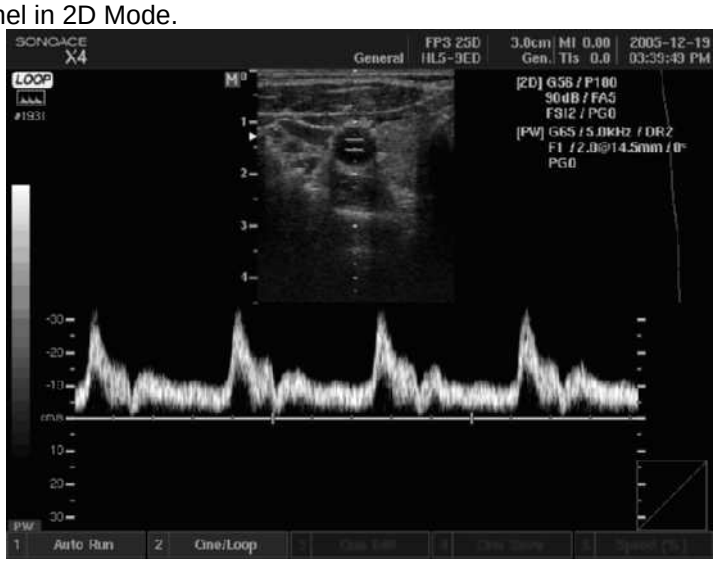
2D Mode and M Mode are displayed simultaneously. Press the **M** button on the control panel in 2D Mode.



[Figure 4.10 2D/M mode]

2D/PW Mode (Optional)

2D Mode and PW Spectral Doppler Mode are displayed simultaneously. Press the **PW** button on the control panel in 2D Mode.



[Figure 4.11 2D/PW mode]

Multi-Image Mode

The multi-image viewing function is only available when the images and conditions on both sides are identical.

Dual-2D Mode

This mode allows you to compare 2D images side by side.
Press the **Dual** button on the control panel in 2D Mode, **M Mode** and PW Spectral Doppler Mode. Press the **2D** button to exit Dual-2D Mode and return to the basic 2D Mode.
To change the active image, press the **Update, Dual,** or **Set** button.

[Figure 4.12 Dual-2D Mode]

3D Mode

3D

The 3D Mode displays tissues or objects in the human body as three-dimensional images instead of two-dimensional images.

The 3D mode uses the Volume data acquired by the probe as continuous 2D images for rendering, producing three-dimensional volume data displays of objects that can better assist in the diagnosis process.

Volume rendering refers to the calculation process used in formulating a 3D volume structure from 2D scans. Using the gray value of the light path through each pixel of the 2D image, the corresponding voxel, or volume element, of the 3D image is calculated. The rendering algorithm determines the way the way the 3D structure is visualized. Surface rendering is employed in the SONOACE X4.

How to Improve 3D Image Quality

- Consider the direction, division and size of the viewpoint, as well as the visibility of an object.
- Before 3D scanning, adjust the contrast of the specific textures in 2D Mode.
- The ROI box determines the contents of the image box to be rendered. The images outside the ROI box, except for the ultrasound data, are not included in the rendering process and are cut out.
- The bigger the ROI box, the slower the rendering speed. Therefore, set an appropriate ROI box size.
- To determine surface contour, the surfaces of objects should be insulated with hypoechoic textures - such as amniotic fluid - which don't generate echos.
- To obtain a high quality 3D surface, adjust the low-threshold value.
- In order to acquire a clear image from the ROI box start boundary to the specific surface, noise can be eliminated if the gray scale value is smaller than the surface value.
- High-threshold is generally set at the maximum value of 255. If the Surface Rendering Algorithm is higher than the threshold value, it marks the boundaries of the surface. The boundary can be adjusted with the threshold-high slider.

Acquiring a 3D Image

The following explains how to acquire a 3D image.

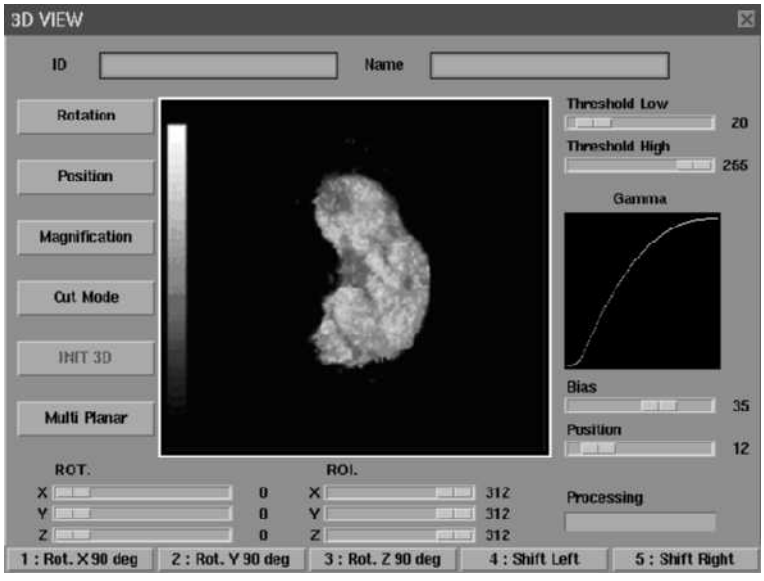
1. Press the **[F8] 3D** button on the keyboard.
2. The ROI box appears. Set the required area using the **Trackball**, and press the **Set** button. The position and size of the area can be changed by pressing the **Change** button before pressing **Set** button.
3. Pressing **Set** button starts the 3D scanning of the area. A maximum of 200 frames can be scanned at one time. A bar, indicating the scanning progress, appears at the bottom of the screen.
4. To scan the specific frame and finish scanning, press **Set** button again. To cancel the scanning during the process, press the **Exit** button.
5. Once scanning is completed, '3D View Mode' is turned on.

NOTE

- To see the 3D scan of a fetus in a frontal view, position the fetal head in the direction of "Direction Mark", putting it in the coronal plane. Then scan the fetus from back to abdomen.
- The 3D image of the fetal face is more easily found in the coronal plane than in the sagittal plane.

3D View

3D images can be seen through the 3D View application.



[Figure 4.13 3D View]

Viewing a 3D Image

- Select the menus using the **Trackball** and the **Set** button.
- To return to the initial screen of 3D View, press the **Init 3D** button.
- The Preview function allows the operator to check changes in the values of **Rotation**, **Magnification**, and **Position** in advance. To obtain a clearer image in the Preview screen, press the **Set** button.
- To close 3D View Mode, press the **X** on the screen. All scanned data and 3D images will be lost if 3D View Mode is closed before saving data. Therefore, ensure that all the necessary images are saved using the **Save** button on the control panel prior to pressing the **X**.

3D Image Optimization

Threshold (Low, High) Adjustment

Adjust the slide bar of the threshold using the **Trackball** and the **Set** button.

If the slide bar is moved to the left, cyst components – and not bone components – are shown. If the slide bar is moved to the right, bone components – and not cyst components – are shown.

Gamma Adjustment

Adjust the ‘Bias’ and ‘Pos’ slide bars on the right side of the screen using the **Trackball** and **Set** button.

- Pos (Position): Designates the bending start point of the Gamma Curve.
- Bias: Sets the brightness and contrast by adjusting the curve bend.

The changed values are applied to the Gamma curve and 3D image.

Changing ROI Size

Adjust the ROI control slide bar using the **Trackball** and the **Set** button. Changed values can be checked in the Preview screen.

Initialization

To return to the initial status in 3D View Mode, press the **Init 3D** button or the **Flexible Soft button [5] INIT 3D** in **Rotation**, **Position**, or **Magnification** Modes.

Rotation

After entering Rotation mode by pressing the **Rotation** button, the 3D image can be rotated using the **Trackball**.

Moving the **Trackball** right or left rotates the 3D image about the X axis, and moving it up or down rotates the image about the Y axis. Moving it while pressing the **Set** button rotates the image about the Z axis.

The rotated 3D image is shown in the Preview screen. After checking the changed values, apply them to the entire screen by pressing the **Flexible Soft button [4] Apply**.

Pressing the **Exit** applies the changes to the 3D image and exits Rotation mode.

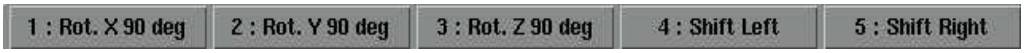
To activate **Position**, **Magnification** or **Cut Mode** functions while rotating the image, press the Flexible Soft Menu of the corresponding function. To return to the initial image, press the **Flexible Soft button [5] INIT 3D**.

[Figure 4.14 Flexible Soft Menu - Rotation Mode]

※ Other ways to rotate the image,

1. The ROT slide bar at the bottom of the screen can be adjusted using the **Trackball** and the **Set** in the 3D View initial screen.

2. Use the Flexible Soft Menu in the initial 3D View screen. Use the **Flexible Soft button [1] ~ [3]** to rotate the 3D image 90° degrees about each axis.



[Figure 4.15 Flexible Soft Menu – 3D Mode]

Position

The 3D image position can be adjusted with the **Trackball** after entering Position mode. After checking changed values in the Preview screen, apply the changes to the entire screen by pressing the **Flexible Soft button [4] Apply**.

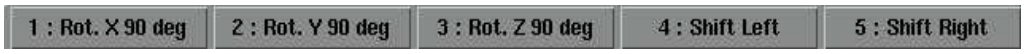
Pressing the **Exit** applies the changes to the 3D image and exits **Position** mode.

To activate the **Rotation**, **Magnification** or **Cut Mode** functions while adjusting the image position, press the corresponding Flexible Soft Menu of each function. To return to the initial image, press the **Flexible Soft button [5] INIT 3D**.

[Figure 4.16 Flexible Soft Menu – Position Mode]

※ Other ways to move the image

Use the Flexible Soft Menu in the 3D View initial screen. To move the 3D image right or left, use the **Flexible Soft button [4] Shift Left or [5] Shift Right**.



[Figure 4.17 Flexible Soft Menu – 3D Mode]

Magnification

To magnify or reduce the image size, enter Magnification mode by pressing the **Magnification** button, and move the **Trackball** right or left. After checking changed values in the Preview screen, apply the changes to the entire screen by pressing the **Flexible Soft button [4] Apply**.

Pressing the **Exit** button applies the changes to the 3D image and exits the Magnification mode.

To activate the **Rotation**, **Position** or **Cut Mode** function while adjusting the image size, press the corresponding Flexible Soft Menu of each function. To return to the initial image, press the **Flexible Soft button [5] INIT 3D**.

[Figure 4.18 Flexible Soft Menu – Magnification Mode]

Cut Mode

Press the **Cut Mode** button on the left side of the screen to enter Cut mode. Determine the area to cut using the **Trackball**, and press the **Set** button. Then, the "+" cursor appears. After contouring the area to cut, press **Set** button again, and the cutting is finished. To cancel the cutting area, press the **Exit** button.

Press the **Flexible Soft button [1] Inside Contour** to outline an area to be cut. The **Flexible Soft button [2] Point Eraser** function is used to cut a portion of the image. The default setting is Inside Contour.

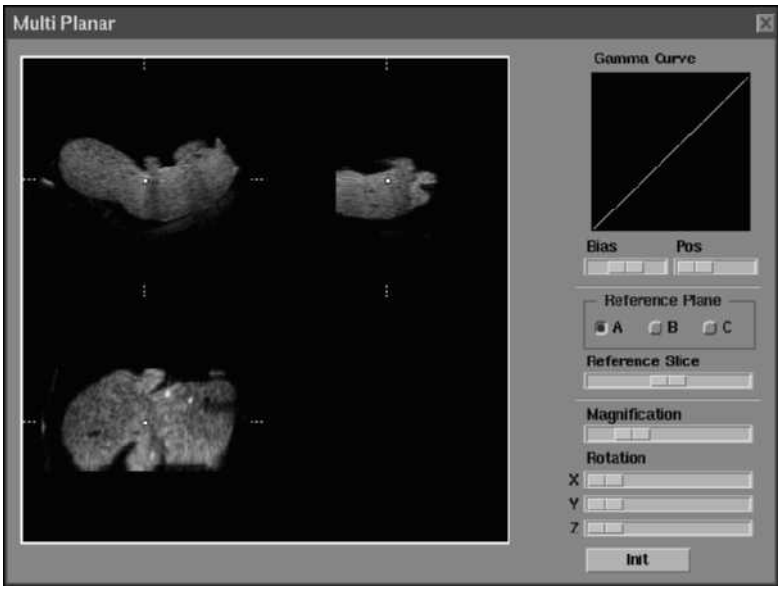
To cancel cutting, press the **Flexible Soft button [3] Undo**. To redo the cancelled job, press the **Flexible Soft button [4] Redo**.

To cancel all cuttings and return to the initial 3D screen, press the **Flexible Soft button [5] Undo All**.

[Figure 4.19 Flexible Soft Menu – Cut Mode]

Multi-planar View

Press **Multiplanar**, and 3D multiplanar screen appears. Shows volume data in cross-section images of Coronal Section, Sagittal Section, and Axial Section.



[Figure 4.20 Multi-planar view]

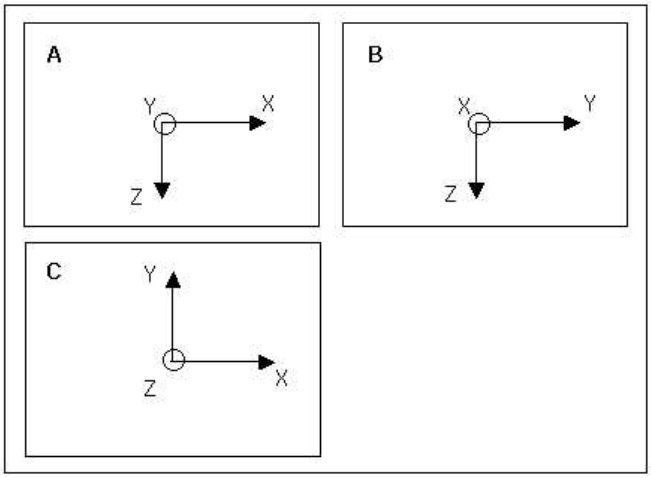
■ **Reference Plane**

Select the reference plane on the Multi Planar window:

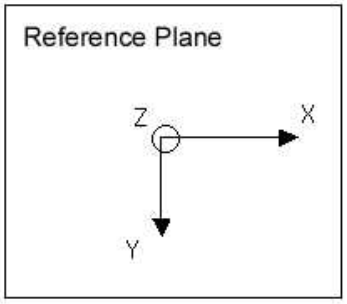
- A plane: Coronal Section
- B plane: Sagittal Section
- C plane: Axial Section

Multi Planar has its standard coordinates system and rotates/moves along that system. However the reference plane rotates/moves along the own coordinates system of reference plane. If you select a reference plane, it rotates/moves along the coordinates system of reference plane. The other planes are rotate/move along its standard coordinates system.

Use X/Y/Z slide on the screen to rotate reference plane.



[Figure 4.21 The standard coordinates systems of Multi-planar]



[Figure 4.22 The coordinates system of the reference plane]

To init all setting, press **Init** on the screen. To finish the 3D Multiplanar and go back to 3D View, press **X**.

NOTE	Refer to '3D Image Optimization' for more information like Gamma Curve setting.

Chapter 5

Measurements And Calculations

Measurement Accuracy

Measurement values can vary, depending on the nature of the ultrasound, the body's response to ultrasound, the measurement tools, algorithms, product settings, probe type and user operation.
Before using this product, make sure to read and understand the following information regarding the causes of measurement errors, and measurement optimization.

Causes of Measurement Errors

Image Resolution

The resolution of ultrasound images may be limited by the available space.

- Errors due to a signal range may be minimized by adjusting focus settings. Optimizing focus settings increases the resolution of the measurement area.
- In general, lateral resolution is lower than axial resolution. Therefore, measurements should be performed along the axis of the ultrasound beam to obtain accurate values.
- Gain has a direct impact on resolution. Gain can be adjusted by using the Gain button for each mode.
- In general, increasing the frequency of ultrasound enhances resolution.

Pixel Size

- An ultrasound images in the product consist of pixels.
- Since a single pixel represents the basic unit of an image, a measurement error may result in the displacement of approximately ±1 pixel when compared to the original image size.
- However, this error becomes significant only when a narrow area in an image is measured.

Ultrasound Velocity

- The velocity of ultrasound used during measurement is usually 1,540 m/s on average.
- The velocity of ultrasound may vary depending on the cell type.
- The possible range of error is between approximately 2-5% depending on the structure of cells (about 2% for typical cells and about 5% for fatty cells).

Doppler Signal Adjustment

- During velocity measurement, an error may occur depending on the cosine angle between the blood flow and the ultrasound beam.
- For Doppler velocity measurements, the most accurate results can be ensured when the ultrasound beam is aligned in parallel with the blood flow.
- If that is not possible, the angle between them should be adjusted by using the **Angle** option.

Aliasing

- PW Spectral Doppler Mode uses a signal sampling technique to calculate the frequency (or velocity) spectrum.
- Adjust the baseline or the velocity scale to minimize aliasing. A lower frequency probe can also be used to reduce aliasing.

Calculation Equation

- Some of the calculation equations used for clinical purposes originate from hypotheses and approximation.
- All calculation equations are based on medical reports and articles.

Human Error

- Human error may occur due to inappropriate use or lack of experience.
- This can be minimized through compliance with and thorough understanding of the manuals.

Optimization of Measurement Accuracy

2D Mode

- Resolution is in proportion to the frequency of the probe.
- Penetration is in inverse proportion to the frequency of the probe.
- The highest resolution can be obtained at the focus of the probe where the ultrasound beam is narrowest.
- The most accurate measurements can be obtained at the focus depth. The accuracy decreases as the distance from the focus increases, widening the beam width.

- Using the zoom function or minimizing the depth display makes distance or area measurements more accurate.

M Mode

- The accuracy of time measurements can be increased when the sweep velocity and the display format are set to high values.
- The accuracy of distance measurements can be increased when the display format is set to higher values.

Doppler Mode

- It is recommended to use lower frequency ultrasound for measurement of faster blood flows.
- The size of the sample volume is limited by the axial direction of the ultrasound.
- Using lower frequency ultrasound increases penetration.
- The accuracy of time measurements can be increased when the sweep velocity is increased.
- The accuracy of velocity measurements can be increased when the vertical scale is set to smaller values.
- It is most important to use an optimal Doppler angle to enhance the accuracy of velocity measurements.

Cursor Position

- All measurements are affected by input data.
- To ensure accurate positioning of the cursor:

  Adjust the images on the screen so that they are displayed at maximum granularity.

  Use the front edge or boundary point of a probe to make the start and end points of a measurement object more distinct.

  Make sure that the probe direction is always aligned during measurement.

Measurement Accuracy Table

The following tables show the accuracy of the measurements available using the product. Ensure that the results of measurement accuracy checks are kept within the ranges specified in the table. Except for certain applications or probes, the following accuracy ranges should be maintained for measurement of a straight distance.

NOTE To ensure accurate measurements, an accuracy check should be performed at least once per year. If the measurement accuracy falls outside the ranges specified in the following table, contact Medison Customer Service.

2D Mode

The following measurements have been taken with RMI403GS and RMI413 Phantom.

Measurement Type	Range	Accuracy	Notes
Axial Distance	0.01-25.00 cm	+/- 2% or 2 mm	
Lateral Distance	0.01-35.00 cm	+/- 2% or 2 mm	
Diagonal Distance	0.01-25.00 cm	+/- 2% or 2 mm	
Area	0.01-1,000cm^2	+/- 4% or 0.25 cm^2	
Circumstance	0.03-10,000 cm	+/- 3% or 5 mm	
Volume	0.01-39,000.00 cm^3	+/- 8%	

The accuracies are calculated using following equations:

Distance error (2% or 2mm) = Image Pixel error (1% or 1mm) + Hardware error (1% or 1mm)

Area error (4%)= Distance 1 x Distance 2

Volume error (8%)= Distance 1 x Distance 2 x Distance 3

Circumference error (3% or 5mm)= Distance error (2% or 2mm) + Calculation precision (1% or 3mm)

M Mode

The following measurements have been taken with RMI403GS and RMI413 Phantom.

Measurement Type	Range	Accuracy	Notes
Depth	25 cm	+/- 2% or 2 mm	
Time	0.01-10.2 sec	+/- 2% or 0.2 sec	
Velocity	0.01-1,000 cm /sec	+/- 4 %	

The accuracies are calculated using the following equations:

Distance error (2% or 2 mm) = Image Pixel error (1% or 1 mm) + Hardware error (1% or 1 mm)

Time error (2% or 0.2 sec)= Image Pixel error (1% or 0.1 sec) + Hardware error (1% or 0.1 sec)

Velocity error (4%)= Distance / Time

Doppler Mode

The following measurements have been taken with an RMI 1425A Phantom.

Measurement Type	Range	Accuracy	Notes
Time	0.01-4.3sec	+/- 2% or 0.2 sec	
Velocity	0.15-200 cm /sec	+/- 15 %	

NOTE

The accuracies cited in the above table have been obtained from the cursor positions in Doppler Mode and when measurements were made. The velocity tests can therefore be used to check these values since these are not indicators of the underlying absolute velocity. The absolute velocity accuracy is tested using phantom measurements.

※ Absolute Doppler Velocity Accuracy:

Accuracy is defined as the difference between a calibrated phantom velocity and that annotated as the time-averaged mean by the system. The time-averaged mean is calculated as the average over a predetermined period of time of the intensity-weighted mean of the spectrum.

All probes have been tested to ensure that the time-averaged mean velocity falls within +/- 15% of that annotated on the phantom. Due to Doppler phantom constraints, these tests have been conducted in the range 15 cm/sec to 110 cm/sec.

Basic Measurements

A specific distance, area, etc. can be measured in Freeze mode. To perform the task, press the **Caliper** button.

Press the **Caliper** button multiple times to select a measuring method. The set of available measuring methods may differ according to the application in use.

Measurements	Measurement Methods
Distance Measurement	2D Distance (Line) 2D Distance (Trace) 2D Hip Joint M Distance Doppler Velocity Doppler Velocity (A/B) Doppler Trace
Circumference & Area Measurement	2D Ellipse 2D Trace
Volume Measurement	3D Volume: 3 Distance 3D Volume: 1 Distance 3D Volume: Distance + Ellipse

To erase measurement results from the screen, press the **Clear** button on the control panel.

To finish measurements and return to the diagnosis mode, press the **Freeze** or **Exit** button on the control panel or press **Flexible Soft button [5] Exit**.

To print out the measurement screen, press the **Echo Print** button on the control panel.

NOTE	For further information on the general settings of basic measurements, refer to ‘Chapter 3 Settings’.

Distance Measurement

2D Distance (Line) Measurement: measures the distance between two points

The 2D Distance measurement function is available in all diagnosis modes. Its results are shown in cm (or mm). A maximum of four sets of measurements can be displayed at one time.

1. Press the **Caliper** button, and the measurement item appears on the left side of the screen.
2. Select '2D Distance (Line)' by pressing **Flexible Soft button [1] Distance** or by pressing **Change** or **Caliper** button several times.
3. Use the **Trackball** to position the cursor on the start and end points of the area to be measured. Press the **Set** button to fix the points.
4. Press the **Change** button before assigning the end point to change the position of the start point.
5. After position setup, distance and average are displayed on the screen.
6. A new cursor appears for a new measurement. If more than four distance measurements are performed, the distance measurements are calculated in order.

The ratio of the first distance to the second, and the ratio of the third distance to the fourth are calculated and displayed as percentages.

2D Distance (Trace) Measurement: measures a non-straight distance between two points

This measurement function can be performed in all diagnosis modes. The results are displayed in cm (or mm) on the screen. A maximum of four sets of measurements can be displayed at one time.

1. Press the **Caliper** button, and the measurement item appears on the left side of the screen.
2. Select '2D Distance (Trace)' by pressing **Flexible Soft button [1] Distance** or by pressing **Change** or **Caliper** button several times.
3. Use the **Trackball** to position the cursor on the start and end points. Press the **Set** button to fix the points.
4. Press the **Change** button before assigning the end point to change the position of the start point. Pressing the **Del** on the keyboard before pressing **Set** button erases part of the trace line.
5. After position setup, distance and average are displayed on the screen.

6. A new cursor appears for a new measurement. If more than four distance measurements are performed, the distance measurements are calculated in order.

The ratio of the first distance to the second, and the ratio of the third to the fourth are calculated and displayed as percentages.

2D Hip Joint Measurement

This measurement is available in all diagnosis modes.

1. Press the **Caliper** button, and the measurement item appears on the left side of the screen.
2. Select '2D Hip Joint' by pressing **Flexible Soft button [4] 2D Hip Joint** or by pressing **Change** or **Caliper** button several times.
3. Use the **Trackball** to position the cursor on the start and end points of the first straight line of Hip Joint. Press the **Set** button to fix the points.
4. Press the **Change** button before assigning the end point to change the position of the start point.
5. Set the second and third lines of the Hip Joint in the same way.
6. After position setup, the measurement results are displayed on the screen.

Apply the alpha angle (α) between the first line and the second line, and the beta angle (β) between the first and the third to the table shown below, and calculate the type.

TYPE	α	β
1a	$60 \leq \alpha < 90$	$0 < \beta < 55$
1b	$60 \leq \alpha < 90$	$55 \leq \beta < 90$
2a/b	$50 \leq \alpha < 60$	$0 < \beta < 90$
2c	$43 \leq \alpha < 50$	$77 \leq \beta < 90$
d	$43 \leq \alpha < 50$	$0 < \beta < 77$
3/4	$0 < \alpha < 43$	

Circumference and Area Measurement

2D Ellipse Measurement: measures elliptical objects

This measurement is available in all diagnosis modes. The measurement results are displayed in cm or mm (circumference) or cm^2 or mm^2 (area). A maximum of four sets of measurements can be displayed at one time. Average circumference and average area are shown together.

$$Circ = 2\pi \cdot \sqrt{\frac{1}{2} \cdot \left\{ \left(\frac{A}{2}\right)^2 + \left(\frac{B}{2}\right)^2 \right\}}$$, (A: Long axis, B : Short axis)

$Area = \pi \times a \times b$, (a, b: Axis)

1. Press the **Caliper** button, and the currently selected measurement item appears on the left side.
2. Select '2D Ellipse' by pressing **Flexible Soft button [2] Area/Circ** or by pressing **Change** or **Caliper** button several times.
3. Use the **Trackball** to position the cursor on the two points of the ellipse. Press the **Set** button to fix the points.
4. Press the **Change** button before assigning the end point to change the position of the start point.
5. After the ellipse appears with the two points as an axis, adjust the shape (or another axis) of the ellipse using the **Trackball**. Then, press the **Set** button.
6. After position setup, the measurement results are displayed on the screen.
7. A new cursor appears for a new measurement.

2D Trace Measurement: measures objects with an irregular shape

This measurement function is available in all diagnosis modes. The measurement results are displayed in cm or mm (circumference) or cm^2 or mm^2 (area). A maximum of four sets of measurements can be displayed at one time. Average circumference and average area are shown together. The measurement formulas and methods are outlined here.

$$Circ = sum\sqrt{\{X(n) - X(n-1)\}^2 + \{Y(n) - Y(n-1)\}^2}$$, (N = 1,2… last point)

$$Area = sum\left[\sqrt{X(n-1) \times Y(n) - X(n) \times Y(n-1)}\right]$$, (N = 1,2… last point)

1. Press the **Caliper** button, and the currently selected measurement item appears on the left side.

2. Select '2D Trace' by pressing **Flexible Soft button [2] Area/Circ** or by pressing **Change** or **Caliper** button several times.

3. Use the **Trackball** to position the cursor on one point of the contour of the area to be measured. Press the **Set** button to fix the point. Draw the contour of the area using the **Trackball**, and press **Set** button.

4. Press the **Change** button before assigning the end point to change the position of the start point. Part of the trace line can be erased by pressing the **Del** on the keyboard before pressing **Set** button.

5. If the cursor goes back to the original place or **Set** button is pressed, the measurement results are displayed on the screen.

6. A new cursor appears for a new measurement.

Volume Measurement

3D Volume: 3 Distance: uses three distances (axis)

This measurement function is available in all diagnosis modes. The measurement results are displayed in cm^3 (or mm^3). The measurement formulas and methods are outlined below.

$$Vol = \frac{4}{3}\pi \cdot \frac{D_1}{2} \cdot \frac{D_2}{2} \cdot \frac{D_3}{2}$$, (D; distance)

1. Press the **Caliper** button, and the measurement item appears on the left side of the screen.
2. Select '3D Volume: 3 Distance' by pressing **Flexible Soft button [3] Volume** or by pressing **Change** or **Caliper** button several times.
3. Draw three straight lines using the cursor. For more information about line drawing, refer to '2D Distance (Line) Measurement' in this chapter.
4. After measuring the length of the three lines, the measurement results are shown on the screen.
5. A new cursor appears for a new measurement.

3D Volume: 1 Distance: uses one distance (diameter)

This measurement function is available in all diagnosis modes. The measurement results are displayed in cm^3 (or mm^3). A maximum of four sets of measurements can be displayed at one time. The measurement formula and methods are outlined below.

$$Vol = \frac{4}{3}\pi \cdot \left(\frac{D}{2}\right)^3$$, (D; distance)

1. Press the **Caliper** button, and the measurement item appears on the left side of the screen.
2. Select '3D Volume: 1 Distance' by pressing **Flexible Soft button [3] Volume** or by pressing **Change** or **Caliper** button several times.
3. Draw one straight line using the cursor. For more information about line drawing, refer to '2D Distance (Line) Measurement' in this chapter.
4. The volume of a globe with the diameter, which is the line between the two points, is calculated and displayed on the screen.
5. A new cursor appears for a new measurement.

3D Volume: Distance + Ellipse: uses one ellipse and distance

This measurement function is available in all diagnosis modes. The measurement results are displayed in cm^3 (or mm^3). A maximum of two sets of measurements can be displayed at one time. The measurement formulas and methods are outlined below.

$$Vol = \frac{\pi}{6} \times a \times b \times d \quad , \quad (a : \text{Short axis}, \quad b : \text{Long axis}, \quad d : \text{Distance})$$

1. Press the **Caliper** button, and the measurement item appears on the left side.
2. Select '3D Volume: Distance + Ellipse' by pressing **Flexible Soft button [3] Volume** or by pressing **Change** or **Caliper** button several times.
3. Draw one straight line using the cursor. For information about line drawing, refer to '2D Distance (Line) Measurement' in this chapter.
4. After drawing one straight line, draw one ellipse. For information about ellipse drawing, refer to '2D Ellipse Measurement' in this chapter.
5. The volume of the ellipse is calculated with the distance and the ellipse and is displayed on the screen.
6. A new cursor appears for a new measurement.

NOTE	Since Dual Mode simultaneously displays two images on the screen, the operator doesn't have to return to the diagnosis mode to measure volume in Dual Mode.

Measurement in M Mode

M Distance: measures the distance, time interval, velocity between two points

The distance measurement method in M Mode is the same as that used in 2D Mode.

M Mode shows the changes occurring in the image according to time. If the distance (cm or mm) between two points is measured, the time interval (sec), velocity (cm/s or mm/s), etc. can be checked.

A maximum of four sets of measurements can be displayed at one time.

1. Press the **Caliper** button, and the ‘M Distance’ item appears on the left side of the screen.

2. Set two points using the cursor and measure the distance between them. For more information about distance measurement, refer to ‘2D Distance (Line) Measurement’ in this chapter.

3. After the position setup, the measurement result is shown on the screen.

4. A new cursor appears for a new measurement.

Measurement in Spectral Doppler Mode

NOTE	■ Since a Spectral Doppler Image is displayed with time (X axis) and velocity (Y axis), setting one point above the image will allow the velocity to be checked. ■ The symbols +, X, *, and ◎ before the V, which is used to indicate the velocity, indicate the shape of the measuring cursor.

The distance measurement method in Spectral Doppler Mode is the same as that in 2D Mode.

Doppler Velocity: measures PSV, EDV and its related parameters

The velocity (V1, V2 : cm/s or mm/s), RI (Resistivity Index), velocity ratio (V1/V2), velocity change (dV: cm/s or mm/s) at each point, time interval (dT: sec) and acceleration velocity (Acc: cm/s^2 or mm/s^2) between two points are measured. PSV(Peak Systolic Velocity), EDV(End Diastolic Velocity), Peak G(Peak Gradient), and S/D are calculated from those value and also displayed on the screen.

A maximum of four sets of measurements can be simultaneously displayed. The following shows the measurement formulas and methods.

- $RI = ABS\,(\frac{PSV - EDV}{PSV}), \qquad (ABS; ABSolute\,value)$
- $dV = V_2 - V_1 = EDV - PSV$
- $dT = V_2 - V_1 = T_{EDV} - T_{PSV}$
- $Acceleration = \frac{(V_2 - V_1)}{(T_2 - T_1)} = \frac{dV}{dT}$
- $Peak \cdot G = 4 \times PSV^2$
- $S/D = ABS\,(\frac{PSV}{EDV})$

1. Press the **Caliper** button, and the ‘Doppler Velocity’ item appears on the left side of the screen.
2. Set two points using the cursor and measure the distance between them. For information about distance measurement, refer to ‘2D Distance (Line) Measurement’ in this chapter.
3. After position setup, the measurement result is shown on the screen.
4. A new cursor appears for a new measurement.

Doppler Velocity (A/B): measures velocity between two points and its ratio

The velocity (V_A, V_B : cm/s or mm/s), the RI (Resistivity Index) at each point and the velocity ratio (A/B) of the two points are measured.

A maximum of four sets of measurements can be displayed simultaneously. The following shows the measurement formula and methods.

- $RI = \frac{V_A - V_B}{V_A}$

1. Press the **Caliper** button, and the currently selected item appears on the left side of the screen.
2. Select 'Doppler Velocity (A/B)' by pressing **Flexible Soft button [1] Distance** or by pressing **Change** or **Caliper** button several times.
3. Using the **Trackball**, put the cursor on the two points to measure velocity. Press the **Set** button to fix the points.
4. Pressing the **Change** button before **Set** button allows the position of the measurement area to be reset. At that time, the names of Point A and Point B can be changed.
5. After the position setup, the velocity at each point and the velocity ratio between the two points are displayed on the screen.
6. A new cursor appears for a new measurement.

Doppler Trace: average velocity measurement using trace

The time duration value (dT: sec), integration value of blood flow velocity (VTI: cm or mm), average velocity (Mean V: cm/s or mm/s), maximum velocity (Peak V: cm/s or mm/s), and Mean G (mmHg) are displayed. PSV(Peak Systolic Velocity), EDV(End Diastolic Velocity), Peak G(Peak Gradient), S/D, RI(Resistivity Index), and PI(Pulsatility Index) are calculated from those value and also displayed on the screen.

A maximum of four sets of measurements can be simultaneously displayed. The following shows the measurement formulas and methods.

- $dT = T_2 - T_1$
- $VTI = \int v \times dT \ , \quad (VTI : Velocity\ Time\ Integral)$
- $Mean\ V = \frac{VTI}{Duration\ of\ \ flow}$
- $Pi = 4 \times V_i^{\ 2}$

- $Mean \cdot G = \dfrac{sum\ of\ Pi \times dT}{Duration\ of\ flow}$
- $Peak \cdot G = 4 \times PSV^2$
- $S / D = ABS(\dfrac{PSV}{EDV})$
- $RI = ABS\ (\dfrac{PSV - EDV}{PSV})$
- $PI = ABS\ (\dfrac{PSV - EDV}{Mean\ V})$

1. Press the **Caliper** button, and the currently selected measurement item appears on the left side of the screen.
2. Select 'Doppler Trace' by pressing **Flexible Soft button [1] Distance** or by pressing **Change** or **Caliper** button several times.
3. Move the cursor with the **Trackball** to the start point of the area to measure velocity. Press the **Set** button to fix the point. Using the **Trackball**, draw the contour of the area to measure velocity, and press **Set** button.
4. The part of the trace line can be erased by rotating the **Trackball** to the left before pressing **Set** button.
5. After position setup, the measurement results are displayed on the screen.
6. A new cursor appears for a new measurement.

Calculations by Application

The Basic of Calculation by Application

This product provides measurement packages according to each application such as Obstetrics, Gynecology, Cardiology, Vascular, Urology and Fetal Echo.

Before Starting a Measurement

Check the patient information. If the patient information is not entered, press the **Patient** button and input the data.

Check the probe and application. To change the setting, press the **Probe** button.

Measurement Items (Menu) Selection

Press the **Calculator** button on the control panel. The available applications vary with the selected probe.

- **Menu A / Menu B**

When there are a lot of measurement items (menus), they are divided into two menu groups. Select them using the **Flexible Soft button [1]** or the **Change** button on the control panel.

- **Chg Method (Change)**

This menu can be selected by pressing the **Flexible Soft button [1] Chg Method** or the **Change** button on the control panel. Once the measurement is started, the selected measurement method cannot be changed.

In case of measuring distance, choose a measurement method from Line or Trace. When circumference and area are measured, choose a measurement method from Ellipse and Trace.

Measurement Results

- **Printing Measurement Results**

  Press the **Echo Print** button on the control panel to print the results via an echo-printer.

- **Displaying Measurement Results**

  Adjust the measurement information and result values using the Flexible Soft Menu on the control panel.

- **Rm Data (Remove)**

  Pressing the **Flexible Soft button [2] Rm Data** erases all the measurement data.

- **Cancel/Undo (Undo)**

  Pressing the **Flexible Soft button [3] Cancel/Undo** cancels the latest measurement.

- Rslt Disp Cnt (Result Display Count)
  If the user presses the Flexible Soft button [4] Rslt Disp Cnt**, the item number of the measurement result values is displayed in the order of 1 ⇨ 2 ⇨ 3 ⇨ 4 ⇨ Hide ⇨ 1 at the upper, right-hand section of the image. The information related to the item number is displayed at the upper, left-hand portion of the screen for about a second.**

- **Deleting Measurement Results**

  Press the **Clear** button on the control panel to clear the measurement results on the screen. Note that the measurement results will still be saved in the report.

Closing Measurement Menu

1. Press the **Return** button in the pop-up menu to complete the measurement and go to the upper menu.
2. Press the **Exit** button on the control panel to exit the measurement menu.
3. Press the **End Exam** button, and complete the measurement to save and manage the document of a specific patient. To start a new exam, first select a patient by registering a new patient or searching a patient by his or her ID.

Doppler Spectrum Measurement Method

Trace the spectral waveform to measure PSV (Peak Systolic Velocity), EDV (End Diastolic Velocity), Vmean, Gmean, Gpeak, S/D, PI (Pulsatility Index), RI (Resistivity Index), TAM etc. from the waveform displayed in Spectral Doppler Mode**.**

Trace methods: Auto Trace, Limited Trace, Manual Trace, and Measurement Each Item One by One.

■ **Auto Trace: Automatically calculates Spectrum Cycle**

– **When Control Threshold is set as 'Enable' in the 'Setting Measurements',**

1. Press the **Calculator** button on the control panel after obtaining a specific image.
2. Select **Auto Trace** in the measurement menu. The spectral waveform is automatically traced and the measurement value is calculated.
3. Press the **Change** button to set the area to trace. The trace direction can be set for All, Above, or Below. Select one of them using the baseline as a standard. The selected value is displayed at the top of the screen. The trace direction can be set in the 'Setting Measurements' and saved as default.
4. Rotate the **Menu** dial-button right or left to change the trace threshold. Tracing starts again, and a new trace line is drawn.
5. Press the **Menu** dial-button or the **Set** button, and **Auto Trace** is completed.
6. The values such as PSV, EDV, TAM, Vmean, Gmean, Gpeak, S/D, PI, and RI are measured and displayed on the screen.

– **When Control Threshold is set as 'Disable' in the 'Setting Measurements',**

1. Press the **Calculator** button on the control panel after obtaining a specific image.
2. Select **Auto Trace** in the measurement menu. The spectral waveform is automatically traced and the measurement value calculated.
3. The values such as PSV, EDV, TAM, Vmean, Gmean, Gpeak, S/D, PI, and RI are measured and displayed on the screen.

For detailed information on the Control Threshold setup, refer to 'Setting Measurements' in 'Chapter 3. Settings'.

■ **Precautions about Frozen Doppler Spectrum Auto Trace**

Set the direction of the spectral waveform to trace by designating an option (Above/Below/All) in the 'Setting Measurements',

Take precautions when using the Frozen Automatic Doppler Trace function.

- Even though aliasing occurs due to too low a PRF compared to the velocity of the measured area, a contour trace is possible if the PRF is differentiated from the original signal. However, Peak Trace may not be accurate.
- When a peak is uncertain or intermittent as in the spectral waveform in veins, Contour Trace is possible, but a peak trace might not be obtainable.
- When it is difficult to divide spectrums due to too high or too low a Doppler Gain Setting, errors in the measurement results could occur.

- When the spectrum signals are interrupted due to too high a Doppler Wall Filter setting, Contour trace is possible, but Peak Trace may not be accurate.

- When Peak Trace is interrupted due to abnormal Doppler noise or artifact, Contour trace is possible, but Peak Trace may not be accurate.

- When PW Gain is changed on a frozen image, Contour Trace/Peak Trace may not work properly. To activate Auto Trace, the PW Gain of the frozen image should maintain the same value on the one screen display.

- If noise is weak or absent in the image without spectrums, Contour Trace is not activated. In the case of excessive noise, the result may not be accurate.

- If the Clutter filter is used too much, Auto Trace/ Limited Trace may not be activated.

■ **Limited Trace: Calculates Doppler Spectrum Cycle of the Designated Range**

– **When Control Threshold is set as 'Enable', in the 'Setting Measurements',**

1. Press the **Calculator** button on the control panel after obtaining a specific image.
2. Select **Limited Trace** in the measurement menu, and the bar appears on the spectral waveform.
3. Use the **Trackball** to position the bar on the start point of the area to measure, and press the **Set** button.
4. When another bar appears, position it on the end point of the area and press **Set** button again to complete **Limited Trace**.
5. Press **Change** button to change the trace direction. The trace direction can only be changed before the second bar is set. The trace direction can be set for All, Above, or Below. Select one of them using the baseline as a standard. The selected value is displayed at the top of the screen. The trace direction can be set in the 'Setting Measurements' and saved as default.
6. To change the threshold trace, rotate the **Menu** dial-button to the left or right. The tracing starts again, and a new trace line is drawn.
7. Press **Menu** dial-button or **Set** button to complete **Limited Trace**.
8. The values such as PSV, EDV, TAM, Vmean, Gmean, Gpeak, S/D, PI, and RI are measured and displayed on the screen.

– **When Control Threshold is set as 'Disable', in the 'Setting Measurements',**

1. Press the **Calculator** button on the control panel after obtaining a specific image.
2. Select **Limited Trace** in the measurement menu, and the spectral waveform is traced and its measurement value is calculated.
3. The values such as PSV, EDV, TAM, Vmean, Gmean, Gpeak, S/D, PI, and RI are measured and displayed on the screen.

For further information on the Control Threshold setup, refer to 'Setting Measurements' in 'Chapter 3 Settings'.

■ **Manual Trace: Manually calculates Doppler Spectrum Cycle**

1. Press the **Calculator** button on the control panel after obtaining a specific image.
2. Select **Manual Trace** in the measurement menu, and a + cursor appears on the spectral waveform.
3. Position the cursor on the start point of the spectrum to measure. Press the **Set** button and trace the waveform using the **Trackball**.
4. Press **Menu** dial-button or **Set** button to complete **Manual Trace**. If the user rotates the **Trackball** to the left or presses the **Del** on the keyboard before pressing **Set** button, the part of the measurement line that is being traced can be erased.
5. The values such as PSV, EDV, TAM, Vmean, Gmean, Gpeak, S/D, PI, and RI are measured and displayed on the screen.

■ **Measurement Each Item One by One: Calculates Doppler Spectrum Cycle using PSV and EDV**

1. Press the **Calculator** button on the control panel after obtaining a specific image.
2. Select **PSV** or **EDV** in the measurement menu, and a + cursor appears on the spectral waveform.
3. Move the cursor to the systolic velocity point, and press **Set** button. Then, another + cursor appears.
4. Move the cursor to the diastolic velocity point and press **Set** button.
5. The values such as PSV, EDV, TAM, Gpeak, S/D, PI and RI are measured and displayed on the screen.

■ **Doppler Measurement Items**

Result	Calculation	Date	Equation
PSV (Peak Systolic Velocity)	Velocity	cm/s	
EDV (End Diastolic Velocity)	Velocity	cm/s	
Vmean (Mean Velocity)	Velocity Calculated	cm/s	
Gmean (Mean Gradient)	Gradient	mmHg	
Gpeak (Peak Gradient)	Calculation	mmHg	4 × PSV × PSV
RI (Resistively Index)	Calculation	Ratio	(PSV – EDV) / PSV
S/D (PSV/EDV)	Calculation	Ratio	PSV / EDV
PI (Pulsatility Index)	Calculation	Ratio	(PSV – EDV) / Vmean
TAM(Time Average Mean)	Velocity	cm/s	
Fetal HR	HR	BPM	HR = #beats × 60 / Time

Volume Flow Measurement Method

■ Both Volume Flow and stenosis can be measured.

■ Measure Volume Flow by selecting **Volume Flow** in the measurement menu and measuring related items. Also, the Volume Flow value can be calculated by measuring other items.

■ The following are the calculation formulas for Volume Flow.

$$VolumeFlow(A) = Area \times TAM \times 60$$

$$VolumeFlow(D) = \frac{\pi \times d^2}{4} \times TAM \times 60$$

■ Use Vessel Area, TAM values to calculate Volume Flow.

- There are two ways to measure Vessel Area: one uses the circumference (Vessel Area) and the other uses the distance (Vessel Dist). For further information, refer to ‘Basic Measurements’ in this chapter.
- The TAM (Time Avg. Mean Velocity) value is calculated only when Auto trace or Limited trace is activated. For more information, refer to ‘Doppler Spectrum Measurement Method’ in this chapter.

■ There are two ways to measure Stenosis % of each vascular system**:** one using the area (%StA), and the other using the distance (%StD).

- %Stenosis Area. : Calculates stenosis ratio using the area of vessels.

1. Select the **%StA** menu, and a cursor appears in 2D Mode.
2. Measure the area of the vessel outer wall in the same way as in Circ/Area measurement.
3. When a new cursor appears, measure the area of the vessel inner wall under stenosis.
4. %Stenosis Area. = (Outer Area – Inner Area) / Outer Area × 100.

- %Stenosis Dist.: Calculates stenosis ratio using the diameter of vessels.

1. Select the **%StD** menu, and a first cursor appears in 2D Mode.
2. Measure the diameter of the vessel in the same way as in Distance measurement.
3. A new cursor appears. Measure the diameter of the vessel inner wall under stenosis.
4. %Stenosis Dist. **=** (Outer Distance – Inner Distance) / Outer Distance × 100.

OB Calculations

Before Obtaining OB Calculations

OB Basic Information

Type the information needed for OB diagnosis in the patient information window.

- Enter LMP, then EDD (Estimated Delivery Date) and GA (Gestational Age) are automatically calculated. LMP is required for the calculation of values such as EDD and SD.
  - EDD (LMP) = LMP + 280days
  - GA (LMP) = Current System Date - LMP
- A maximum of four fetuses can be input in the Gestations item. The default item value is '1'. In the case of twins, enter '2'.

  For further information about patient information menus and how to input patient information, refer to 'Entering Patient Data' in 'Chapter 3 Settings'.

OB Measurement Menu Setup

Set GA Equation, GA Table and OB Measurement menus. The user can manually write, back up and restore the GA Table. For more information on GA Equation and Table, refer to the Reference Manual.

For more information about other measurement menus and setup, refer to 'Setting Measurements' in 'Chapter 3. Settings'.

Measurement Items

Measure Fetal Biometry, Fetal Cranium, Fetal Long Bones, AFI, etc.

- GS, CRL, YS, BPD, OFD, HC, APD, TAD, MAD, AC, FTA, FL, SL, TTD, APTD, and APTD * TTD are included in **Fetal Biometry**.
- HUM, ULNA, TIB, RAD, FIB, CLAV, and Vertebral are included in **Fetal Long Bones**.
- In **Fetal Cranium,** CEREB, OOD, IOD, CM, NF, NT, and Lateral Ventricle are included.
- FOOT, EAR, and MP are included in **Fetal Others**.

- There are Umbilical Artery, MCA (Mid Cerebral Artery), Placenta Artery, Left Uterine Artery, Right Uterine Artery, Left Fetal Carotids, Right Fetal Carotids, Fetal Aorta, Ductus Venous, Volume Flow, and Fetal HR in **Doppler**. In this item, PSV, EDV, Trace, Vmean, TAM, S/D, PI, RI, Gpeak, Gmean, etc. are included.

- The measurement method is the same as in the distance, circumference, area and volume measurement of basic measurement.

[Figure 5.1 OB Measurement Menu]

Pregnancy Calculation

1. Press the **Calculator** button on the control panel to select the **OB menu**.
2. Select a measurement item, and a cursor appears on the screen.
3. Make a measurement using the **Trackball** and **Set** button.

Distance measurement is most important in Fetal Biometry and Fetal Long Bones. The items that measure circumference are HC, AC, etc. The items that measure area are FTA, etc. Refer to the 'Reference Manual – Part 1' for detail reference.

How to Measure a Distance Measurement Item

- BPD: Measure the maximum transverse diameter value when symmetrical thalamus appears on the midline.
- OFD: Measure the distance from the front of the head to the back in the same way as in BPD.
- CRL: Measure the distance from head to rump of embryo.
- FL: Femur length measurement. Measure the length of the femur that is closer to

the probe.

- MAD : Calculate the average value of the transverse and anterior-posterior lengths of the fetal abdomen.

  MAD = (APD + TAD) / 2

■ How to Measure a Circumference Measurement Item

- HC: Calculate head circumference in the same way as in BPD. If the user measures BPD and OFD, HC is automatically calculated.

  $$HC = \pi * \sqrt{(BPD^2 + OFD^2)/2}$$

  Exception: when you use Merz reference, $HC = 2.325 \times \sqrt{BPD^2 + OFD^2}$

- AC: Calculate abdominal circumference on the fetal transverse image when DV (ductus venosus) is shown clearly. If the user measures APD and TAD, AC is automatically calculated. At that time, position the cursor on the outside including the skin.

  $$AC = \pi * \sqrt{(APD^2 + TAD^2)/2}$$

  Exception: when you use Merz reference, $AC = \pi \times (APD + TAD)/2$

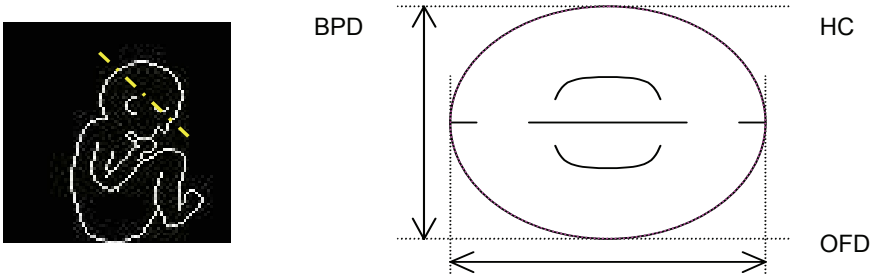
- FTA : This is the measurement of the fetal trunk area (chest or abdomen). Draw a circle using the trace or ellipse, and the value is automatically calculated.

  $$FTA = AC^2/4/\pi$$

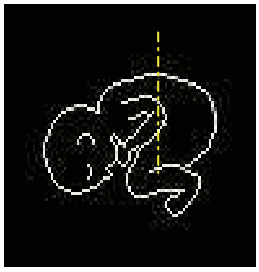
NOTE	For more information, refer to 'Basic Measurements'.

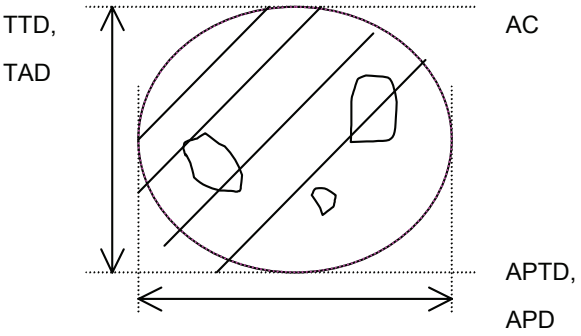
■ Measurement Item Position (Measurement points)

- BPD, OFD, HC –fetal head

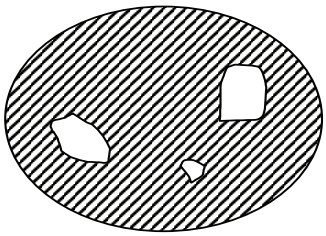


- APD, TAD, APTD, TTD – fetal abdomen or fetal trunk

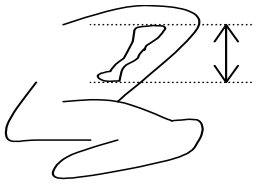




- FTA –fetal trunk



- FL – fetal femur



- LV – fetal Vertebrae

In a report, a maximum of three mean average of new GA values and recently measured values are recorded automatically. (If an item is measured less than three times, the value may not be accurate.) The average values are used for GA and EDD calculation, and displayed on a graph.

Calculating Fetal Weight

- The fetal weight is shown in g (Gram), oz (ounce), lb (pound) unit in 2D Mode and Dual Mode.
- The user can calculate the fetal weight by measuring one set among (BPD, AC), (BPD, FL, FTA), (BPD, APTD, TTD, FL), (BPD, APTD, TTD, SL), (BPD, TTD), (AC, FL), (BPD, AC, FL), (HC, AC, FL), (BPD, HC, AC, FL), (AC) and (BPD, APTD, TTD). For example, Tokyo1 University method about Obstetrics Setup displays the fetal weight by measuring BPD, APTD and TTD.
- After all GA values are measured, the fetal weight is automatically measured and displayed on the report. Refer to 'Estimated Fetal Weight Formula' in the Reference Manual.

NOTE	For reference, Osaka University /Tokyo University methods are mainly used in Asia, Merz method in Europe, and Shepard/ Hadlock methods on the American continent.

AFI Calculation Method

The AFI is calculated by adding up the values of four measurements (Q1, Q2, Q3, Q4).

1. Measurements are performed by dividing the pregnant woman's abdomen into four parts. The distance between the fetus and the farthest point of each area is measured.
2. Select and measure each quadrant. Or select and measure all quadrants by selecting the **All** menu.
3. To obtain the specific image from each quadrant plane, press the **Freeze** button to go to the diagnosis mode. After obtaining the image, press **Freeze** button again to return to the measurement mode.
4. The measurement values taken from each plane are added and displayed on the screen.

Measurements in Spectral Doppler Mode

To calculate Fetal Doppler, trace the spectral waveform in Spectral Doppler Mode or mark a point on the waveform.

1. Press the **Calculator** button on the control panel to select the **OB menu**.
2. Select the menu to measure, and a cursor appears on the screen.
3. Make a measurement using the **Trackball** and the **Set** button on the control panel.

The following table shows the measurement methods of each menu.

Menu	Sub menu	Result
Volume Flow	Trace – Auto, Limited, Manual	Doppler Waveform Trace
	PSV	Velocity
	EDV	Velocity
	%StA	Calculation
	%StD	Calculation
	Vessel Area	Area
	Vessel Distance	Distance
Umbilical Artery	Same as above	Same as above
MCA(Mid Cereb Artery)	Same as above	Same as above
Rt. / Lt. Uterine Artery	Same as above	Same as above
Placenta Artery	Same as above	Same as above
Rt. / Lt. Fetal Carotids	Same as above	Same as above
Fetal Aorta	Same as above	Same as above
Ductus Venous	Same as above	Same as above

The measurement items in Spectral Doppler Mode are measured using the same method. The Volume Flow and Stenosis can be obtained. For more information, refer to 'Volume Flow Measurement Method'.

Fetal HR Calculation

Select **Fetal HR**, and heart rate can be calculated.

- Set the start and end points of the spectral waveform, and make a measurement.
- Rotate the **Menu** dial-button to select 'Number of Beats'. Calculate the average mean of Fetal HR.
- This links up with Fetal HR in Fetal echo.

Menu	Sub menu	Result
Fetal HR	Fetal Heart Rate	Time interval & no. of beats

GYN Calculations

Before Obtaining GYN Calculations

Prior to measure, press the Patient button and input patient information for GYN diagnosis in the patient information screen. Gynecology Basic Information are GRAVIDA, PARA, ABORTA, Exp. Ovul., and Day of Cycle.

Measurement Items

Measure Uterus, Lt. Ovary, Rt. Ovary, Lt. Follicles, Rt. Follicles, Lt. Ovarian A., Rt. Ovarian A., Cyst, Mass, etc. Lt. Ovarian A., Rt. Ovarian A, etc. are measured in Spectral Doppler Mode. Other items are measured in 2D Mode.

In the menus, most measurements are distance measurements. The measurement method is the same as in the basic measurements.

[Figure 5.2 GYN Measurement Menu]

GYN Measurements in 2D Mode

1. Select the **Gynecology menu** by pressing the **Calculator** button on the control panel.
2. Select the specific measurement menu, and a cursor appears on the screen.
3. Make the measurement using the **Trackball**, and the **Set** button on the control panel.

The following table shows the measurement methods of each menu.

Menu	Sub menu	Input Meas.
Uterus	Uterus Length	Distance
	Uterus Height	Distance
	Uterus Width	Distance

	Endo. Thickness	Distance
	Cervix Length	Distance
	Cervix Height	Distance
	Cervix Width	Distance
Right / Left Ovary	Length	Distance
	Height	Distance
	Width	Distance
Cyst / Mass	Same as above	Same as above
Right / Left Follicle	Required for One to 12 Follicles	Distance

When the Long axis image and Transverse axis image of the uterus are needed for measuring volume, press the **Freeze** button to return to the scan mode.

GYN Measurements in Spectral Doppler Mode

1. Select the **Gynecology menu** by pressing the **Calculator** button on the control panel.
2. Select the required measurement menu, and a cursor appears on the screen.
3. Perform the measurement using the **Trackball** and **Set** button on the control panel.

The following table shows the measurement methods of each menu.

Menu	Sub menu	Input Meas.
Right / Left Ovarian Artery	Trace – Auto, Limited, Manual	Doppler Waveform Trace
	PSV	Velocity
	EDV	Velocity

The user can obtain the values such as PSV, EDV, Vmean, Gmean, Gpeak, S/D, PI and RI from the spectral waveform in Spectral Doppler Mode. For more information, refer to ‘Doppler Spectrum Measurement Method’.

Cardiac Calculations

NOTE	Since the cardiac blood flow is fast, m/s is used as a velocity unit.

Before Obtaining Cardiac Calculations

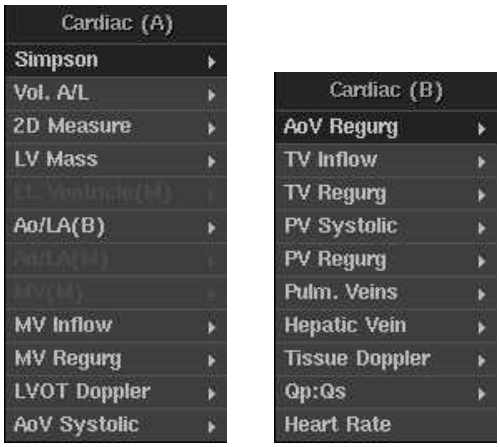
■ Cardiac Basic Information

Prior to measure, press the Patient button and input patient information for Cardiac diagnosis in the patient information screen. Cardiac Basic Information**:** Height, Weight and HR (Heart Rate) When the patient's height and weight are entered, BSA (Body Surface Area) is automatically calculated and displayed.

For more information about patient information menus and how to input the information, refer to 'Entering Patient Data' in 'Chapter 3. Settings'.

■ Cardiac Measurement Menu Setup

Set the related menus for convenient measurement.
The user can also set the calculation methods for area and volume.
For further information, refer to 'Setting Measurements' in 'Chapter 3. Settings'.



[Figure 5.3 Cardiac Measurement Menu]

Measurement Items

The measurement methods are the same as those for the basic measurements.

2D Mode	2D Measure, Ao/LA (Aorta/Left Atrium), LV (Left Ventricle) mass, Simpson, Vol A/L (Area Length)
M Mode	Ao/LA (Aorta/Left Atrium), Lt. (Left) Ventricle, MV (Mitral Valve), Heart Rate
Spectral Doppler Mode	AoV (Aortic Valve) Systolic, AoV (Aortic Valve) Regurgitation, LVOT Doppler, MV (Mitral Valve) Inflow, MV (Mitral Valve) Regurgitation, TV (Tricuspid Valve) Inflow, TV (Tricuspid Valve) Regurgitation, PV (Pulmonary Valve) Systolic, PV (Pulmonary Valve) Regurgitation, Tissue Doppler, Pulmonary Veins, Qp:Qs, Heart Rate, Hepatic Vein

Cardiac Measurements in 2D Mode

1. Select the **Cardiac menu** by pressing the **Calculator** button on the control panel. The cardiac menu is divided into 2 menus. Select the Cardiac (A) or Cardiac (B) menu by pressing the **Flexible Soft button [1], Calculator** or **Change** button on the control panel.
2. Select the specific measurement menu, and a cursor appears on the screen.
3. Perform the measurement using the **Trackball**, and the **Set** button on the control panel.

The following table shows the measurement methods of each menu.

Menu	Sub menu	Input Meas.
Simpson	A4C Diastole	20 Diameter & Length
	A4C Systole	20 Diameter & Length
	A2C Diastole	20 Diameter & Length
	A2C Systole	20 Diameter & Length
Vol. A/L (Volume Area/Length)	LV Vol. Diastole	Area & Length
	LV Vol. Systole	Area & Length
2D Measure	All	Distance (Thickness)
	IVSd (Inter Ventricular Septal thickness Diastolic)	Distance (Thickness)
	IVSs (Inter Ventricular Septal thickness Systolic)	Distance (Thickness)
	LVDd (Left Ventricle Diameter Diastolic)	Distance (Thickness)
	LVDs(Left Ventricle Diameter Systolic)	Distance (Thickness)

	LVPWd (Left Ventricle Posterior Wall Dimension Diastolic)	Distance (Thickness)
	LVPWs (Left Ventricle Posterior Wall Dimension Systolic)	Distance (Thickness)
LV (Left Ventricle) Mass	Epi. Area (Epicardial)	Area
	Endo. Area (Endocardial)	Area
	LV Length (Left Ventricle Length)	Distance
Ao/LA (Aorta/Left Atrium)	Ao-LA	Distance
	LVOT Dia (Left Venticle Outflow Tract Diameter)	Length
	Ao Root Dia (Aorta Root Diameter)	Length
	LA Dia (Left Atrium Dimension)	Length

■ **Simpson and Vol. A/L**

Measure the cardiac circumference and axis.

- **20 Diameter & Length:** A cursor to trace the area appears. After the area measurement, a new cursor to measure length appears. After drawing an axis within the area, calculate the area by dividing it equally into 20 sections with the axis as a standard.

■ **2D Measure**

Make the measurements of the sub-menus of **2D Measure**.

- **All** measures six items of 2D Measure (IVSd, IVSs, LVDd, LVDs, LVPWd, LVPWs) at once using the Rotational Guide Line.

  Move the Guide Line using the **Trackball** and adjust angle using **Menu** dial button. After pressing **Set** button to fix Guide Line, set the measure point with the **Trackball.** Six items are measured at once.
- **IVSd** and **IVSs** measure the AIVS and PIVS at the heart diastole and heart systolic phases.
- **LVDd** and **LVDs** measure ENDO at the heart diastole and heart systolic phases.
- **LVPWd** and **LVPWs** measure EPI at the heart diastole and heart systolic phases.
- AIVS: Anterior Interventricular Septum
  PIVS: Posterior Interventricular Septum
  ENDO: Endocardial Surface of Left Ventricular Wall
  EPI: Epicardial Surface of Left Ventricular Wall

■ **LV Mass**

When measuring **LV Mass**, the user can obtain the images at different angles needed for the sub-menus by using the **Freeze** button on the control panel. In Dual 2D Mode, simultaneous images are activated, and the image doesn't have to be scanned during the measurement.

- **LV (Left Ventricle)** is used only when measuring mass. It can be measured only in the case of the diastole of Left Ventricle.
- Myocardial thickness = SQRT(Dia.A / Pi) – SQRT(Sys.A / Pi)

■ **Ao/LA**

The sub-menus of **Ao/LA** are measured as shown below.

- **Ao-LA** measures Aorta and Left Atrium in sequence.
- **LVOT Dia** measures the point of Aortic Valve Annulus.
- **Ao Root Dia** measures the distance from Anterior Aortic Wall to Posterior Aortic Wall.
- **LA Dia** measures the distance from Posterior Aortic Wall to Left Arterial Wall.

Cardiac Measurements in M Mode

1. Select the **Cardiac menu** by pressing the **Calculator** button on the control panel. The cardiac menu is divided into 2 menus. Select the Cardiac (A) or Cardiac (B) menu by pressing the **Flexible Soft button [1], Calculator** or **Change** button on the control panel.
2. Select the specific measurement menu, and a cursor appears on the screen.
3. Perform the measurement using the **Trackball**, and **Set** button on the control panel. The user can measure all items at one time or select and measure the specific items in M Mode.

The following table shows the measurement methods of each menu.

Menu	Sub menu	Input Meas.
Lt. Ventricle	IVSd (Inter Ventricular Septal thickness Diastolic)	Distance (Thickness)
	LVDd (Left Ventricle Diameter Diastolic)	Distance (Thickness)
	LVPWd (Left Ventricle Posterior Wall Dimension Diastolic)	Distance (Thickness)
	IVSs (Inter Ventricular Septal thickness Systolic)	Distance (Thickness)
	LVDs (Left Ventricle Diameter Systolic)	Distance (Thickness)
	LVPWs (Left Ventricle Posterior Wall Dimension Systolic)	Distance (Thickness)

	RVDd (Right Ventricle Diameter Diastolic)	Distance (Thickness)
	All (IVSd, LVDd, LVPWd, IVSs, LVDs, LVPWs)	Same as above
Ao/LA (Aorta/Left Atrium)	Ao Root Dia (Aortic Root Dimension)	Distance
	AoV Cusp Sep. (Aortic Valve Cusp Separation)	Distance
	LA Dia (Left Atrial Dimension)	Distance
	LV PET (Left Ventricle Pre Eject Time)	Time
	LV ET (Left Ventricle Eject Time)	Time
	All (Ao Root Dia, AoV Cusp Sep., LA Dia, LV PET, LV ET)	Same as above
MV (Mitral Valve)	A-C Interval	Time interval
	D-E (D – E Excursion)	Distance
	E-F Slope	Slope (Velocity)
	EPSS (E Point Septal Separation)	Distance (Thickness)
	All Points (D-E Excursion, E-F slope, A-C Interval, E Point Septal Separation)	Same as above
Heart Rate	Heart Rate	Time interval & no. of beats

■ **Lt. Ventricle**

- The sub-menus of **Lt. Ventricle** are measured in the same way as in **2D Measure**.
- **RVDd** is measured in the same way as in **LVDd.**

■ **Ao/LA**

The sub-menus of **Ao/LA** are measured as shown below.

- **Ao Root Dia** measures the distance between the Anterior Aortic Wall and Posterior Aortic Wall.
- **AoV Cusp Sep.** measures the distance between the Coronary Cusp and Non Coronary Cusp.
- **LA Dia** measures the distance between the Posterior Aortic Wall and Left Arterial Wall.
- **LV PET** measures the distance between the ECG's Q Wave and Aortic Valve Opening.
- **LV ET** measures the distance between the Aortic Valve Opening and Aortic Valve Closing.

■ **MV**

The sub-menus of **MV** are measured as shown below.

- **A-C Interval** calculates the time duration by measuring the distance between the A point and C point in the Mitral Valve measurement screen**.**
- **D-E** measures the distance between the E point of the Anterior Mitral Valve and the

D point of the Mitral Valve Opening.

- **E-F Slope** calculates the velocity by measuring the distance between the E point and F point in the Mitral Valve measurement screen**.**
- **EPSS** measures the distance between the E point in the Mitral Valve and Posterior Interventricular Septum. The user can measure only in the upper direction of the E point, and only in the lower direction in Apex.

■ **Heart Rate**

Select **Heart Rate**, and heart rate is calculated.

- Set the start and end points of the spectral waveform as the baseline.
- Rotate the **Menu** dial-button to select 'Number of Beats'. Calculate the average mean of the Fetal HR.

Cardiac Measurements in Spectral Doppler Mode

1. Select the **Cardiac menu** by pressing the **Calculator** button on the control panel. The cardiac menu is divided into 2 menus. Select the Cardiac (A) or Cardiac (B) menu by pressing the **Flexible Soft button [1], Calculator** or **Change** button on the control panel.
2. Select the specific measurement menu, and a cursor appears on the screen.
3. Perform the measurement using the **Trackball** and the **Set** button on the control panel.

There are four ways to measure LVOT Doppler, MV Inflow / MV Regurgitation, AoV Systolic / AoV Regurgitation, TV Inflow / TV Regurgitation, PV Systolic / PV Regurgitation**:** Auto Trace, Limited Trace, Manual Trace, Measurement Each Item One by One.

The following table shows the measurement methods of each menu.

Menu	Sub menu	Input Meas.
MV (Mitral Valve) Inflow	Trace –Limited, Manual	Doppler Waveform Trace
	E-DT-A	Velocity & Time
	Peak E	Velocity
	Peak A	Velocity
	Acc (Acceleration Time)	Time or Calculated from Trace
	Dec (Deceleration Time)	Time or Calculated from Trace
	PHT (Pressure Half Time)	Time or Calculated from Trace
	IVRT (IsoVolumic Relaxation Time)	Time
	R-R Interval (Rate-Rate Interval)	Time Interval & No. of beats
MV (Mitral	Trace – Auto, Limited, Manual	Doppler Waveform Trace

Valve) Regurg	Peak V (Velocity)	Velocity
	VTI (Velocity Time Integral)	Calculated
	Trace – Auto, Limited, Manual	Doppler Waveform Trace
LVOT (Left Ventricular Outflow Tract) Doppler	Peak V (Velocity)	Velocity
	VTI (Velocity Time Integral)	Calculated
	Dia (Diameter)	Distance
AoV (Aortic Valve) Systolic	Trace – Auto, Limited, Manual	Doppler Waveform Trace
	Peak V (Velocity)	Velocity
	VTI (Velocity Time Integral)	Calculated
	Acc (Acceleration Time)	Time or Calculated from Trace
	Ejection (Ejection Time)	Time
	R-R Interval (Rate-Rate Interval)	Time Interval & No. of beats
AoV (Aortic Valve) Regurg	Trace –Limited, Manual	Doppler Waveform Trace
	Peak V (Velocity)	Velocity
	VTI (Velocity Time Integral)	Calculated
	PHT (Pressure Half Time)	Time or Calculated from Trace
TV (Tricuspid Valve) Inflow	Trace –Limited, Manual	Doppler Waveform Trace
	E-DT-A	Velocity & Time
	Peak E	Velocity
	Peak A	Velocity
	Acc (Acceleration Time)	Time or Calculated from Trace
	Dec (Deceleration Time)	Time or Calculated from Trace
	PHT (Pressure Half Time)	Time or Calculated from Trace
	R-R Interval (Rate-Rate Interval)	Time Interval & No. of beats
TV (Tricuspid Valve) Regurg	Trace – Auto, Limited, Manual	Doppler Waveform Trace
	Peak V (Velocity)	Velocity
	VTI (Velocity Time Integral)	Calculated
PV Systolic	Trace – Auto, Limited, Manual	Doppler Waveform Trace
	Peak V (Velocity)	Velocity
	Acc (Acceleration Time)	Time or Calculated from Trace
	R-R Interval (Rate-Rate Interval)	Time Interval & no. of beats
PV Regurg	Trace – Auto, Limited, Manual	Doppler Waveform Trace
	Peak V (Velocity)	Velocity
	VTI (Velocity Time Integral)	Calculated
	PHT (Pressure Half Time)	Time or Calculated from Trace
Plum. Veins (Pulmonary	Dias Vel. (Diastolic Velocity)	Velocity
	Sys Vel. (Systolic Velocity)	Velocity

Veins)	A. Rev Vel. (Artery Reversal Velocity)	Velocity
	A. Rev Dur. (Artery Reversal Duration)	Time
Tissue Doppler	E-DT-A	Velocity & Time
	Peak E'	Velocity
	Peak A'	Velocity
	Peak S	Velocity
	Acc (Acceleration Time)	Time or Calculated from Trace
	Dec (Deceleration Time)	Time or Calculated from Trace
	IVCT (IsoVolume Contraction Time)	Time or Calculated from Trace
	IVRT (IsoVolume Relaxation Time)	Time or Calculated from Trace
Qp:Qs	Sys. VTI ([Systemic] Flow Area Trace)	Calculated
	Sys. HR ([Systemic] Heart Rate)	Heart Rate
	Sys. Dia ([Systemic] Outflow Tract Diameter)	Diameter
	Pulm. VTI ([Pulmonic] Flow Area Trace)	Calculated
	Pulm. HR ([Pulmonic] Heart Rate)	Heart Rate
	Pulm. Dia ([Pulmonic] Outflow Tract Diameter)	Diameter
Heart Rate	Heart Rate	Time interval & no. of beats
Hepatic Vein	All	N/A
	Dias Vel. (Diastolic Velocity)	Velocity
	Sys Vel. (Systolic Velocity)	Velocity
	Rev Vel. (Reversal Velocity)	Velocity

For more information, refer to 'Doppler Spectrum Measurement Method'.

NOTE The Auto Trace function is not provided in MV Inflow and TV Inflow.

■ The values of Peak, Acc Time, Dec Time. Ejection Time, VTI, PHT, R-R Interval, etc. are automatically measured by tracing the Spectral Doppler image. Each item can also be selectively measured.

- **Peak V:** Measures the higher velocity value.
- **Peak E**: Measures the Ventricular Systolic peak.
- **Peak A**: Measures the Atrial Systolic peak.
- **Acc**: Measures the time duration when blood flow is accelerated. **Dec** Measures the time duration when blood flow is decelerated.
- **[E-DT-A]** : Measure **Peak E,Dec.**, and **Peak A** in order.
- **Ejection**: Measures the time duration by measuring the distance between the Aortic Valve Opening and Aortic Valve Closing.

- **VTI:** Calculates the value using the formula of **VTI = Sum of $V_i \times \Delta t$** after tracing the Spectral Doppler image.
- **PHT**: Calculates Half-Time using the Pressure gradient value obtained between the E point of Valve and the baseline.
- **R-R Interval**: Measures the distance between consecutive R waves on the ECG.

■ **LVOT Doppler**

Measure Left Ventricular Outflow. Its sub-menu **Dia**. measures the Aortic Valve Annulus point in the 2D image.

■ The sub-menus of **Plum. Veins** are measured as shown below.

- **Dias Vel.** and **Sys Vel.** measure the velocity at the diastole and systolic phases.
- **A. Rev Vel.** measures the Peak Velocity at Atrial Reversal.
- **A. Rev Dur.** measures the time duration by measuring the distance between the Mitral Valve Closing and the heart diastole phase.

■ In the sub-menu of **Tissue Doppler, Peak S** measures the systolic peak, and **IVCT** 와 **IVRT** measure Isovolumic Contraction and Isovolumic Relaxation phases, respectively.

■ The sub-menus of **Qp:Qs** are measured as shown below.

- **Sys. VTI** and **Pulm. VTI** measure the VTI by tracing LVOT Flow and RVOT Flow respectively.
- **Sys. HR** and **Pulm. HR** measure the heart rate by measuring diastole phase and systolic phase respectively in LVOT Flow and RVOT Flow.
- **Sys. Dia** and **Pulm. Dia** measures the distance of Outflow Tract in the 2D images of LVOT Flow and RVOT Flow, respectively.

■ Select **Heart Rate** to calculate the heart rate.

- Select and measure the start and end points of the spectral waveform.
- Measure the average value of the heart rate by selecting ‘Number of Beats’ with the **Menu** dial-button.

■ Select **Hepatic Vein** to measure Hepatic Vein.

- **Dias Vel.** measures the Peak Velocity at diastole.
- **Systolic Vel.** measures the Peak Velocity at systole.
- **Reversal Vel.** measures the Peak Velocity at reversal.

Vascular Calculations

Before Obtaining Vascular Calculations

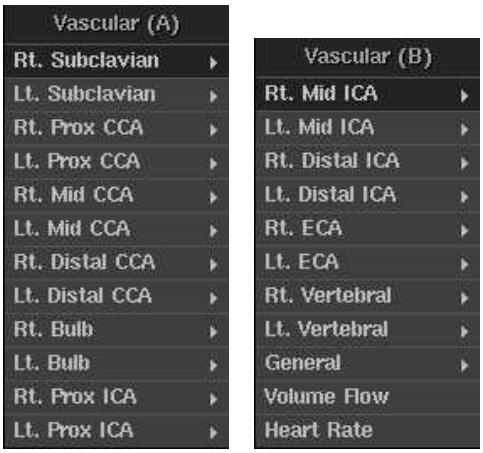
Set the related menus for convenient measurement.

The user can also set the Peak Velocity used to calculate 'A/B Ratio' and 'ICA/CCA Ratio'.

For more information, refer to 'Setting Measurements' in 'Chapter 3. Settings'.

Measurement Items

- The user can measure Rt./ Lt. Subclavian, Rt./Lt. Prox CCA, Rt./Lt. Mid CCA, Rt./Lt. Distal CCA, Rt./Lt. Bulb, Rt./Lt. Prox ICA, Rt./Lt. Mid ICA, Rt./Lt. Distal ICA, Rt./Lt. ECA, Rt./Lt. Vertebral, General, Volume Flow, Heart Rate, etc.
- All vascular systems are measured using the same method. The measurement methods are the same as for basic measurements.
- It is convenient to calculate each measurement value on the Spectral Doppler image.



[Figure 5.4 Vascular Measurement Menu]

Vascular Measurements

1. Select the **Vascular menu** by pressing the **Calculator** button on the control panel. The vascular menu is divided into 2 menus Select the Vascular (A) or Vascular (B) menu by pressing the **Flexible Soft button [1], Calculator** or **Change** button on the control panel.
2. Select the required measurement item and menu, and a cursor appears on the screen.
3. Perform the measurement using the **Trackball** and the **Set** button on the control panel.

The following table shows the measurement methods of each menu.

Menu	Sub menu	Input Meas.
Rt./ Lt. Subclavian	Trace – Auto, Limited, Manual	Doppler Waveform Trace
	PSV	Velocity
	EDV	Velocity
	%StA	Calculation
	%StD	Calculation
	Vessel Area	Area
	Vessel Distance	Distance
Rt./Lt. Prox CCA	(Proximal Common Carotid Artery) Same as above	Same as above
Rt./Lt. Mid CCA	Same as above	Same as above
Rt./Lt. Distal CCA	Same as above	Same as above
Rt./Lt. Bulb	Same as above	Same as above
Rt./Lt. Prox ICA	(Proximal Internal Carotid Artery) Same as above	Same as above
Rt./Lt. Mid ICA	Same as above	Same as above
Rt./Lt. Distal ICA	Same as above	Same as above
Rt./Lt. ECA	(External Carotid Artery) Same as above	Same as above
Rt./Lt. Vertebral	Same as above	Same as above
General	Same as above	Same as above

- The values such as PSV, EDV, Vmean, Gmean, Gpeak, TAM, S/D, PI, RI, etc. can be obtained from the spectral waveform in Spectral Doppler Mode. There are four measurement methods: Auto Trace, limited Trace, Manual Trace, and Measurement Each Item One by One. For more information, refer to 'Doppler Spectrum Measurement Method'.
- **Stenosis % Calculation :** There are two ways to obtain the Stenosis % of each vascular system: **%StA** using the area and **%StD** using the distance. Refer to 'Volume Flow Measurement' for more information.
- **Vessel Area Measurement:** There are two ways to obtain Vessel Area: **Vesl. Area** using the circumference and **Vesl. Dist** using the distance.
- The user can obtain the **Volume Flow** values using the **TAM (Time Average Mean Velocity)** value obtained from the spectral waveform and the **Vessel Area** value obtained using Vesl. Area or Vesl. Dist.

Volume Flow Measurements

The Volume Flow menu is shown below. For more information, refer to ‘Volume Flow Measurement Method’.

Menu	Sub menu	Result
Volume Flow	Auto Trace	Doppler Waveform Trace
	Vessel Distance	Distance

Heart Rate Calculations

Select **Heart Rate** to calculate the heart rate.

- Select and measure the start and end points of the spectral waveform.
- Calculate the average value of the heart rate by selecting ‘Number of Beats’ with the **Menu** dial-button.

Menu	Sub menu	Result
Heart Rate	Heart Rate	Time interval & no. of beats

Urology Calculations

Before Obtaining Urology Calculations

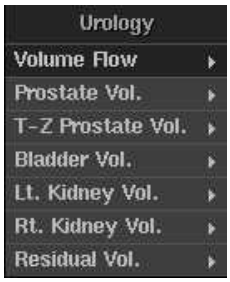
For more convenient measurement, set the related menus.

The user can select the Volume Method. There are four types of Volume Method. The factor value can be set manually for the formulas that need it.

For more information, refer to 'Settings Measurements' in 'Chapter 3. Settings'.

Measurement Items

- Measure BLVOL (Bladder Volume), Prostate Vol, TZVOL (Transitional Zone Prostate Volume), Residual Volume, Lt. Kidney Vol., Rt. Kidney Vol. in 2D Mode. Also, Vessel Area and Vessel Distance can be measured to calculate Volume Flow.
- Residual Pre/Post and PSA Density Volume can be measured.
- The measurement methods are the same as for the basic measurements.



[Figure 5.5 Urology Measurement Menu]

Volume Measurements

1. Select the **Urology menu** by pressing the **Calculator** button on the control panel.
2. Select the required measurement item and menu, and a cursor appears on the screen.
3. Perform the measurement using the **Trackball** and the **Set** button on the control panel.

- The measurement of Transitional Zone Prostate Volume, Bladder Volume, Left Kidney Volume, and Right Kidney Volume is the same as in Prostate Volume.
- There are two ways to measure in each menu: one is measuring the item values from one image, and the other is measuring the item values from several images. The measurement methods of each menu vary with the Volume Method set in the Setup menu.

■ If **3Distance** or **3Distance * Factor** is set in Setup, three diameter values can be obtained in order.

Menu	Sub menu	Result
Bladder Volume	All	
	1st Dia. (Diameter)	Distance
	2nd Dia. (Diameter)	Distance
	3rd Dia. (Diameter)	Distance
Prostate Volume	All	
	1st Dia. (Diameter)	Distance
	2nd Dia. (Diameter)	Distance
	3rd Dia. (Diameter)	Distance
Residual Volume	Pre All	
	Pre 1st Dia. (Diameter)	Distance
	Pre 2nd Dia. (Diameter)	Distance
	Pre 3rd Dia. (Diameter)	Distance
	Post All	
	Post 1st Dia. (Diameter)	Distance
	Post 2nd Dia. (Diameter)	Distance
	Post 3rd Dia. (Diameter)	Distance
Transitional Zone Prostate Volume	All	
	1st Dia. (Diameter)	Distance
	2nd Dia. (Diameter)	Distance
	3rd Dia. (Diameter)	Distance
Left (Right) Kidney Volume	All	
	1st Dia. (Diameter)	Distance
	2nd Dia. (Diameter)	Distance
	3rd Dia. (Diameter)	Distance
	Renal Pelvis	Distance

■ If **Ellipsoid** is set in Setup, Main Diameter and Beside Diameter values can be obtained in order.

Menu	Sub menu	Result
Bladder Volume	All	
	Main Dia. (Diameter)	Distance
	Beside Dia. (Diameter)	Distance
Prostate Volume	All	
	Main Dia. (Diameter)	Distance
	Beside Dia (Diameter)	Distance
Residual Volume	Pre All	
	Pre Main Dia. (Diameter)	Distance
	Pre Beside Dia. (Diameter)	Distance
	Post All	
	Post Main Dia. (Diameter)	Distance
	Post Beside Dia. (Diameter)	Distance
Transitional Zone Prostate Volume	All	
	Main Dia. (Diameter)	Distance
	Beside Dia. (Diameter)	Distance
Left (Right) Kidney Volume	All	
	Main Dia. (Diameter)	Distance
	Beside Dia. (Diameter)	Distance
	Renal Pelvis	Distance

■ If **Sum of 20 Disks** is set in Setup, the user can calculate the measurement value by measuring the prostate circumference and prostate axis using the **Trackball** and the **Set** button.

Menu	Sub menu	Result
Bladder Volume	Bladder Vol.	20 Diameter & Area
Prostate Volume	Prostate Vol.	20 Diameter & Area
Residual Volume	Pre Vol.	20 Diameter & Area
	Post Vol.	20 Diameter & Area
Transitional Zone Prostate Volume	Transitional Zone Prostate Vol.	20 Diameter & Area
Left (Right) Kidney Volume	Left (Right) Kidney Vol.	20 Diameter & Area
	Renal Pelvis	Distance

Volume Flow Measurements

The Volume Flow menu is shown below. For more information, refer to ‘Volume Flow Measurement Method’.

Menu	Sub menu	Result
Volume Flow	Trace – Auto, Limited, Manual	Doppler Waveform Trace
	PSV	Velocity
	EDV	Velocity
	%StA	Calculation
	%StD	Calculation
	Vessel Area	Area
	Vessel Distance	Distance

Fetal Echo Calculations

Before Obtaining Fetal Echo Calculations

Set the related menus for convenient measurement.

The user can also set the measurement method to calculate volume.

Refer to the 'Setting Measurements' section in "Chapter 3. Settings" for more information.

Measurement Items

The fetal heart is measured. The measurement methods are the same as in the basic measurements.

2D Mode	2D Echo, CTAR (Cardio-Thorax Area Ratio)
M Mode	Fetal M mode
Spectral Doppler Mode	MPA (Main Pulmonary Artery), Duct.Art (Ductus Arteriosus), IVC (Inferior Vena Cava), Duct.Vein (Ductus Venosus), Ascending Aorta, Descending Aorta, MV Inflow, MV Regurg, TV Inflow, TV Regurg, PLI (Preload Index)

[Figure 5.6 Fetal Echo Measurement Menu]

Fetal Echo Measurements in 2D Mode

1. Select the **Fetal Echo** menu by pressing the **Calculator** button on the control panel.
2. Select the specific measurement menu, and a cursor appears on the screen.
3. Perform the measurement using the **Trackball** and the **Set** button on the control panel.

The following table shows the measurement methods of each menu.

Menu	Sub menu	Input Meas.
2D Echo	Asc. Aorta (Ascending Aorta)	Distance
	MPA (Main Pulmonary Artery)	Distance
	Duct. Art (Ductus Arteriosus)	Distance
	Left Atrium	Distance
	Right Atrium	Distance
	Right Ventricle	Distance
	Inter Ventricular Septum	Distance
	Lt. Ventricle Dia.(Diastole)	Distance
	Lt. Ventricle Sys.(Systole)	Distance
	LVPW (Left Ventricle Posterior Wall)	Distance
	Heart Circ. (Circumference)	Circ/Area
	Thoracic Circ. (Circumference)	Circ/Area
CTAR (Cardio-Thorax Area Ratio)	Thorax AP (Anteroposterior) Diameter (ThAPD)	Distance
	Thorax Transverse Diameter (ThTD)	Distance
	Heart AP Diameter (HAPD)	Distance
	Heart Transverse Diameter (HTD)	Distance
	All (ThAPD, ThTD, HAPD, HTD)	Same as above

- Use the Distance measurement method to measure Asc. Aorta (Ascending Aorta), MPA (Main Pulmonary Artery), Duct. Art (Ductus Arteriosus), Lt. Atrium (Left Atrium), Rt. Atrium(Right Atrium), Rt. Ventricle(Right Ventricle), IVS (Inter Ventricular Septum), LVDd (Left Ventricle Diameter Diastole), LVDs (Left Ventricle Diameter Systole), and LVPW (Left Ventricle Posterior Wall).

- Use the Circ/Area calculation method to measure Heart Circ. (Heart Circumference), and Thora Circ. (Thoracic Circumference).

■ The CTAR menu measures and compares the size of the fetal chest and heart. You can obtain the value by comparing ThAPD, ThTD, HAPD, and HTD values.

$$CTAR = \frac{HAPD \times HTD}{ThAPD \times ThTD} \times 100$$

Fetal Echo Measurements in M Mode

1. Select the **Fetal Echo** menu by pressing the **Calculator** button on the control panel
2. Select the specific measurement menu, and a cursor appears on the screen.
3. Perform the measurement using the **Trackball** and the **Set** button on the control panel.

There are two ways to measure the LV (Left Ventricle) in M Mode. One is measuring all items at one time, and the other is measuring each item one at a time.

The following table shows the measurement methods of each menu.

Menu	Sub menu	Input Meas.
Fetal M Mode	IVSd (Inter Ventricular Septal Thickness Diastolic)	Distance (Thickness)
	LVDd (Left Ventricle Diameter Diastolic)	Distance (Thickness)
	LVPWd (Left Ventricle Posterior Wall Dimension Diastolic)	Distance (Thickness)
	IVSs (Inter Ventricular Septal Thickness Systolic)	Distance (Thickness)
	LVDs (Left Ventricle Diameter Systolic)	Distance (Thickness)
	LVPWs (Left Ventricle Posterior Wall Dimension Systolic)	Distance (Thickness)
	RVDd (Right Ventricle Diameter Diastolic)	Distance (Thickness)
	All (IVSd, LVDd, LVPWd, IVSs, LVDs, LVPWs)	Same as above
Fetal HR	Fetal Heart Rate	Time interval & no. of beats

■ Measure the sub menus of **Fetal M Mode** as shown below.

- **IVSd** and **IVSs** measure AIVS and PIVS at the diastolic and systolic phases respectively.
- **LVDd** and **LVDs** measure ENDO at the diastolic and systolic phases respectively.
- **LVPWd** and **LVPWs** measure EPI at the diastolic and systolic phases respectively.
- AIVS: Anterior Interventricular Septum
  PIVS: Posterior Interventricular Septum
  ENDO: End cardinal Surface of Left Ventricular Wall
  EPI: Epicardial Surface of Left Ventricular Wall
- **RVDd** is measured in the same way as in **LVDd**.

- Select **Fetal HR** to calculate the fetal heart rate.
  - Select and measure the start and end points of the spectral waveform.
  - Calculate the average value of the heart rate by selecting 'Number of Beats' with the **Menu** dial-button.
  - This links up with the Fetal HR in Obstetrics.

Fetal Echo Measurements in Spectral Doppler Mode

1. Select the **Fetal Echo** menu by pressing the **Calculator** button on the control panel.
2. Select the specific measurement menu, and a cursor appears on the screen.
3. Perform the measurement using the **Trackball** and the **Set** button on the control panel.
4. There are four measurement methods to measure MPA, Duct.Art, IVC, Duct.Vein, Asc.Aorta, and Dsc.Aorta**:** Auto Trace, Limited Trace, Manual Trace, and Measurement Each Item One by One.

The following table shows the measurement methods of each menu.

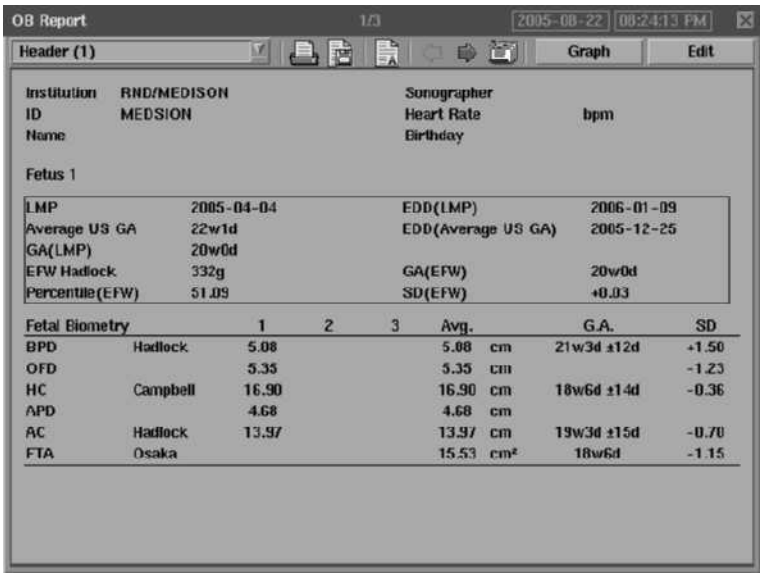
Menu	Sub menu	Input Meas.
MPA (Main Pulmonary Artery)	Trace – Auto, Limited, Manual	Doppler Waveform Trace
	PSV	Velocity
	EDV	Velocity
Ductua Arteriosus	Same as above	Same as above
Inferior Vena Cava	Same as above	Same as above
Ductus Venosus	Same as above	Same as above
Ascending Aorta	Same as above	Same as above
Descending Aorta	Same as above	Same as above
MV (Mitral Valve) Inflow	Peak E	Velocity
	Peak A	Velocity
MV (Mitral Valve) Regurgitation	Velocity	Velocity
Tricuspid Valve Inflow	Peak E	Velocity
	Peak A	Velocity
Tricuspid Valve Regurgitation	Velocity	Velocity
PLI (PreLoad Index)	Systolic Flow	Velocity
	Diastolic Flow	Velocity
	Atrial Reversal Flow	Velocity
Fetal HR	Fetal Heart Rate	Time interval & no. of beats

- Select **Auto Trace**. The image is automatically traced and the measurement values calculated.
- Select **Limited Trace,** and the baseline appears on the image. Set the start and end points of the spectral waveform using the baseline, and the measurement value is automatically calculated. The user can reposition the baseline by pressing the **Change** button.
- Select **Manual Trace,** and a cursor appears on the image. Trace the Doppler waveform, and the measurement value is automatically calculated.
- The user can select and measure each item manually.
  - **PSV** measures the Peak Systolic velocity.
  - **EDV** measures the End Diastolic velocity.
  - **Peak E** measures the Ventricular Systolic peak.
  - **Peak A** measures the Atrial Systolic peak.
- Select **Fetal HR** to calculate the fetal heart rate.
  - Select and measure the start and end points of the spectral waveform.
  - Measure the average value of the heart rate by selecting ‘Number of Beats’ with the Menu dial-button.
  - This links up with the Fetal HR in obstetrics.

Report

Check the measurement and calculation results in the report of each application.

- Press the **Report** button on the keyboard to check the report of the specific application.
- The applications not yet measured are not shown.
- The deviated data from the valid range will be displayed with Invalid mark(*).
- To return to the diagnosis mode, press the **X** on the report screen, or press the **Exit** button on the control panel or the **Report** button on the keyboard.



[Figure 5.7 Report Screen – Example]

Viewing Report

- The measurement and calculation items and their values are displayed.
- When the report screen has more than two pages, use the left/right arrow button on the report screen. To search and check the reports of other applications, use the **Next Package** to move to the specific package.

Editing Report

Press the **Edit** to edit the specific information. After editing, press the **Ok** at the top of the screen to return to the original report screen, and the edited values are shown in the [ ] bracket in the report.

Comment 

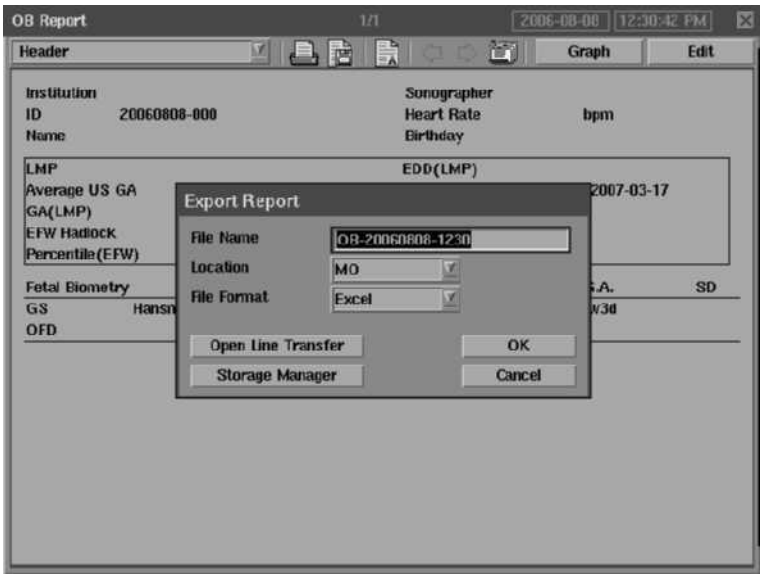
Press the **Comment**. Press the **Ok** at the top of the screen after entering some comment to return to the original report screen.

Printing out Report 

Press the **Print** on the screen.

Exporting Report 

- Press the **Export** on the screen to save the report as MO Disk or Flash Memory. The Export Report window appears on the screen to designate File Name and File Format as shown below.



[Figure 5.8 Report Export – Example]

- The **Export** is not activated if the drive is not connected.
- The file name is automatically given, but the file name can also be inputted manually. The user can choose a file format of either Excel or Text.

Open Line Transfer

Transfer the report to another computer or printer. Press the **Open Line Transfer** on the Export Report window.

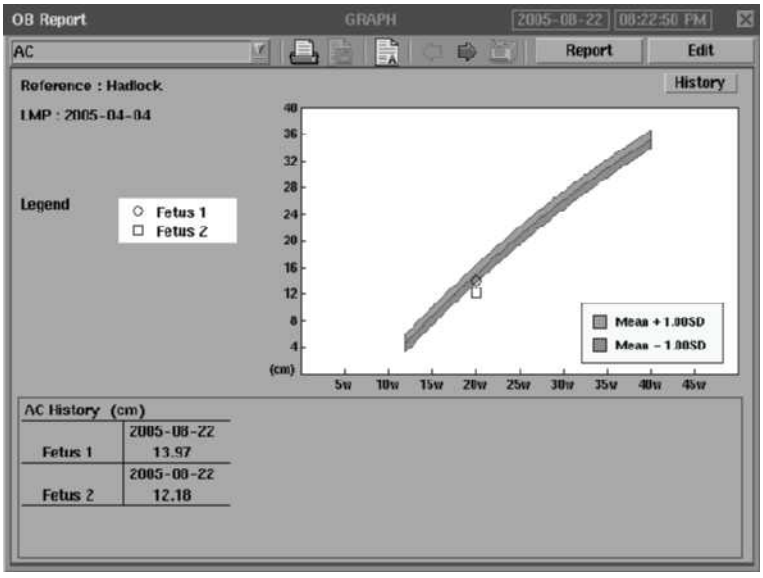
NOTE	■ Connect the USB to RS-232C serial cable to the USB port of the rear panel prior to use this function. ■ If the operating system of the PC connected to this system via the USB to RS-232C Serial Cable is Windows XP™, errors may be caused during report transferring.

Set the computer or printer, connects to this system, like following;

- 9,600 Baud
- 8-bit data
- No parity
- 1 stop bit

Graph Function

- This function is used to display the GA values such as BPD, HC, AC and FL, allowing the user to diagnose fetal growth.
- The function can be used only in the OB report. Press **Graph** on the screen.
- The graph is created using ID, LMP, and measurement date as standards.
- To change to the report screen, press **Report** on the screen.
- To return to the diagnosis mode, press the **X** on the graph screen, or press the **Exit** button on the control panel.



[Figure 5.9 Graph – Example]

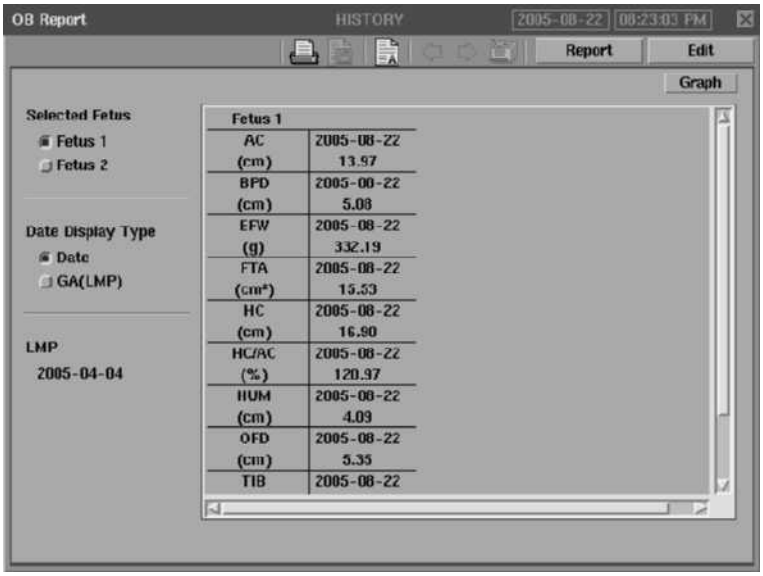
NOTE	Only after the patient name, ID and LMP are entered, the graph and report are automatically saved in the HDD.

Viewing Graph

- The graph of the recently measured values is drawn according to the gestation period (week) and fetal size (mm).
- The G.A. values, including the fetal weight, are displayed at the bottom of the screen. Select a specific item on the combo box using the **Trackball** and the **Set** button, and a graph appears.

Viewing History

- To view the history information, press the **History** on the OB report screen. To return to the graph screen, press the button again.
- Select Fetus and Date Display Type to study.



[Figure 5.11 History – Example]

Chapter 6

Image Managements

Reviewing Images

Dozens of images, including the currently displayed 2D Mode, M Mode screen, and ECG information, are automatically saved in the equipment memory and can be retrieved later whenever the need arises.

Saving and Viewing Cine Images

Pressing **Freeze** button after diagnosis activates the Cine Memory function (Cine Memory). Move the **Trackball** left or right in Freeze mode, and the previous images are searched and displayed. At the top of the screen, the number and position (the currently saved or displayed image number) of the images saved up to now are shown.
The Flexible Soft Menu in Cine Mode is shown below:

- **Flexible Soft button [1] Auto Run**: Cine Mode is automatically played and repeated.
- **Flexible Soft button [2] Cine/Loop**: This is used in M Mode and PW Spectral Doppler Mode It is also available with the **Change** button.
- **Flexible Soft button [3] Cine Edit**: Set the range of the Cine mode. When you press this button, the **Flexible Soft button [3]~[5]** is changed; **[3] Frame Start**, **[4] Frame End**, **[5] Cine Save**.
  - Cine start point: press the **Flexible Soft button [3] Frame Start** and set the start point using the **Set** button
  - Cine end point: press the **Flexible Soft button [4] Frame End** and set the start point using the **Set** button

  Or, set the start point using the **Set** button and press the **Change** button to set the end point.

  After setting, press the **Flexible soft button [5] Cine Save** to save the start and the end point.
- **Flexible Soft button [4] Cine Save**: Save the Cine whole Cine images.
- **Flexible Soft button [5] Speed** : Change the speed of Auto Run. When you press this button repeatedly, it changes as 100%, 70%, 40% and 10%.

Cine Image function in Multi-Image

In Dual Mode, both active and frozen images can be displayed simultaneously on the screen. The frozen image is on the left side of the screen in Dual Mode. Pressing the **Freeze** button while scanning the image on the right side freezes the active image on the right side, and the Cine function is applied to the image on the right. To apply the Cine function to the image on the left, press **Set** button or **Dual** button on the control panel, and the left image is activated.

Saving and Viewing Loop Image

A Loop image can be saved while viewing the M Mode image, PW Spectral Doppler image, etc. The Loop can be viewed by freezing the image that is being scanned with the **Freeze** button on the control panel.

Press the **Change** button on the control panel to toggle between Cine function and Loop function. The currently used function is displayed in the upper left section of the screen.

Annotating Images

Typing Text

Press the **Text** button on the control panel to enter Annotation Mode.

[Figure 6.1 Annotation Mode]

Use the Alpha-Numeric keyboard on the control panel to input text. Use the **Trackball** to move the cursor.

After entering text, press **Exit** button or **Text** button on the control panel to exit the mode.

While entering text, the keys have the specific functions shown below.

[↑] Key	Move the cursor position up by one row on the same column of the current cursor.
[↓] Key	Move the cursor position down by one row on the same column of the current cursor.
[←] Key	Move the cursor position to the left by one column on the same row of the current cursor.
[→] Key	Move the cursor position to the right by one column on the same row of the current cursor.

Text Input Using the Brief Edit Function

Use the Brief Edit function to enter text more quickly and easily. It enables the user to enter only the first few letters of the text entry and then choose a full entry from word list in the system for automatic input.

For example, entering “TA” only will provide a list beginning with “TA” from which the user can choose the appropriate entry – such as “Transabdominal” – for automatic input.

To use this function, select Brief Set **On** on the **General** tab of **[F6] Setup**.

When you use this function, the Brief word window will be displayed on the screen.

[Figure 6.2 Brief word window]

The Brief word list supplied with this product can be added, modified or deleted by the user.

NOTE	For instructions on editing the short entry list, see ‘Chapter 3. Settings’..

Deleting Text

Press the **Clear** button on the control panel. All the text entered on the screen will be deleted.

Displaying Body Marker

Press the **[F3] Body Marker** button on the alpha-numeric keyboard to enter Body Marker input mode.
The types of Body Markers shown in the Flexible Soft Menu vary with the diagnosis mode. A maximum of five Body Markers can be displayed in the Flexible Soft Menu at one time. If the number exceeds the limit, press **[F3] Body Marker** button again.

Selecting Body Marker

Press the corresponding Flexible Soft button of the specific Body Marker from [1] ~ [5] , and the Body Marker is displayed on the screen.

Changing Body Marker Position

1. Press the **Change** button on the control panel.
2. Reposition the Body Marker, using the **Trackball**.

3. Press **Change** button on the control panel again to complete the position change.

Deleting Body Marker

Press the **Clear** button on the control panel.

Probe Cursor on the Body Marker

Once a Body Marker is entered, the probe cursor will appear indicating the position of the probe in use.

- Selecting Probe Cursor

  Four types of the probe cursor are supported. Use the **Menu** dial-button to change or select the cursor.

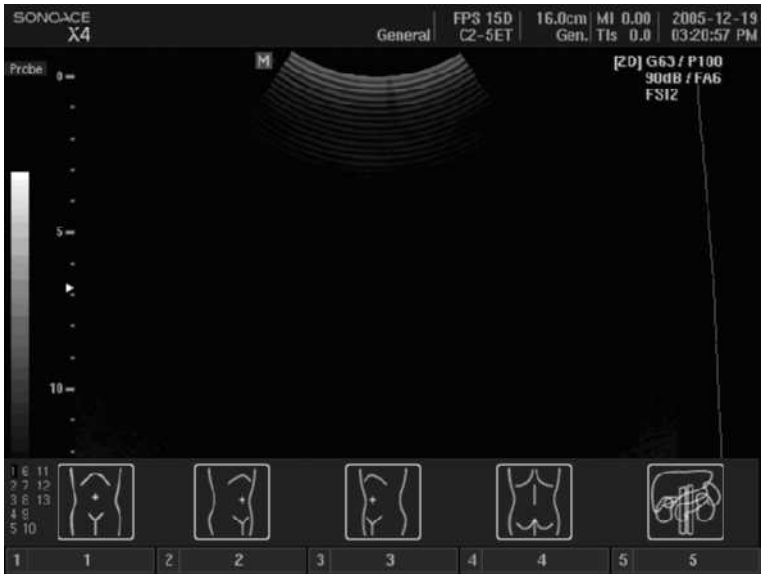
- Changing Probe Cursor Position

  Position the probe cursor on the Body Marker using the **Trackball**.

- Changing Probe Cursor Angle

  Use the **Angle** dial on the control panel to adjust the angle of the probe cursor.

Press the **Set** button to save the status of the body marker. Press the **Exit** button on the control panel to exit Body Marker Mode.



[Figure 6.3 Body Marker Input Mode]

Displaying Indicator

Press the **Indicator** button on the control panel, and the Indicator cursor appears on the screen.

Adjust the cursor direction, using the **Angle** dial on the control panel.

Press **Set** button to enter an indicator. Then, another Indicator will be appeared. You can enter one or more Indicators on the specific position.

Press **Exit** button on the control panel to exit the mode.

[Figure 6.4 Indicator Input Mode]

Deleting Indicator

Press the **Clear** button on the control panel. More than one Indicator can be deleted at once.

Saving and Transferring Images

Saving Images

Press the **Save** button on the control panel. You can save 500 images per each exam.
Images are stored and managed according to patients. Therefore, if the **Save** button is pressed without entering basic patient information, a window to enter patient information appears. General images, 3D images, etc. can be saved, and then edited and managed with SonoView.

WARNING	Ensure a patient ID is entered, since images are saved according to the ID. If not, an image can be lost, and serious errors can occur in the previously saved images.

Saving an Image with Text

NOTE	It's convenient to save an image with description for later search.

For more information about entering text, refer to 'Annotating Images' in this chapter.

Transferring Images

Send images using DICOM. For more information on the DICOM server settings and DICOM operation, see the section on "Setting DICOM" in 'Chapter 3. Settings'.

Transferring Images in Real Scan Mode

There are two methods of sending images: sending one scanned image at a time immediately after each scan, and sending selected images after the scanning process is complete. For more information about transferring images, see the section on "Transfer Mode" in 'Chapter 3. Settings'.

Transferring Images in SonoView

Select an exam in the Exam View screen to transfer all images in the exam, or select and transfer images one by one in the Exam Review screen. For more information, see the section on "SonoView" in this chapter.

Printing and Recording Images

Printing Images

Press the **Echo Print** button on the control panel to print out a scanned image using an echo-printer. For details on how to set-up a printer, refer to ‘Chapter 3. Settings’.

Recording Images

To record an image with the VCR during scanning, press the recording button of the connected standard VCR.

SonoView

SonoView used in the SONOACE X4 is an integrated image management system. The Personal Computer or Embedded PC loaded into the product supports the system.

A variety of functions are provided in SonoView: Saving/Filing of specific images, image viewing, deleting images one by one, and exporting documents with a standard PC.

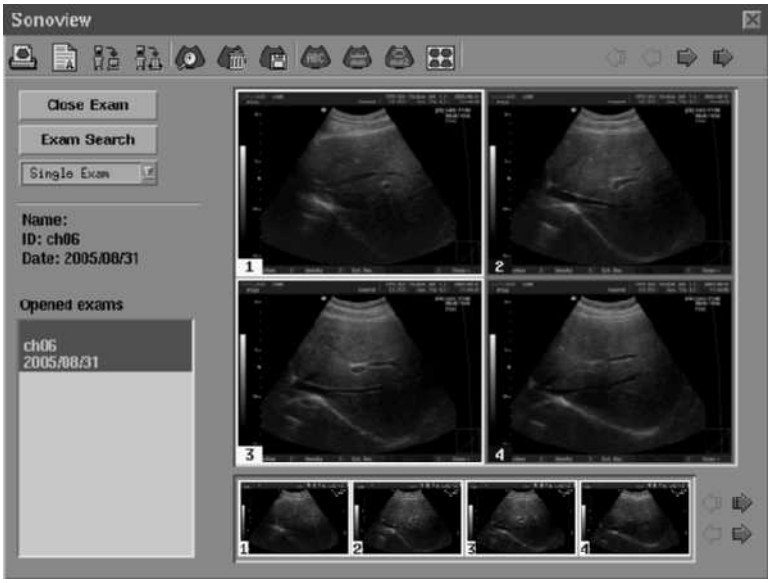
The file types used in this system follow the international standard DICOM (Digital Imaging and Communication in Medicine). As a result, the PACS (Picture Archiving Communication System) can be implemented in the SONOACE X4 without any additional costs, and it's easy to exchange documents with other hospitals or equipment. (cf. DICOM and PACS are well established in advanced countries, but not yet in Korea.)

This system supports the Bitmap file format (ie. *. BMP), which is most commonly used on standard office PCs. It is therefore easy to exchange data on images.

Thanks to these functions, SonoView has enabled systematic management and research of patient medical history.

Starting and Quitting SonoView

Press the **SonoView** button on the control panel. If the ID has already been entered, the images saved during the current examination will be displayed on the Review screen.



[Figure 6.5 SonoView - Review]

NOTE	■ If the ID has not yet been entered, the patient information window will be displayed prior to saving the images. Please enter the ID in the patient information window before saving the images or using SonoView. ■ Each patient's data is identified by the patient's unique ID. For efficient management of IDs, we recommend the use of the patients' chart numbers or the last 6 digits of patients' social security numbers.

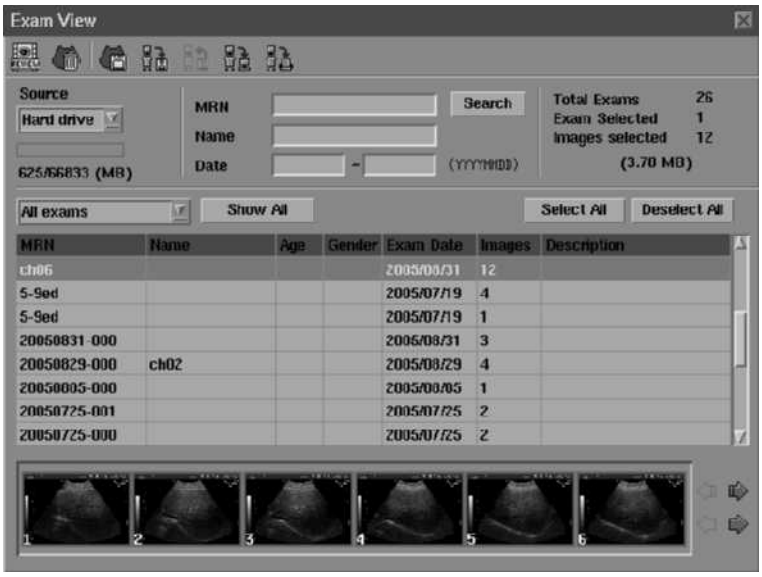
Press the **SonoView** button on the control panel or press **X** on the Review screen to quit SonoView.

Exam View

NOTE	If you select an icon on the Exam View screen, the name of icon will be displayed.

Starting Exam View

Press **Exam Search** on the Review screen. The Exam View screen appears.



[Figure 6.6 Exam View Screen]

In the center of the Exam View screen is the exam list with information on the patients' IDs, names, age, genders, examination dates, and the number of images saved. On the top right-hand corner of the screen are the total number of examinations, number of selected examinations, number of selected images and the size of selected images.

Selecting Exam

Use the trackball and the **Set** button to select an examination. To cancel the exam selection, press the **Set** button once again.

Press **Select All** to select all examinations at once, or press **Deselect All** to deselect all exams.

To view exams saved in a storage devices, select Hard drive, MO drive, FLASH, or ODD from **Source** on the screen. Selecting a source brings up information on the used space and total space for the source.

Searching Exam

Enter the patient's ID, name, and exam date, and press **Search** to bring up an exam list with examinations that are identical or similar to the search conditions. You can search exams using as little as a single character or number for your search string.

Searching by Period

Select a period from the combo box at the top of the exam List. Today, 1Week, 1Mon, 3Mon, and 1Year show the exams for the respective periods dating back from the current date, and All Exams shows all examinations.

Showing All Exam

Select **Show All** at the top of the exam list. All exam lists saved in the selected source will be displayed.

View Exam

Use the trackball and the **Set** button to select an exam to view, and then press **Review Exam** at the top of the screen. The screen will switch to the Review screen and show images for the selected exam.

Deleting Exam

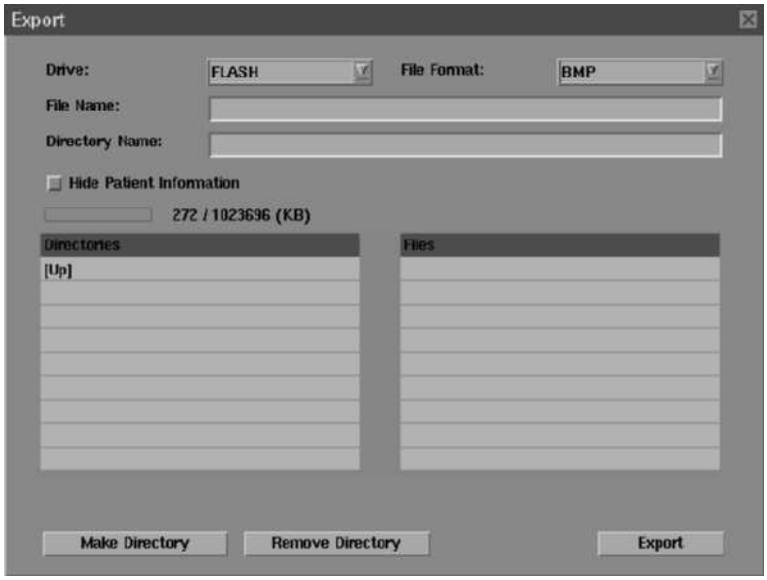
Use the trackball and the **Set** button to select an exam to delete, and then press **Delete Exam** at the bottom of the screen or press the **Del** key on the keyboard. To select multiple images, select images while holding down the **Ctrl** button on the keyboard.

Exam Export

Multiple exams can be selected and exported simultaneously.

1. Select exam(s) and press **Export** to bring up the Export window.

2. Select MO drive, Flash Memory, or ODD as the destination drive for the export. Current directories and files in the selected drive will be displayed on the screen.
3. Select BMP, JPEG, TIFF, or DICOM as the file format.
4. Specify the file name. Exams and images share the same file name: if there are multiple images in the exam, each file name will end with a serial number.
5. Specify the directory name. After entering the directory name, press **Make Directory** to create a folder in the destination medium. The new folder will be reflected as a directory in the selected drive. To delete the directory, press **Remove Directory**.
6. Once all fields have been entered, press **Export**. To cancel, press **X** at the top right-hand corner of the screen.



[Figure 6.7 Exam Export]

Exam Backup

MO, ODD, and Flash Memory can be used.

1. Install the target medium for backup.
   - MO or ODD: Insert the medium in the drive and wait until the LED light goes out.
   - If using Flash Memory, connect it to the USB port on the front or rear panel of the product.
2. Select exam(s) and press **Backup Exams**
3. At the medium selection window, select MO, ODD or Flash and then press **OK**.

Once the backup process is complete, you will be prompted whether to delete the exam(s) saved in the hard disk. Select your response for whether to delete or keep the exam(s). If you select “delete,” all backed up exam(s) will be deleted from the hard disk completely.

Exam Restore

MO, ODD, and Flash Memory can be used.

1. Connect the MO, ODD, or Flash Memory with exam backup information to the product and wait until the LED light goes out.
2. Use Source at the top left-hand corner of the screen to select the connected medium.
3. When the saved exam list appears, select appropriate exam(s) and perform Review, Delete, DICOM Send and other necessary functions. Note that the Delete function cannot be performed when using ODD.

   To move exam(s) to the system hard disk, select the exam(s) and press **Restore**.

Using USB MO Drive

USB MO drives can be connected to the USB port on the rear panel. Only one MO drive can be used at a time, and if two or more drives are connected, only one will be recognized.

When you have finished using the drive, you must use the Eject function from Storage Manager to remove the MO disk or disconnect the drive after turning the product off.

WARNING	If you are using a new MO disk for the first time, use the ‘MO Format’ function from Storage Manager to format the disk first.

Using USB Flash Memory

USB flash memory can be connected to the USB port on the rear panel. Only one flash memory can be used at a time.

You do not need to format new USB flash memory. If you need to format the USB flash memory, ensure that the file system type used is ‘FAT’ or ‘FAT32.’

WARNING	To disconnect the USB flash memory from the product, use the ‘Unplug’ function from Storage Manager to remove it from the product.

Using ODD

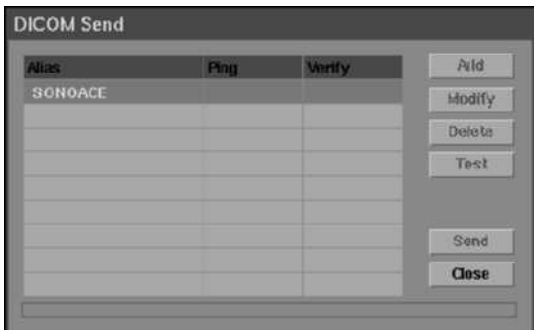
Only one ODD drive can be used at a time. After using the ODD, use the Eject function from Storage Manager to eject the medium.

If using a re-writable ODD, you can erase all recorded data using the Format function from Storage Manager.

Sending Exam

This function uses the DICOM network. The **DICOM Send** button will not work if the DICOM function is not configured.

1. Select exam(s) and press **Send** at the bottom of the screen.



- If you want to add a new server after selecting exam(s), select **Add** from the DICOM Send window, enter the necessary information, and then press **Ok.**
- Press **Modify** to view or edit the server information after selecting exam(s).
- Select **Delete** to delete the server after selecting exam(s), or select **Test** to check the DICOM connection to the server.

2. When all steps are complete, press **Send** to send the selected exam(s) to the selected server.

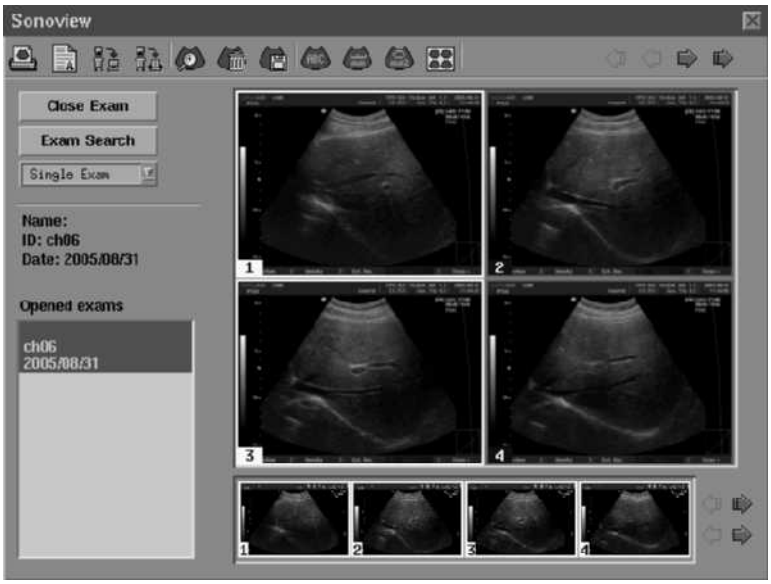
Printing Exam

This function uses printer(s) on the DICOM network. **DICOM Print** will not work if the DICOM function is not configured.

1. Select exam(s) and press DI**COM Print.**
2. Steps for printing exams are the same as for sending exams.

Exam Review

Saved images can be managed using measurement, printing, sending and many other functions.



[Figure 6.8 Exam Review]

NOTE	If you select an icon on the Exam View screen, the name of icon will be displayed.

Exam Information

Patient names, IDs, and exam dates are displayed in the left-hand center of the Exam Review screen.

Opened Exams

This displays the list of exams currently in progress or exams selected from Exam View.

If multiple exams are selected from Exam View, you can use the trackball and the **Set** button to quickly browse through the exams. For example, after selecting multiple exams from Exam View, press **Review Exam** to switch to the Review screen and bring up the list of selected exams in Opened Exams.

Close Exam

Closes the current exam(s).

Exam Search

The Exam View screen appears. You can browse through exams to select, change, save, send, or backup. For more information, see ‘Exam View.’

Single Exam

This displays all the images for selected exams in the order they are saved.

Use the trackball over the Preview window at the bottom of the screen to select image(s) to show on the screen. Images will be numbered according to their order.

Compare Exams

This function is useful for comparing multiple images.

1. Select images in the Preview window at the bottom of the screen. The border of selected images will go bright.
2. Place the cursor over the image display window and press the **Set** button on the control panel to display the image at the selected location. A maximum of 4 images can be compared at the same time.

Selecting imaages and Full Screen Image View

Selecting Images

Use the trackball on the control panel to move the cursor over an image and press the **Set** button. To select multiple images, use the trackball and the **Set** button while holding down the **Ctrl** key on the keyboard.

Full Screen Image View

This displays a full screen view of one selected image.

Place the cursor over the image and press the **Set** button on the control panel twice. To return to the Review screen, press the **Exit** button or press **Close** on the screen.

When in full screen image view, use the arrows on the screen to navigate to the previous or next images.

Using Preview

This function previews selected exam(s).

Images displayed on the current screen are indicated with white borders. You can use the arrow buttons on the right to browse through the images if there are 4 or more images.

Printing

This function prints images or simple reports.

1. Press **Print** from the Exam Review screen.
2. Select settings from the Print window.
   - Column : sets the number of column of image
   - Row : sets the number of row of image
   - Portrait : sets the paper horizontally
   - Landscape : sets the paper vertically
   - Image Only : prints only images
   - Report Only : prints only report
   - Images and Report : prints both images and report
3. Press **Ok** and Print screen will be displayed. Select printer and paper.
4. Click **Print** to start printing. Press **Cancel** to cancel.

Report

You can query the report for the selected exam or enter new information in it.

1. Press **Add Comments** from the Exam Review screen.
2. Enter details in the Report window.
3. Press **Ok** to save the information. Press **Cancel** to cancel.

DICOM Send

This function uses DICOM to send selected images. This button is deactivated for products that do not support the DICOM option.

1. Select image(s) and press **DICOM Send** on the Exam Review screen.
2. The number of selected images will be displayed on the screen. Press **Ok** to bring up the DICOM window.
3. After confirming the settings, press **Send** to send the image(s). Press **Cancel** to cancel.

DICOM Printing

This function uses DICOM to print selected images. This button is deactivated for products that do not support the DICOM option.

1. Select image(s) and press **DICOM Print** on the Exam Review screen.
2. The number of selected images will be displayed on the screen. Press **Ok** to bring up the DICOM window.
3. After confirming the settings, press **Print** to print the image(s). Press **Cancel** to cancel.

For more information on DICOM printers, please refer to the printer manual or the DICOM Conformance Statement.

E-mail

This function sends e-mails with image attachments.

1. Select image(s) and press **E-mail** on the Exam Review screen.
2. Enter the user's name, e-mail address, the recipient's e-mail address, subject and message. Please note that server names and e-mail addresses are case-sensitive.
3. Press **Send** to send the e-mail. Press **Cancel** to cancel.

In order to use the E-mail function, you must specify the e-mail (SMTP) server and you must own an e-mail account on the mail server.

You can specify the Outgoing Mail Server on the E-mail Setup screen.

NOTE	If e-mails cannot be sent even though the mail server is functional, check that the ICMP (ping) is open for the mail server. If the ICMP (ping) is closed, the e-mail function may not work properly.

Magnification

This function magnifies a part of the image displayed on the screen.

1. Press **Magnifier** on the Exam Review screen. The mouse cursor changes to a magnifying glass shape.
2. Place the magnifying glass over an area and press the **Set** button.

Delete

Select image(s) and press **Delete Image** on the Exam Review screen. To delete many images at once, use **Trackball** and **Set** button during pressing **Ctrl** key on the keyboard.

WARNING	Current exam cannot be deleted. The deleted exams are not be recovered.

Export

This function saves the images in BMP, JPEG, TIFF or DICOM file formats.

1. Press **Export** on the Exam Review screen. The mouse cursor changes to a floppy diskette shape.
2. Place the floppy diskette shape over an area and press the **Set** button. The Export window will be displayed.
3. Enter the directory and file names for the image file(s) and press **Export** to save the images in the selected file format.

NOTE	Do not use blank spaces in file names or directory names. The Export function will not work for file names or directory names containing blank spaces.

Text

Use this function to insert text into the image.

1. Press **Add Text** on the Exam Review screen.
2. Place the cursor over the image and press the **Set** button. The image will be displayed in full screen view.
3. Move the cursor to a desired location and insert the text. To change the font size or color, press **Font Style.**

Distance

This function measures the distance between any two points on 2D images.

1. Press **Distance** on the Exam Review screen.
2. Place the cursor over the image and press the **Set** button. The image will be displayed in full screen view.
3. Move the cursor to a desired location and press the **Set** button to set the start point.
4. Use the trackball to move the cursor to another location and press the **Set** button

to set the end point. Press the **Change** button before assigning the end point to change the position of the start point. The distance between the two points will be displayed on the screen.

You can use the same method to take multiple measurements. Note that the measurement results are not saved with the image.

To finish measurement, press the **Exit** button on the control panel or **Close** on the screen.

Ellipse

Use this function to draw an ellipse over the 2D image, and then measure the perimeter and area of the ellipse.

1. Press **Ellipse** on the Exam Review screen.
2. Place the cursor over the image and press the **Set** button. The image will be displayed in full screen view.
3. Move the cursor to a desired location and press the **Set** button to set the start point.
4. Use the trackball to move the cursor to another location and press the **Set** button to set the end point. Press the **Change** button before assigning the end point to change the position of the start point.
5. After adjusting the size of the ellipse, press the **Set** button to confirm the size of the ellipse. The perimeter and area of the ellipse will be displayed on the screen.

You can use the same method to take multiple measurements. Note that the measurement results are not saved with the image.

To finish measurement, press the **Exit** button on the control panel or **Close** on the screen.

Image Selection Window (Layout)

Use this function to configure the number of images to show on the Exam Review screen.

On the Exam Review screen, press **Layout** and select items from 1*1 to 3*3 in the Image Layout window.

Chapter 7

Maintenance

System Maintenance

NOTE	The user must ensure that the safety inspections are performed every 2 years according to the requirements of safety standard EN 60601-1. Only trained persons are allowed to perform the safety inspections mentioned above.

Installation Requirements

When installing:

- Optimal conditions for the system are temperatures of 10° ~ 35° C and humidity of 30% ~ 75%.
- Avoid humidity.
- Avoid direct sunlight.
- Avoid places with extreme temperature variations.
- Avoid heat sources.
- Avoid dusty and unventilated areas.
- Avoid places where the system is likely to be exposed to vibration or impacts.
- Avoid places where the system is likely to be exposed to chemical substances or gases.

CAUTION	Placing the system near generators, X-Ray machines, or broadcast cables may result in screen noise and abnormal visual images. Using the power source with other electric devices may also induce noise.

Cleaning and disinfections

WARNING	Always use protective eyewear and gloves when cleaning and disinfecting the equipment.

Cleaning

1. Turn off the system and disconnect the system power cord from the wall outlet.
2. Use a soft cloth lightly dampened in a mild soap or detergent solution to clean exterior surfaces on the system.

Disinfection

CAUTION	Use only recommended disinfectants on system surfaces.

A disinfectant qualified by the FDA 510(k) process is recommended. The following disinfectants are recommended because of both their biological effectiveness (as qualified through the FDA 510(k) process) and their chemical compatibility with MEDISON ultrasound products.

Solutions	Country	Type	Active ingredient	FDA 510(k)
Cidex	USA	Liquid	Gluteraldehyde	K934434
Cidex Plus	USA	Liquid	Gluteraldehyde	K923744

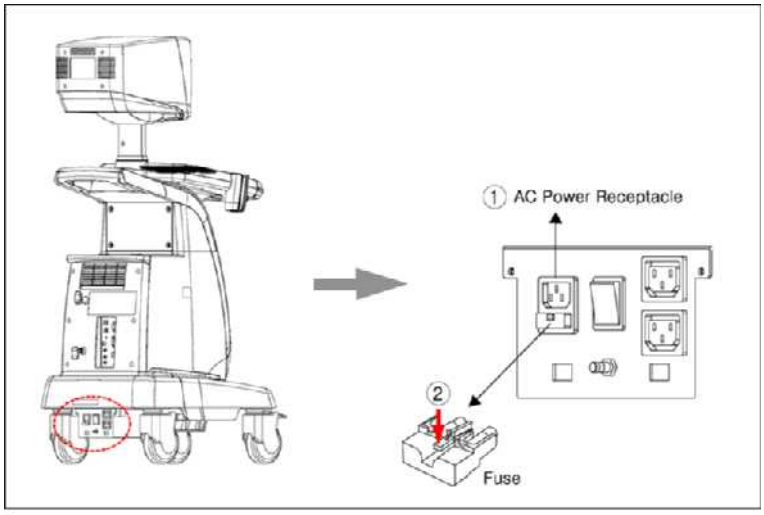
1. Turn off the system and disconnect the system power cord from the wall outlet.
2. Mix the disinfection solution compatible with your system according to label instructions for solution strength.
3. Wipe the system surfaces with the disinfectant solution, following the disinfectant label instructions for wipe durations, solution strength, and disinfectant contact duration.
4. Air dry or towel dry with a sterile cloth according to the instructions on the disinfectant label.

Fuse Replacement

The power protection fuse protects the product from excess current. If the power monitoring protection circuit detects excess current, it shuts off the current to the equipment in order to prevent overheating and to restrict the ultrasound power output.

If the fuse blows, replace it as shown below.

DANGER	To avoid risk of electric shock, always disconnect the plug from the system prior to fuse replacement.



[Figure 7.1 Fuse Replacement]

1. Disconnect the power cord from the system. (See ①)
2. Take the fuse out by pressing the middle of fuse. (See ②)
3. Insert the fuse holder into the appliance inlet.
4. After installing the new fuse, connect the power cord to the system.

Fuse information is shown in the following table.

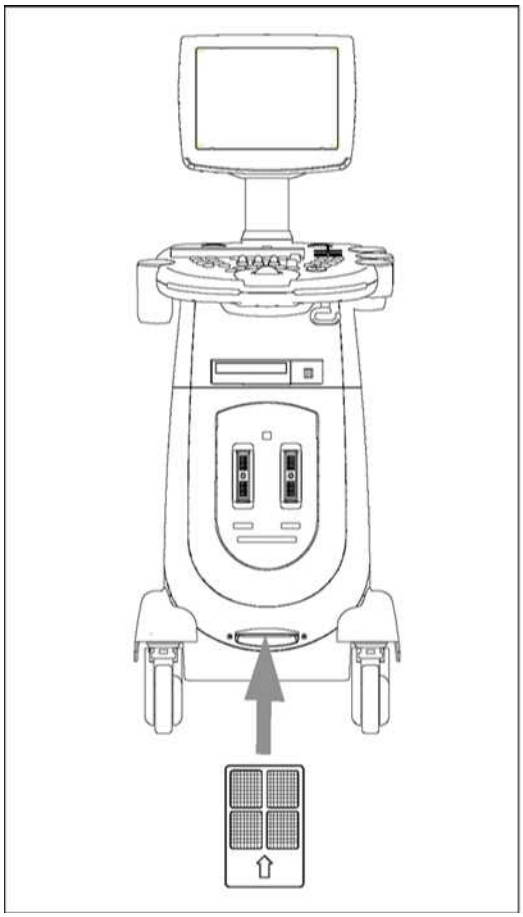
Input Ratings	Fuse Ratings	Company	Order No.
100-120VAC	8A/250V	Orisel	55T210000
200-240VAC	5A/250V	Orisel	55T210000

Cleaning The Air Filters

The air filters minimize the indraft of dust. Clean the air filter to ensure that a clogged filter does not cause the system to overheat and reduce the noise and the system performance.

It is recommended the air filters be cleaned once every three months.

CAUTION	Be sure to lock the brakes on the front wheels before cleaning the air filters to avoid injury by any unexpected movement of the product.



[Figure 7.2 The location of the air filters]

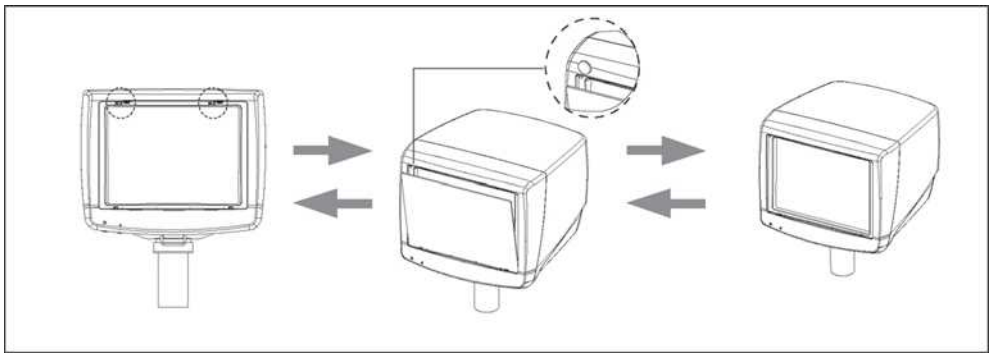
1. Pull the filter under the front of the console to away from the product.
2. Shake the filter to remove the dust and wash in a mild soapy solution.
3. Rinse and air dry or dry with a cloth.
4. Slide the filter back into the product.

NOTE	Allow the wet filter to dry thoroughly before installing. The wet filter can cause the malfunction.

Monitor Filter Replacement

Monitor filter not only makes the eyes less tired but also allow clear viewing of images even in dark places. Monitor filter also protects the monitor surface, preventing scratches and other similar damages.

Follow the instructions below to replace monitor filter.



[Figure 7.3 Monitor filter replacement]

1. Press the two latches on the upper part of the monitor.
2. Hold the upper part of the monitor filter and pull it out carefully. Be careful not to drop the monitor filter when detaching it.
3. Push the new monitor filter in, aligning the lower part of the filter to the slot on the bottom of the monitor.
4. Press the latches again and lightly press the upper part of the filter.

NOTE	You can easily press the latches and detach the filter by using a coin or a thin object.

Accuracy Check

The product's maintenance status may affect the measurements obtained using the product. The product should be maintained in an optimal state to ensure reliable measurements.

To ensure optimal operation of the product, perform an accuracy check every year. The equations and table related to measurement accuracy are included in "Chapter 5 Measurements" in this manual.

Administration of Information

CAUTION	You may lose information files on user settings or patients, because of shock on the product or internal error. Thus, back-up on a regular basis.

User Setting Back up

- Always keep a backup copy of all information related to the user settings in case of data loss.
- Clients cannot back-up the user settings of the product. Contact the MEDISON Customer Service Department to attain support for back-up.
- However, clients may back up the user setting on GA Table used in obstetrics diagnosis. For further information please refer to “Chapter 3. Settings”.

Patient information Back-up

The SonoView program can be used for backing up patients’ basic information and scanned images. The user can choose to save the data, and the data is also saved in the system by default. If the system needs to be reinstalled due to product failure, etc., the MEDISON customer support staff will restore the patients’ basic information and scanned images that are saved in the system. For more information on this, see “Chapter 6 Image Managements.”

Software

The product software may be updated to enhance performance. The user cannot make any changes to the software. Please contact the MEDISON customer service representative for help in software changes.

CAUTION	Minor software updates may be carried out without the prior notice from the manufacturer.

Should errors occur in the operating system (Linux), and should you desire to upgrade the operating system, please follow the instructions of the operating system manufacturer.

Chapter 8

Probes

Probes

The probe is a device that sends and receives ultrasound for acquiring image data. It is also called a Transducer or Scanhead. The ultrasonographic image scanner uses the image data received by the probe to display the images of each organ on the screen. For best quality images, select the appropriate probe for the each application.

The system limits patient contact temperature to 43 degrees Celsius, and acoustic power values to their respective U.S. FDA limits. A power protection fuse circuit protects against over-current conditions. If the power monitor protection circuit senses an over-current condition, then the drive current to the probe is shut off immediately, preventing overheating of the probe surfaces and limiting acoustic output. Validation of the power protection fuse circuit is performed under normal system operation. For invasive probes, additional protections are designed to keep patient contact surface temperature under 43 degrees Celsius in the event of a single fault failure.

The applications for each probe are shown below.

Product	Applications
C2-4ES	General, Abdomen, Cardiac
C2-5ET	General, OB, Gynecology, Abdomen, Fetal Heart, Renal
C3-7ED	General, OB, Gynecology, Abdomen, Fetal Heart, Renal
C3-7EP	General, OB, Gynecology, Abdomen, Fetal Heart, Renal
C4-9ED	General, Neonatal, Pediatric, Vascular
EC4-9ED	General, OB, Gynecology, Urology
EC4-9ES	General, OB, Gynecology, Urology
HL5-9ED	General, Breast, Small Parts, Vascular, Musculoskeletal
HL5-12ED	General, Breast, Small Parts, Vascular, Musculoskeletal
L5-9EE	General, Breast, Small Parts, Vascular, Musculoskeletal
L5-9EC	General, Breast, Small Parts, Vascular, Musculoskeletal
L5-12/50EP	General, Breast, Small Parts, Vascular, Musculoskeletal

TI Table

TI(Thermal Index) is displayed on the title of the screen and shows the estimate of the temperature increase in specific body tissues. The thermal index consists of the following indices: soft tissue (TIs), bone (TIb), and cranial bone (Tic). This product will show the TI automatically by the probe and application. See the following table.

Probes	Applications													
	General	Obstetrics	Gynecology	Abdomen	Fetal Heart	Cardiac	Breast	Vascular	Urology	Renal	Small Parts	Neonatal	Pediatric	Musculoskeletal
C2-4ES	TIs			TIs		TIs								
C2-5ET	TIs	TIb	TIs	TIs	TIb					TIs				
C3-7ED	TIs	TIb	TIs	TIs	TIb					TIs				
C3-7EP	TIs	TIb	TIs	TIs	TIb					TIs				
C4-9ED	TIs							TIs				TIc	TIs	
EC4-9ED	TIs	TIb	TIs						TIs					
EC4-9ES	TIs	TIb	TIs						TIs					
HL5-9ED	TIs						TIs	TIs			TIs			TIs
HL5-12ED	TIs						TIs	TIs			TIs			TIs
L5-9EE	TIs						TIs	TIs			TIs			TIs
L5-9EC	TIs						TIs	TIs			TIs			TIs
L5-12/50EP	TIs						TIs	TIs			TIs			TIs

Ultrasound transmission Gel

Using an inappropriate ultrasound gel may damage the probe. For proper transmission of the acoustic beam, only use ultrasound transmission gel only approved by MEDISON. Refer to the table of 'Cleaning and Disinfecting the Probe' section in this chapter.

WARNING	■ Do not use mineral oil, oil-based solutions, or other non-approved material as they may cause damage to the probe. ■ Do not use gels that contain any of the following agents: - Acetone - Methanol - Denatured Ethyl Alcohol - Mineral Oil - Iodine - Lanoline - Any lotions or gels containing perfume

Sheaths

Sheaths are recommended for clinical applications of an invasive nature, including intraoperative, transrectal, transvaginal, and biopsy procedures. MEDISON does not supply sheaths so that you should purchase appropriate ones on your own.

WARNING	■ Always keep sheaths in a sterile state. ■ Sheaths are disposable. Do not reuse them. ■ If sheaths are torn or soiled after use, wash and disinfect the probe. ■ In neurosurgical applications, a disinfected probe must be used with sterile gel and a sterile pyrogen-free sheath. ■ If the sterile sheath becomes compromised during neurosurgical applications involving a patient with Creutzfeldt-Jakob disease, the probe cannot be successfully sterilized by any disinfection method. ■ Some sheaths contain natural rubber latex and talc, which can cause allergic reactions in some individuals. Please refer to the FDA Medical Alert released on March 29, 1991.

Installing the Sheath

1. Use sterile gloves.
2. Unpack the sheath and fill it with acoustic coupling gel.
3. Insert the probe into the sheath and pull the latex tip to cover the probe completely. If possible, cover the probe cable as well.
4. Ensure that there is no air bubble within the ultrasound gel.
5. If necessary, secure the sheath to the probe and the probe cable.
6. Dispose of the sheath after use.

Probe Precautions

The probe can easily be damaged by improper use or by contacting certain chemical substances. Always follow the instructions in the user manual to inspect the probe cable, case and lens before and after each use.

Check for cracks, broken parts, leaks and sharp edges. If there is any damage, immediately stop using the probe and contact the MEDISON Customer Support Department. Using damaged probes may result in electric shocks and other hazards to the patients and/or users.

CAUTION	■ Do not apply mechanical shock to the probe. ■ Do not place the probe cable on the floor where the cable can be run over by equipment wheels, etc. Do not apply excessive force to bend or pull the cable. ■ Do not immerse the probe into any inappropriate substances such as alcohol, bleach, ammonium chloride, and hydrogen peroxide. ■ Do not expose the probe to temperatures of +50°C or higher.

Use and Infection Control of the Probe

The ultrasonographic image scanner uses ultrasound, and it makes direct contact with the patient when in use. Depending on the types of examinations, such contact can be made to a wide variety of locations including the ordinary skin or the location of blood transfusion during a surgery.

The most effective method to prevent infection among patients is to use each probe only once. However, probes may need to be re-used as they are complex in design and expensive. Consequently, protective devices such as sheaths must be used, and the safety instructions must be folowed carefully in order to minimize the risk of infection among patients.

WARNING	No neurosurgical treatments or examinations should be carried out on a patient with Creutzfeldt-Jakob disease (critical brain disease caused by virus). If the probe has been used on such a patient, it cannot be sterilized by any method whatsoever.

CAUTION	Sufficient washing and disinfecting must be carried out for preventing infection. This is the responsibility of the user who manages and maintains the disinfection procedures for the equipment. Always use legally approved detergents and sheaths.

Electric Shocks

The probe uses electrical energy. If it touches conductive materials, there are risks of electric shocks to the patient or the user.

WARNING	■ Regularly receive short-circuit examination from the MEDISON Customer Support Department.Do not immerse the probe into liquid. ■ Do not immerse the probe into liquid ■ Do not drop the probe or apply mechanical shocks. ■ Inspect the housing, strain relief, lens and seal for damage, and check for any functional problem before and after each use. ■ Do not apply excessive force to twist, pull or bend the probe cable. It may result in a short circuit. ■ The power protection fuse protects the probe and the product from excess current. If the power monitoring protection circuit detects excess current, it immediately shuts off the current to the probe in order to prevent the probe surface from overheating and to restrict the ultrasound power output. ■ The temperature of the product for making contact with patients is limited under 43°C. The ultrasound power output (AP&I) is in compliance with US FDA standards.

Cleaning and Disinfecting the Probe

Using an inappropriate detergent or disinfectant may damage the probe.

WARNING	Always use protective eyewear and gloves when cleaning and disinfecting probes.

▌Information of Detergent, Disinfectant, and Ultrasound Gel

Use an appropriate one with following tables.

Names		Disinfectants									
		T-Spray II	**T-Spray**	**Sani-Cloth**	**Cidex OPA[2,3)]**	**Cidex Plus[2)]**	**Metricide[2)]**	**Omnicide**	**Nuclean**	**Wavicide -01[3)]**	**Sekusept Extra**
Type		Spray		Wipe	Liquid						
Active Ingredient		Quaternary Ammonium(N-Alkyl)			Glutaraldehyde						
CA	C2-4ES	●	●	●	★	●				●	
	C2-5ET	●	●	●	●	●				●	
	C3-7ED		●	●		●		●	x	●	
	C3-7EP		●	●	●	●					
	C4-9ED		●	●	●	●		●	●	●	
EC	EC4-9ED		●	●	●	●		●	●		
	EC4-9ES	●	●	●	★	●			●		
LA	L5-9EE		●	●							
	L5-9EC	●	●	●	★	●		●		●	●
	HL5-9ED		●	●	●	●		●	x	●	
	HL5-12ED		●	●	●	●		●	x	●	
	L5-12/50EP		●	●	●	●				●	

Names		Disinfectants			Cleaner				Gel
		Sporox Ⅱ	**Gigasept AF** [3]	**Gigasept FF**	**Enzol**	Klenzyme	**Isoproppyl alcohol(70%)**	**Metrizyme**	**Aquasonics 100**[3]
Type		Liquid				NA	Liquid		Gel
Active Ingredient		Hydrogen Peroxide	Succindia-ldehyde, formalde-hyde	Bersteins-aure	Proteolytic Enzymes	Alcohol	Propyle-ne Glycol	Proteol-ytic Enzymes	
CA	C2-4ES	x	x	●	●	●	x	●	●
	C2-5ET	●			●	●	●	●	●
	C3-7ED	x			x	●	x	●	●
	C3-7EP	x			●	●		●	●
	C4-9ED	x			●	●	x	●	●
EC	EC4-9ED				●	●	x	●	●
	EC4-9ES				●	●	x	●	●
LA	L5-9EE								
	L5-9EC	x	x	●	●	●	x	●	●
	HL5-9ED	x			●	●	x	●	●
	HL5-12ED	x			●	●	x	●	●
	L5-12/50EP	x			•	•		•	•

NOTE

x = Not compatible(DO NOT USE)

● = Compatible

Blank = Untested (DO NOT USE)

★ = Staining may occur on housing parts; however, the acoustic performance and image quality are not affected.

(1) Compatible but no EPA Registration

(2) FDA 510(k) qualified

(3) Has CE mark

(4) Discontinued

(5) Under Development

Following is information about manufacturer (or Distributor) of Detergent, Disinfectant, and Ultrasound Gel.

Product	Manufacturer or Distributor	Telephone number
Aquasonics	Parker Co.	+1-800-631-8888(USA)
Cidex	CIVCO Co.	+1-800-445-6741(USA) +1-319-656-4447(Worldwide)
Enzol	CIVCO Co.	+1-800-445-6741(USA) +1-319-656-4447(Worldwide)
GIgasept AF	S&M(Schulke&mayr) Co.	+44-114-254-3500(UK)
Gigasept FF	S&M(Schulke&mayr) Co.	+44-114-254-3500(UK)
Isoproppyl alcohol (70%)	Local drugstore	None
Klenzyme	Steris Co.	+1-800-548-4873(USA)
Metricide	CIVCO Co.	+1-800-445-6741(USA) +1-319-656-4447(Worldwide)
Metrizyme	Metrex Research Corp.	+1-800-841-1428(USA)
Milton	Product & Gamble Australia Pty. Ltd.	+61-1800-028-280(Australia)
Nuclean	Nation Diagonostics Co.	+1-800-526-3867(USA) +44(0)-148-264-6020(UK)
Omnicide	Cottrell Ltd.	+1-800-THE-EDGE(USA)
Sani-cloth	PDI Nice/Pak Products Co.	+1-914-365-1602(USA)
Sekusept Extra	Henkel Hygiene GmbH.	+49-0211-797-0(Germany)
Sporox II	Sultan Chemist Inc.	+1-800-637-8582(USA)
T-Spray	CIVCO Co.	+1-800-445-6741(USA) +1-319-656-4447(Worldwide)
Virkon	Antec International LTD.	+1-403-286-1771(USA)
Wavicide	Wave Energy System Inc.	+1-800-252-1125(USA)

Cleaning

Cleaning is an important procedure that is carried out before disinfecting the probe. The probe must be cleaned after each use.

CAUTION	■ Do not use a surgical brush when cleaning probes. The use of even soft brushes can damage the probe. ■ During cleaning and disinfection, keep the parts of the probe that must remain dry higher than the other parts during wetting until all parts are dry. This will help prevent liquid from entering non-liquid-tight areas of the probe.

1. Disconnect the probe from the system.
2. Remove any biopsy adapters or biopsy needle guides. (Biopsy adapters are re-usable and can be disinfected).
3. Discard sheaths. (Sheaths are single-use items).
4. Use a soft cloth lightly dampened with mild soap or compatible cleaning solution to remove any particulate matter and body fluid that remain on the probe or cable.
5. To remove remaining particulates, rinse with water up to the immersion point.
6. Wipe with a dry cloth.
7. If necessary, wipe first with a water-dampened clothe to remove soap residue.

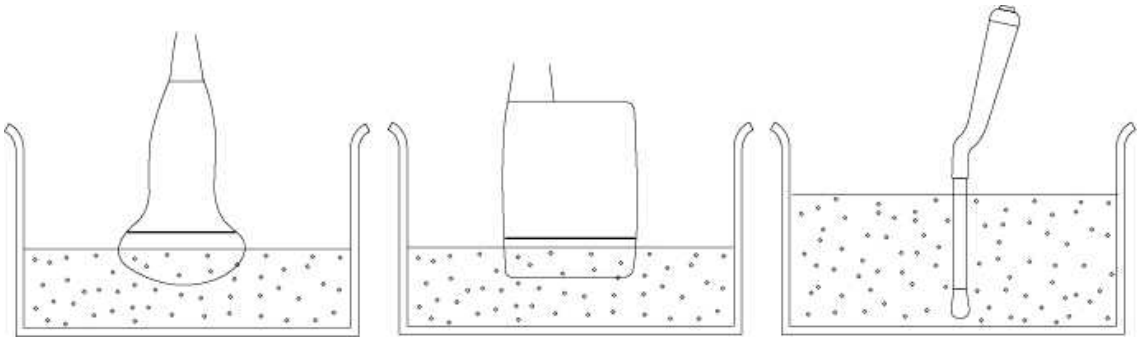
Disinfection

Only disinfect vaginal and rectal probes. A 10^{-6} reduction in pathogens should be reached following the disinfection procedures in this Manual and using the following MEDISON recommended solutions.

WARNING	■ If a pre-mixed solution is used, be sure to observe the solution expiration date. ■ The type of tissue it will contact during use dictates the level of disinfection required for a device. Ensure that the solution strength and duration of contact are appropriate for disinfection.

CAUTION	■ Using a non-recommended disinfectant or not following the recommended disinfection method can damage and/or discolor the probe and will void the probe warranty. ■ Do not immerse probes for longer than one hour, unless they are sterilizable. ■ Only sterilize probes using liquid solutions. Avoid using autoclave, gas (EtO), or other non-MEDISON-approved methods.

1. Follow the instructions on the disinfectant label for storage, use and disposition of the disinfectant.
2. Mix the disinfectant compatible with your probe according to lavel instructions for solution strength.
3. Immerse the probe into the disinfectant as shown in the illustration below.
4. Using the instructions on the disinfectant, rinse the probe after the immersion process is complete.
5. Air dry the probe or towel it dry with a clean cloth.



[Figure 8.1 Disinfection]

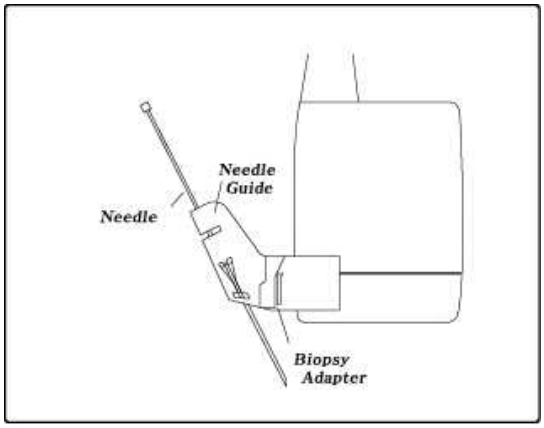
Biopsy

A biopsy is an examination method that surgically extracts tissue from the patient for examination. The probe and the biopsy kit are used together when conducting a biopsy with the ultrasonographic image scanner.

The ultrasound system shows the needle, which penetrates through the skin surface and veins, along with the examination location, minimizing the risk to the patient.

Biopsy KIT Components

The biopsy kit consists of the adaptor, needle guide and needle. The components vary depending on the probe type. The components and accessories can be purchased from MEDISON.



[Figure 8.2 Biopsy Kit Components]

- Adaptor: Secures the needle guide to the probe tightly.
- Needle Guide: Guides the angle (direction) of the needle so that it can reach the examination location accurately. It also secures the needle so that the needle is not loose.
- Needle: This is the needle that is inserted into the patient's body.
- Sheath: Prevents the probe and adaptor from getting soiled by any unwanted substances during the examination (blood and other body fluids).
- Ultrasound Gel: The space between the probe and the sheath is filled with the ultrasound gel to obtain images of the best quality.

Using the Biopsy Kit

WARNING

- Verify the condition of the biopsy needle before use. Do not use a bent biopsy needle.
- The biopsy needle may bend during tissue penetration. The precise location of the needle must be checked by monitoring the echo generated from the needle.
- Never use the biopsy kit to biopsy prostate tissue.
- Verify the condition of the biopsy needle before use. Do not use a bent biopsy needle.

Before Using Biopsy Kit

Ultrasonographic scanning using the biopsy kit must be conducted by medical doctors or experienced medical staff with appropriate qualifications. Always, without fail, verify all safety prevention procedures and disinfection.

Use only MEDISON-approved biopsy kits. Other bands may not properly fit MEDISON probes. Improper installation may result in patient discomfort.

Inspect all components. Ensure that the biopsy kit you are using is the correct one for the probe, the system, and system software.

WARNING

- Do not attempt to use the biopsy until you read the instructions for installing the sheath and verifying alignment of the needle guide.
- Always ensure that the probe and the needle guide are secured on both the left and the right.
- Do not use in IVF, CVS, or PUBS procedures.

Biopsy Procedure

The system generates a needle guideline though the displayed real-time ultrasound images to indicate the anticipated path of the needle. You can use this guideline to ensure that the needle or instrument is following the correct path.

1. Ready the patient according to the procedure appropriate for the examination objectives.
2. Install the sheath and the biopsy kit.
3. Set the system controls for the biopsy procedure.If necessary, apply acoustic gel to

the patient.

4. Begin scanning the patient. Adjust the patient so that the location for examination fits into the needle guideline on the screen.
5. Insert the needle into the needle guide. Perform the puncture by sliding the needle through the groove in the guide until the needle intercepts the target.

   To keep the needle securely in the needle guide, press down on the top of the biopsy adapter with your index finger.
6. When the examination location is reached, take the needle out of the needle guide.
7. Detach the needle guide, adapter and sheath from the probe.
8. Dispose of the components that are not designed for reuse.

Needle Guide Alignment

Alignment of the needle guide displayed on the system is for the purpose of verifying whether the needle and the needle guide are properly installed. This must be done prior to the biopsy examination. Do not use the needle guide if the needle is not following the intended path. Contact MEDISON Customer Service Department for service.

Reverberation or other tissue artifacts may produce false needle images which can cause confusion. Ensure the needle path is along the guideline, and that you are not using a false needle image to locate the needle.

WARNING	■ The needle used for this alignment verification must not be used for the actual procedure. Always use a new, sterile needle for each biopsy procedure. ■ To assist in accurate projection of the needle, use a straight, new needle for each alignment procedure.

1. Attach the biopsy kit.
2. Set the system depth for the procedure to be performed and select the Biopsy menu.
3. Immerse the probe into the water bath, and insert the needle into the needle guide.
4. Confirm that the needle image is on the needle guidelines. If so, the needle guide is properly aligned.
5. If the needle image is out of the needle guideline, check the needle guide or the probe adapter.

Cleaning and Disinfecting Biopsy Kit

Wash and disinfect the biopsy kit to reduce pathogens to the level of 10^{-6}. Some components of the biopsy kit may be disposable. Please read the biopsy kit user manual carefully before use.

Refer to the table of 'Cleaning and Disinfecting the Probe' section in this chapter for detail.

WARNING	Always use protective eyewear and gloves when cleaning and disinfecting biopsy kit.

Cleaning and disinfection of stainless steel biopsy kit

Cleaning

1. After use, remove the biopsy kit from the probe.
2. Disassemble the biopsy kit into its component parts, if applicable.
3. Using a small brush and water, scrub each part to remove trapped material from the biopsy kit.
4. Rinse with water to remove remaining particulates.

Disinfection

1. Disinfect the adapter by autoclaving (Steam) or using gas (Ethylene Oxide).
2. After disinfection, follow the proper post-disinfection procedure for the disinfection method used. (Please refer to the disinfection user manual, etc.)
3. Inspect the biopsy kit for damage such as cracks, rust or breakage. If damage is evident, discontinue use of the biopsy kit and contact MEDISON Customer Service Department.

Cleaning and Disinfection of plastic biopsy kit

Cleaning

1. After use, remove the biopsy kit from the probe.
2. Disassemble the biopsy kit into its component parts, if applicable. Discard the single-use parts. These parts cannot be disinfected.
3. Using a small brush and water, scrub each part to remove trapped material from the reusable components.
4. Rinse with water to remove remaining particulates.

Disinfection

CAUTION	Plastic biopsy kits can only be disinfected using a chemically compatible cold-disinfectant. Disinfection by autoclaving or by using gas or radiation will cause damage to these parts.

Please refer to the user manual of the disinfectant for storage, use, and disposition of the disinfectant.

1. Check the disinfection duration (generally 10 hours) and temperature of the disinfectant.
2. After disinfection, follow the proper post-disinfection procedure for the disinfection method used.
3. Inspect the components for damage such as cracks, rust or breakage. If damage is evident, discontinue use of the biopsy kit and contact MEDISON Customer Service Department.

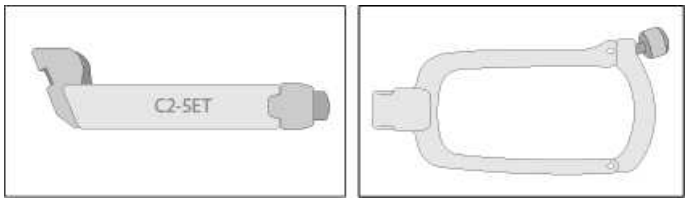
Assembling the Biopsy Kit

C2-5ET Biopsy guide

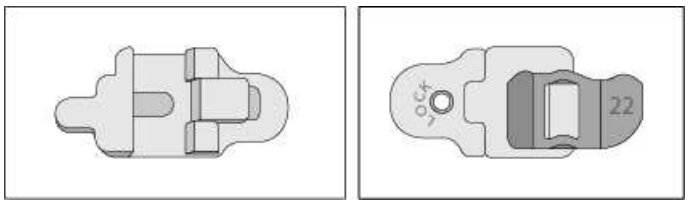
■ Specification

Model name	BPK-C2-5ET	
Component	Biopsy Adapter	1 EA
	Box	1 EA
	Needle Guide Pack	24EA
Material	Acetal Copolimer	
Available Gauges	16G, 18G, 22G	

■ Adapter Configuration



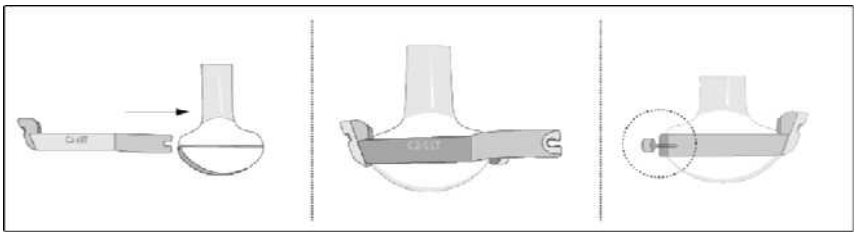
Biopsy Adapter



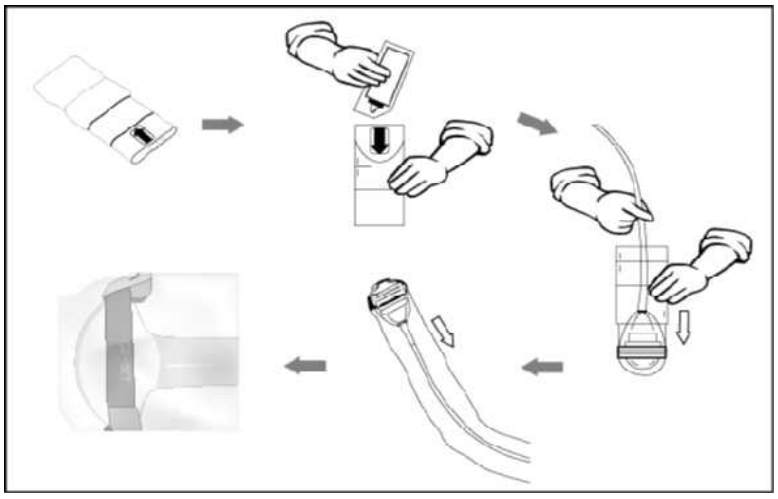
Needle Guide

■ Installation

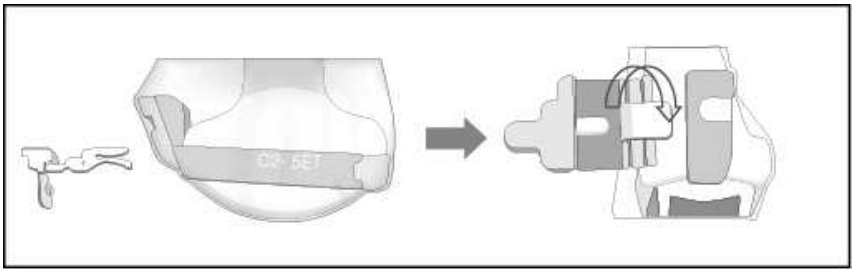
1. Mount the Biopsy Adapter onto the probe.



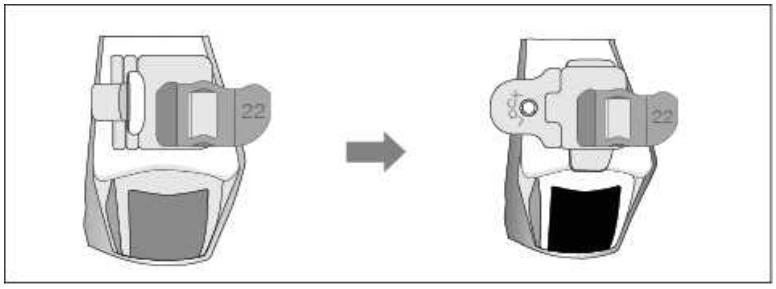
2. Place the Probe Cover all the way down to the Adapter.



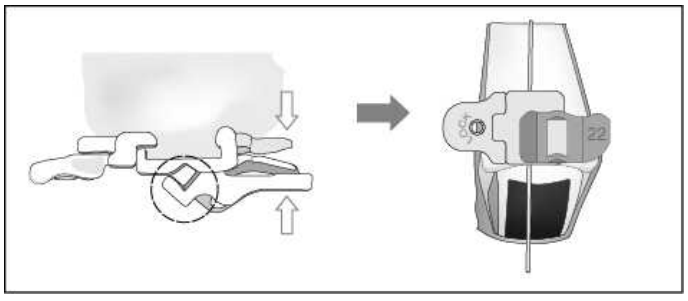
3. Choose a needle guide of the desired gauge and secure it to the adapter.



4. Lock the needle guide.



5. Press the needle guide and install the needle into the needle guide.

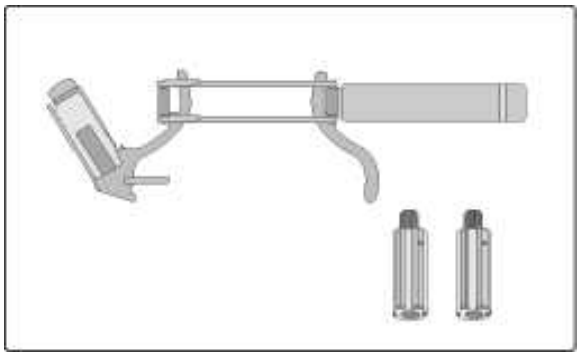


C3-7ED, C3-7EP Biopsy guide

■ Specification

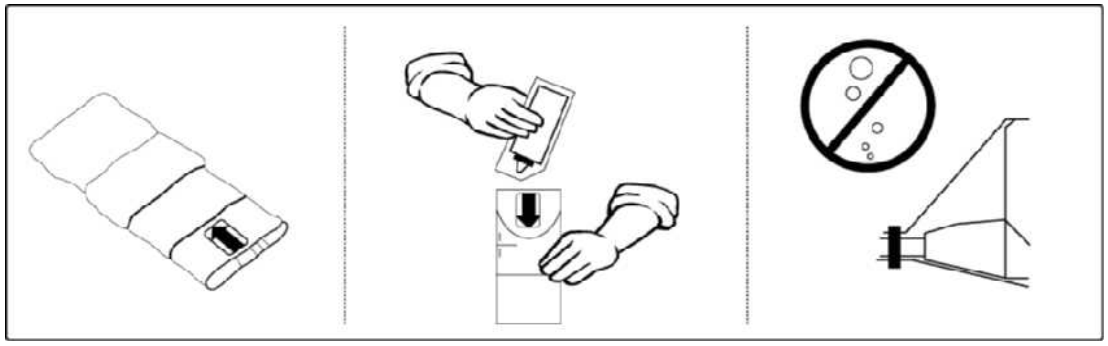
Model name	BP-C3-7IM
Component	Adapter 1EA Needle Guide Kit (Odd & Even Gauge Clip) 2EA Box 1EA User Manual 1EA
Material	Stainless
Available Gauges	15G, 16G, 17G, 18G, 19G, 20G, 21G, 22G

■ Biopsy Kit Configuration



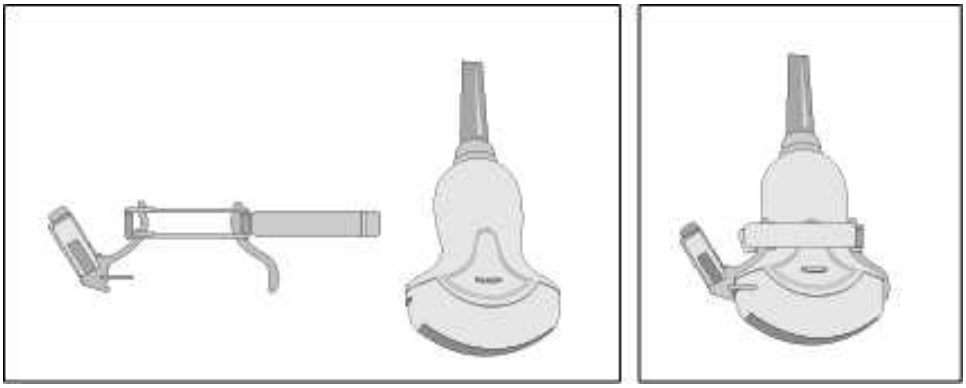
■ Installation

1. Fill the sheath with the ultrasound gel.



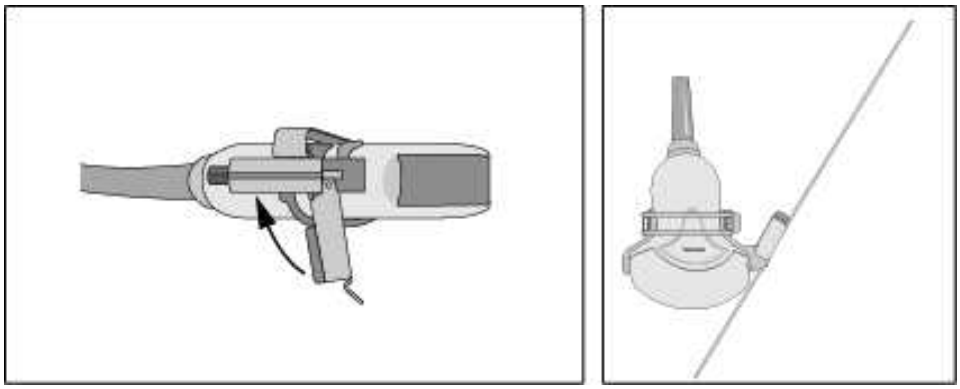
Sheath Gel inside Sheath

2. Mount the Adapter onto the indicated hole of the probe housing.



3. Install the needle guide onto the adapter.

4. Place the sheath on the adapter and insert the needle into the needle guide.

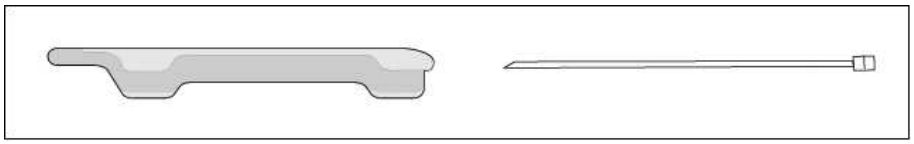


EC4-9ES Biopsy Guide

- **Specifications**

Model name.	BP-KIT-003
Component	Biopsy Adapter 1 EA Box 1 EA
Material	PUR 2160
Available Gauges	17G

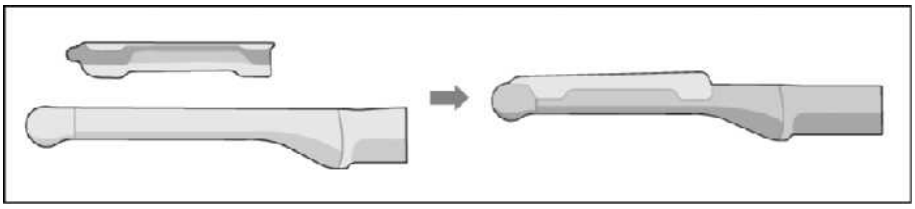
■ **Adapter Configuration**



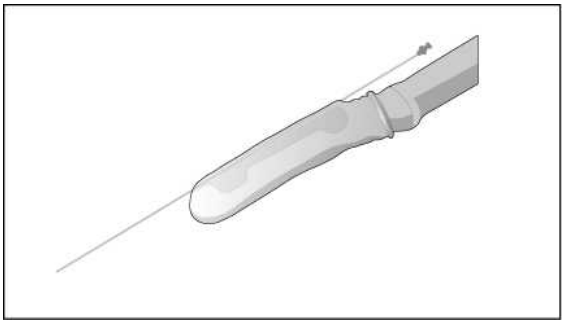
Biopsy Adapter Needle Guide

■ **Installation**

1. Mount the Adapter onto the probe.



2. Place the cover supplied with the kit all the way down to the adapter and then secure the guide.

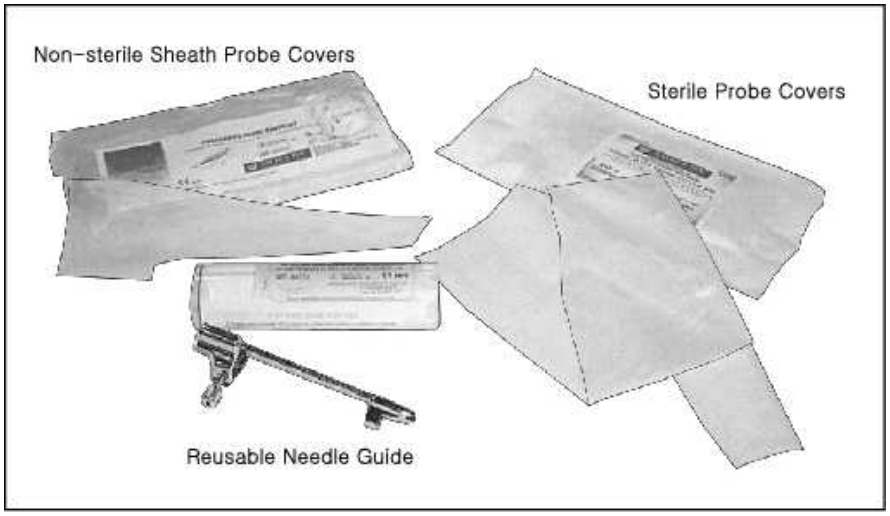


EC4-9ES Biopsy Guide (Reusable Type)

■ **Specifications**

Model name.	BP-KIT-007	
Component	Adapter	1EA
	Sterile Sheath	10EA
	Non-sterile Sheath	10EA
Material	303-304 Surgical Stainless Steel.	
Available Gauges	17G	

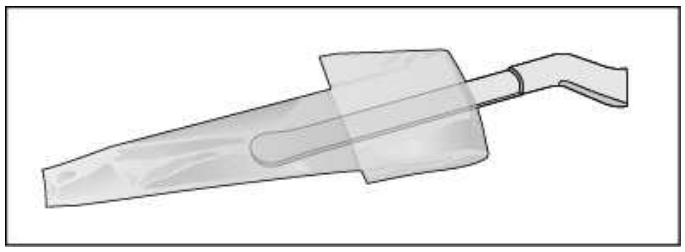
■ **Biopsy Kit Configuration**



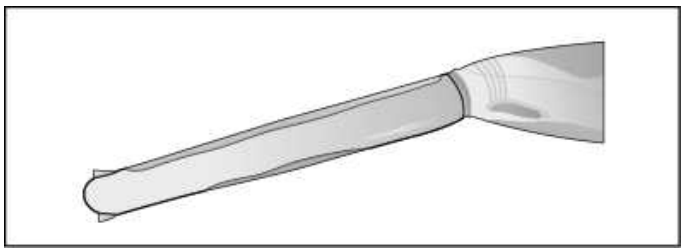
※ Sterile Sheath: For vaginal insertion
Non-sterile Sheath: For anal insertion

■ **Installation**

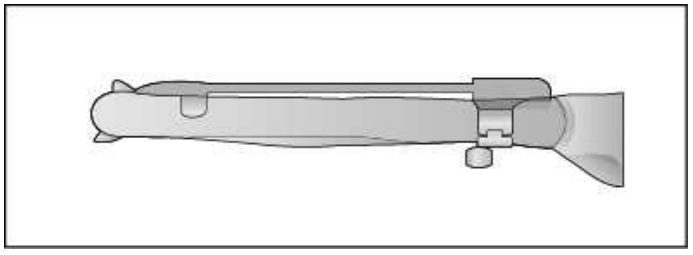
1. Fill the sheath with ultrasound gel and insert the probe.



2. Secure the sheath to the front portion of the handle with a rubber band as illustrated.



3. Mount the adapter to the probe and insert the needle.

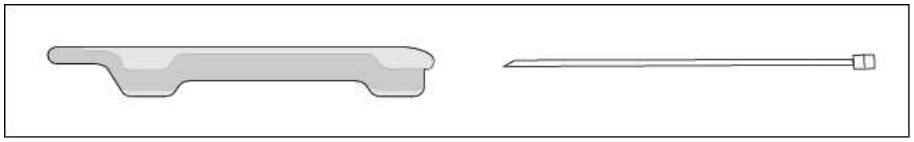


EC4-9ED Biopsy Guide (Disposable Type)

■ Specifications

Model name.	BP-KIT-002-01
Component	Adapter 1EA Needle Guide KIT 20EA (Needle Guide Kit is composed with Sheath, Ultra Sound Gel, and Needle Guide Straw.)
Material	PUR 2160
Available Gauges	17G

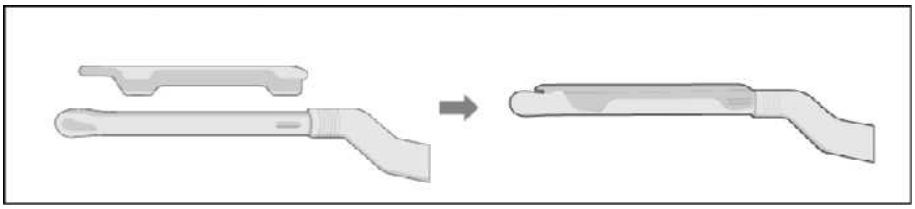
■ Biopsy Kit Configuration



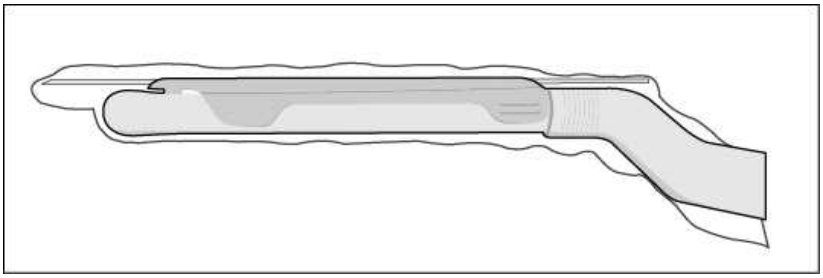
Biopsy Adapter Needle Guide

■ Installation

1. Mount the adaptor onto the probe.



2. Place the sheath and secure the needle guide.
3. Place the thin sheath on the adapter again and insert the needle into the needle guide for use.



EC4-9ED Biopsy Guide (Reusable Type)

■ **Specifications**

Model name.	BP-KIT-008
Component	Adapter 1EA Sterile Sheath 10EA Non-sterile Sheath 10EA
Material	303-304 Surgical Stainless Steel.
Available Gauges	17G

NOTE Refer to EC4-9ES biopsy guide (Reusable type) for Biopsy Kit configuration and instruction.

HL5-9ED, HL5-12ED Biopsy guide

■ **Specifications**

Model name	BP-KIT-006
Component	Adapter 1EA Needle Guide Kit (Odd & Even Gauge Clip) 3EA/Each (Needle Guide Kit is composed with Sheath, Ultra Sound Gel, and Needle Guide Straw.)
Material	Body: Acetal Copolymer Screw: 303 Stainless
Available Gauges	16G, 18G, 22G

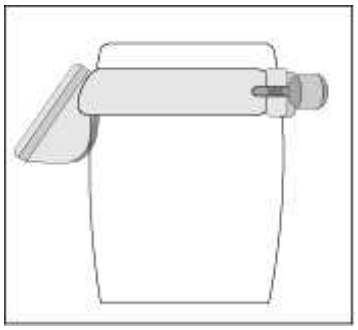
※ You can buy a pack of Adapter or needle guide kit. One pack is consisted of 24ea per each gauge.

■ **Biopsy Kit Configuration**

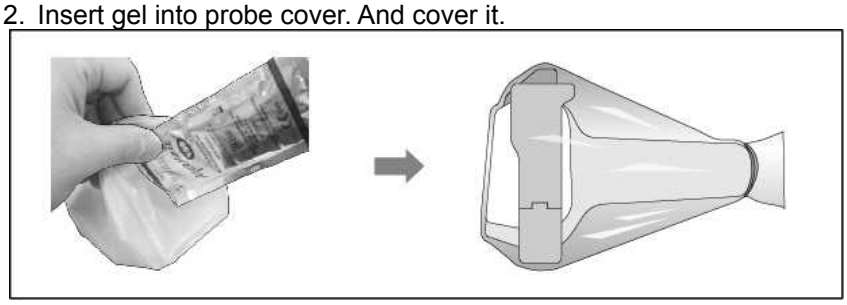
Biopsy Adapter Needle Guide Kit

■ **Installation**

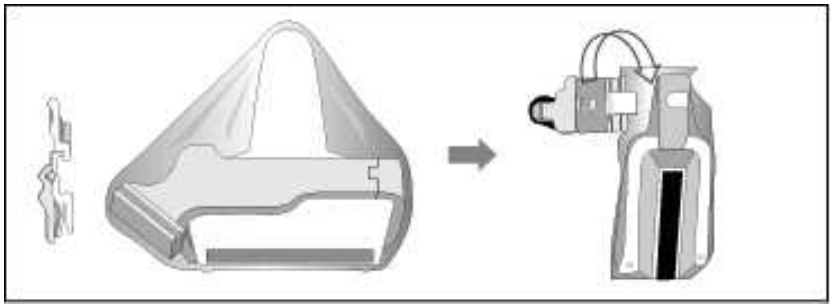
1. Mount the Adapter onto the probe.



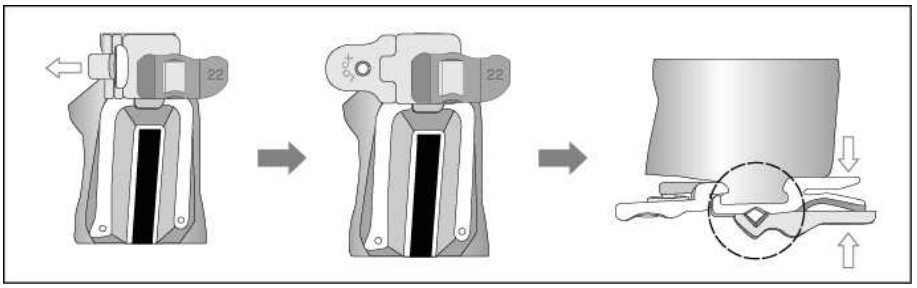
2. Insert gel into probe cover. And cover it.



3. Install the needle guide onto the Adapter.

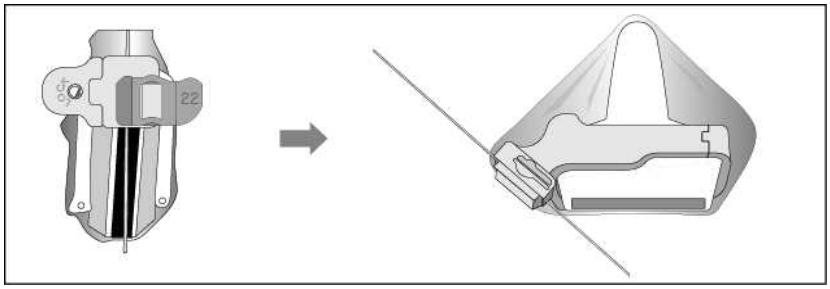


4. Lock the needle guide like (a), and do like (b).



(a) (b) (c)

5. Press the needle guide like (c), and install the needle into the needle guide.

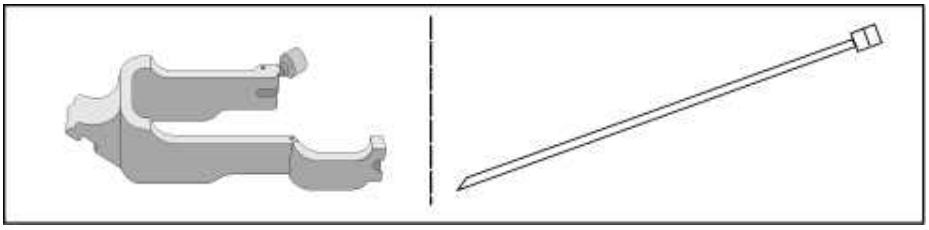


L5-9EE Biopsy guide

■ Specifications

Model name	BP-KIT-013
Component	Biopsy KIT(Adapter&Guide) 1 EA Case 1 EA User Manual 1Volume
Material	Acetal Copolimer
Available Gauges	16G, 18G, 22G

■ Adapter Configuration

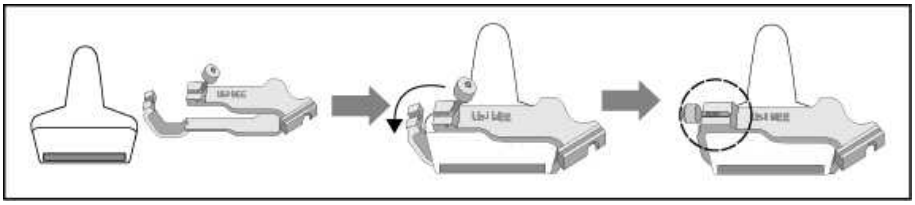


Biopsy Adapter Needle

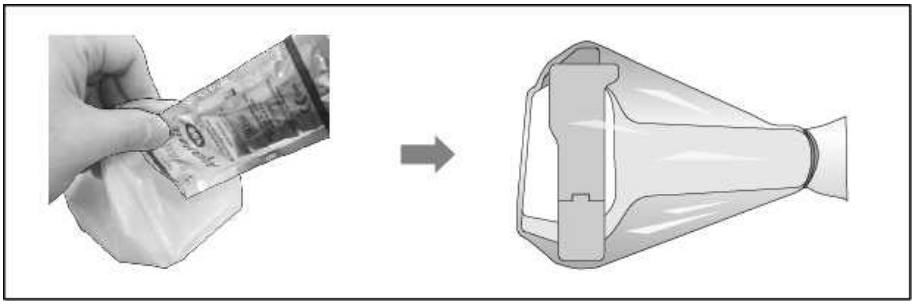
Needle Guide Kit

■ **Installation**

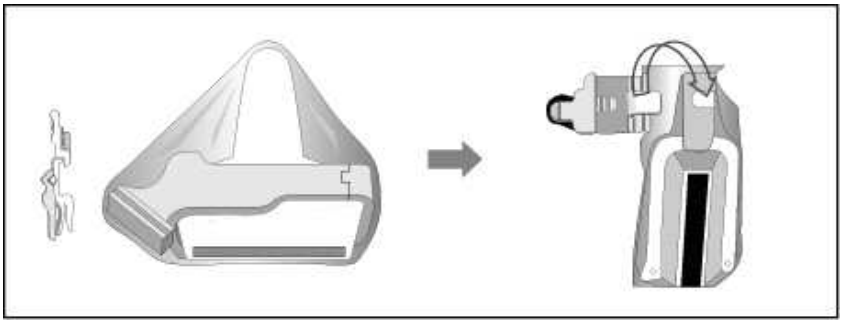
1. Mount the Biopsy adaptor over the probe.



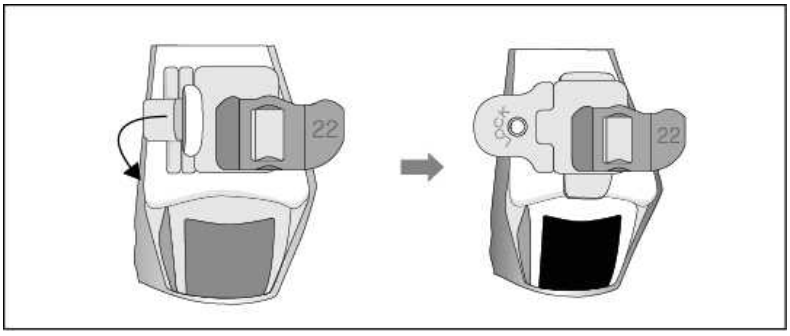
2. Insert gel into the sheath. And cover it.



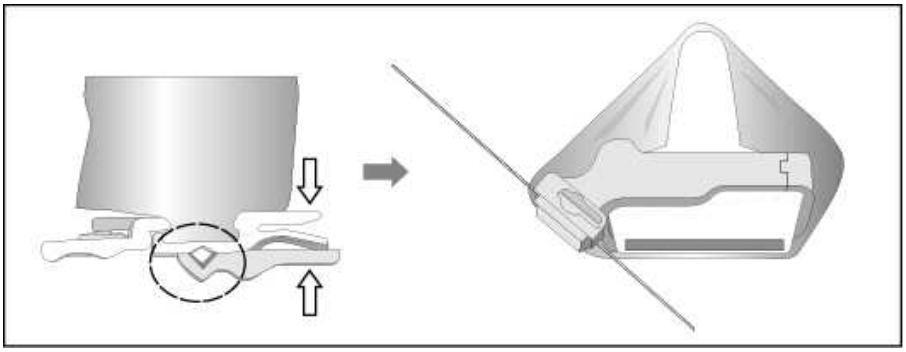
3. Choose a needle guide of the desired gauge and secure it to the adapter.



4. Lock the needle guide.



5. Press the needle guide and install the needle into the needle guide.

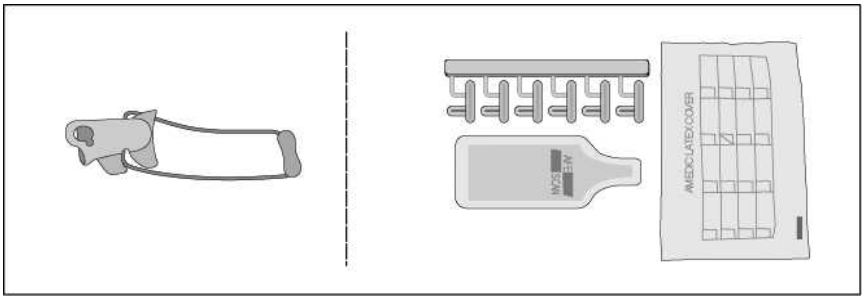


L5-9EC Biopsy Guide

■ **Specifications**

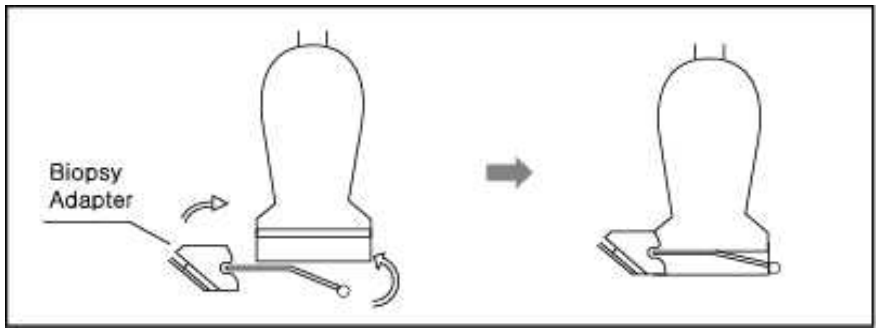
Model name	BPL-75/40-AC
Component	Biopsyadapter 1EA Box 1EA
Material	Stainless (re-usable)
Available Gauges	8F, 14G, 16G, 18G, 20G, 22G

■ **Adapter Configuration**

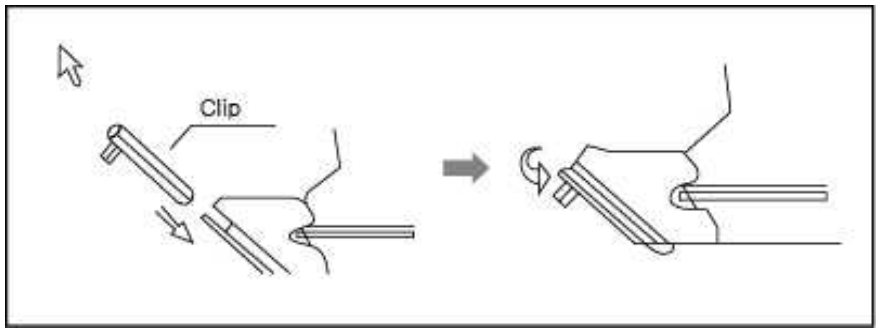


■ **Installation**

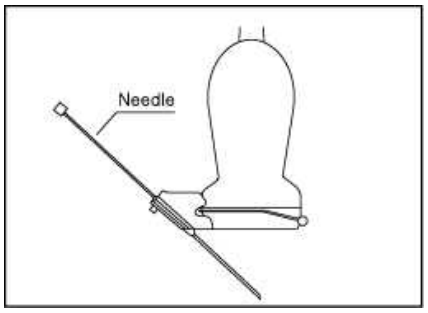
1. Mount the adaptor onto the probe.



2. Choose a needle guide of the desired gauge and secure it to the adapter.



3. Insert the needle into the needle guide for use.



L5-12/50EP Biopsy Guide

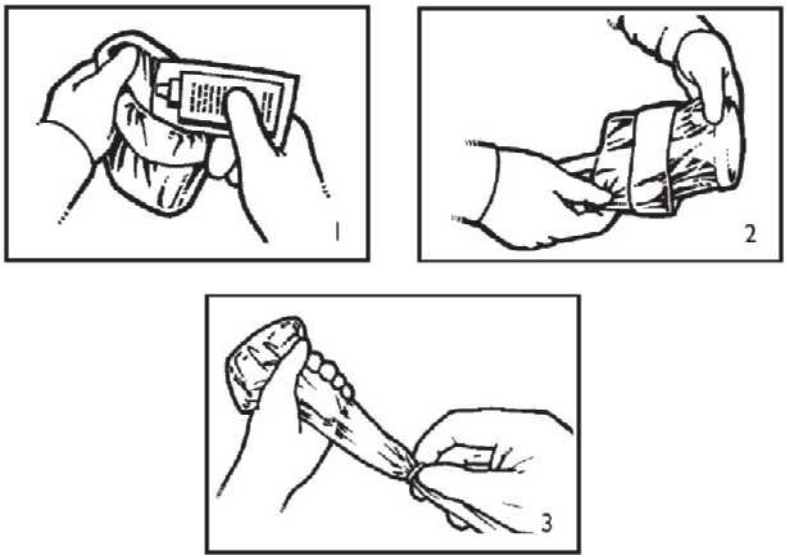
NOTE	To purchase this biopsy kit, please contact the local office.

■ Specification

Model name	BP-KIT-020	
Component	Biopsy Adapter Needle Guide	1EA 8EA
Material	Polyurethane	
Available Gauges	16G, 18G, 22G	

■ Installation

1. Insert gel into the cover for the Kit and cover the adapter completely.



2. Mount the needle guide for the desired gauge onto the adapter.

3. Lock the needle guide.

4. Insert the needle into the needle guide for use.