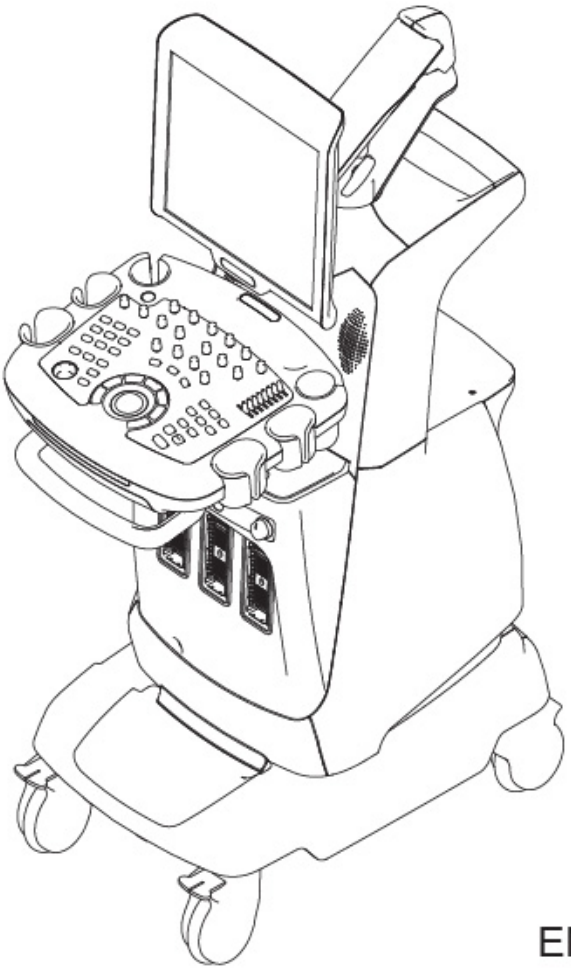
SERVICE MANUAL

SONOACE X8

REVISION 01



ENGLISH

Safety Requirements

Classifications:

- 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 Eqiupment, Part 1General Requirements for Safety.
- IEC/EN 60601-1-1 Safety requirements for medicalelectrical 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

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

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

This is GMP symbol for Good Manufacturing Practice of Korea quality system regulation.

READ THIS FIRST

Before asking for the product to be repaired, read this service manual thoroughly, learn how to troubleshoot, and make sure you understand the precautions fully.

The repair of the system and the replacement of parts must be carried out by an authorized dealer or the customer care department of MEDISON Co., Ltd.

The company is shall not be held liable for any injury and damage caused by not following this warning.

For safe use of this systemproduct, you should read 'Chapter 2. Safety' in this manual, prior to starting to useing this system.

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.

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1 General Information

1.1 Overview

Chapter 1 contains the information necessary to plan the Troubleshooting of SONOACE X8

The SONOACE X8 is a high-resolution color ultrasound scanner with high penetration and a variety of measurement functions

Contents General Information

1.2 Features and Advantages of SONOACE X8

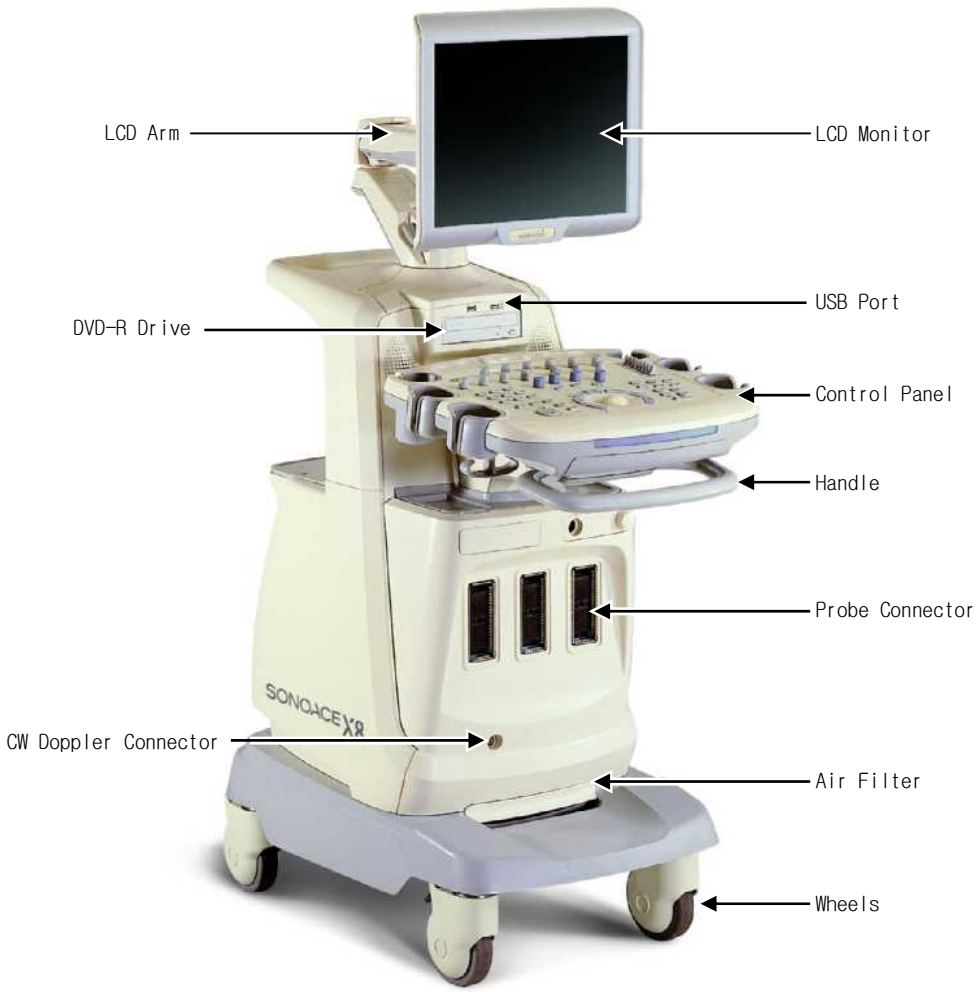
- High-end Digital Beamforming : The SONOACE X8 utilizes the newly developed Digital Beam forming technology.
- A variety of applications : The SONOACE X8 is optimized for use in a variety of ultrasound departments, including general, abdomen, obstetrics, gynecology, vascular, extremity, pediatric, cardiac, breast, urology, and etc.
- Various diagnostic Modes : 2D Mode, M Mode, Color Doppler Mode, Power Doppler Mode, PW Spectral Doppler Mode, CW Spectral Doppler Mode, etc.
- 3D / 4D images can be obtained.
- Measurement and Report Functions : Besides the basic distance, area, circumference and volume measurement functions, the SONOACE X8 also provides application-specific measurement functions. The report function collates measurement data.
- Review of Scanned Images : The SONOACE X8 displays Cine images of 5242 frames and loop images of 8192 lines.
- SonoView™ : This is a total ultrasound image management system, which allows a user to archive, view and exchange documents.
- Digital Imaging and Communication in Medicine (DICOM) 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 X8.

1.3 Product Configuration

This Product consists of the monitor, the control panel, the console, and the probes.

1.3.1 Console

The console consists of two parts – the inner unit and the outer unit. The interior of the console mainly contains devices that produce ultrasound images. On the exterior of the console are various connectors, probe holders, storage compartments, handles, wheels, etc.

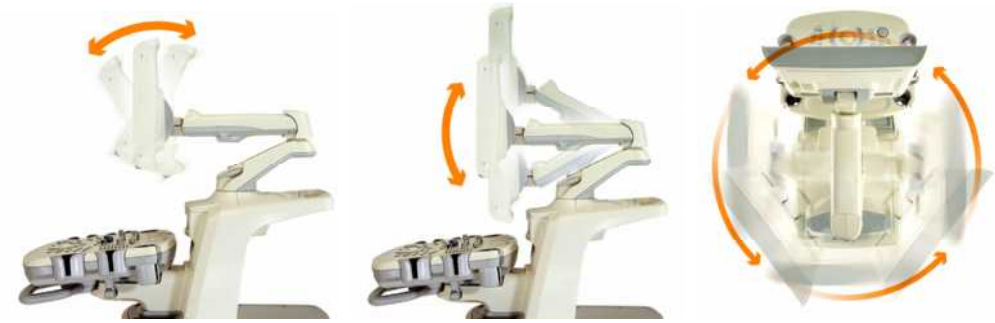


[Figure 1-1] Console of SONOACE X8

[Figure 1-2] Console of SONOACE X8

1.3.2 LCD Monitor

The monitor of this system is a color VGA monitor, which displays ultrasound images and additional information. Use the monitor arm to adjust the height or position of the monitor.



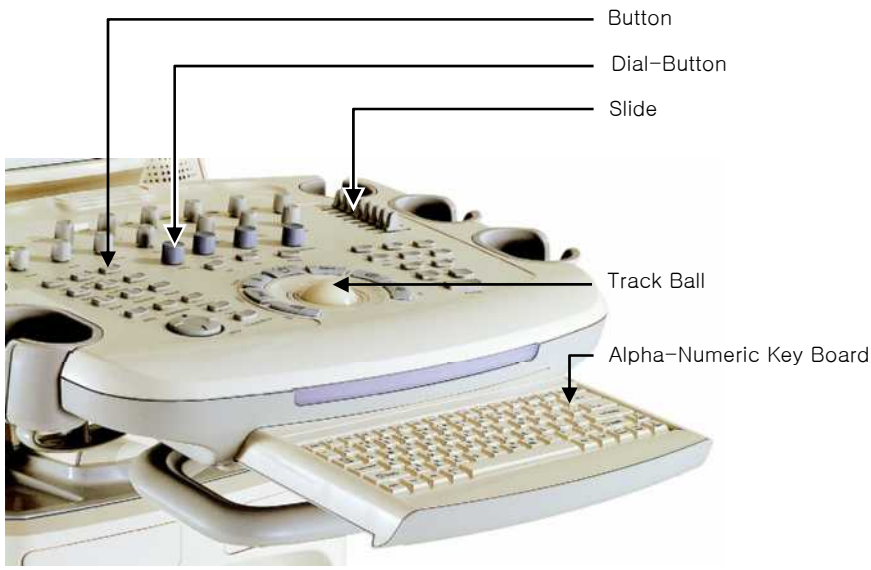
[Freely Movement] [Articulation (360°)]

[Figure 1-3] LCD Arm

1.3.3 Control Panel

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

1) Function keys for mode selection and scanning, located on the right side of the control panel.
2) Function keys for annotation and measurements, located around the Trackball.
3) Menu selection buttons, located on the left side of the control panel.
4) An alpha-numeric keyboard, located under the control panel.



[Figure 1-4] Control Panel

1.3.4 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 9 Probes'.

1.4 Specifications

Physical Dimensions	Height: 1329mm (with monitor) Width: 510mm Depth: 885mm Weight: more than 101kg (with monitor)
Monitor	17 inch LCD monitor
Electrical Parameters	100-120V/200-240VAC, 10A, 50/60Hz
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
Imaging modes	2D imaging mode M imaging mode Color Doppler Imaging(CDI) mode Power Doppler Imaging(PDI) mode Directional Power Doppler Imaging(DPDI) mode Power Pulse Inversion Imaging(PPII) mode Pulse Wave(PW) Spectral Doppler imaging mode Continuous Wave(CW) Spectral Doppler imaging mode 3D imaging mode Dual modes Quad modes Combined modes Simultaneous mode Zoom mode
Focusing	Transmit focusing, maximum of eight points (four points simultaneously selectable) Digital dynamic receive focusing (continuous)
Application	Abdomen, Obstetrics, Gynecology, Adult Cardiac, Pediatric Cardiology, Small Part, Vascular, Pediatric Abdomen, Musculoskeletal, TCD General, Renal, Aorta, Appendix, Fetal Hart, Superficial, Carotid, Arterial, Venous, Shoulder/Knee, Hand/Foot, Elbow/Wrist, Aortic Arch, Cervix, Prostate, Bladder

Measurement Packages	Obstetrics Gynecology Cardiology Fetal Echo Vascular (Carotid, Upper Extremity, Lower Extremity, Varicose) Urology Radiology * Refer the Chapter 5 of User manual
Measurement	Trackball operation of multiple cursors 2D mode: Linear measurements and area measurements using elliptical approximation or trace M mode: Continuous readout of distance, time, and slope rate Doppler mode: Velocity and trace
Image Storage	Cine loop memory (maximum 5242 frames) Image filing system
Gray Scale	256 (8 bits)
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
Signal processing (Post-processing)	Spatial Compound Imaging Dynamic MR Frame average Edge Enhancement / Blurring Gamma-scale windowing Image orientation (left/right and up/down, rotation) White on black/black on white Zoom
Probes	Curved Linear Array C2-5EL C3-7EP Linear Array HL5-12ED L5-12EC L5-12/50EP

Probes	Phased Array P2-4AH P3-5AC Endocavity Curved Linear Array NER4-9ES NEV4-9ES Volume Probe 3D2-6ET 3D4-8EK 3D4-8ET 3D5-9EK CW CW2.0 CW4.0
Probe connections	4 probe connectors (including CW probe connector)
Rear Panel Input / Output Connections	VHS and S-VHS, VCR left and right audio Microphone B/W printer video and remote control VGA monitor Parallel port USB LAN
Auxiliary	VCR Video Page Printer Color Video Page Printer USB Video Printer USB Color Video Printer Inkjet Printer Laser Printer USB MO Driver Foot Switch USB Flash Memory Media Microphone EXT Monitor

2 Safety

2.1 Overview

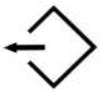
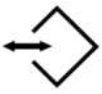
Chapter 2 contains the information necessary to Safety

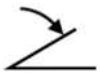
Contents Safety

2.2 Safety - Related Information

2.2.1 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.

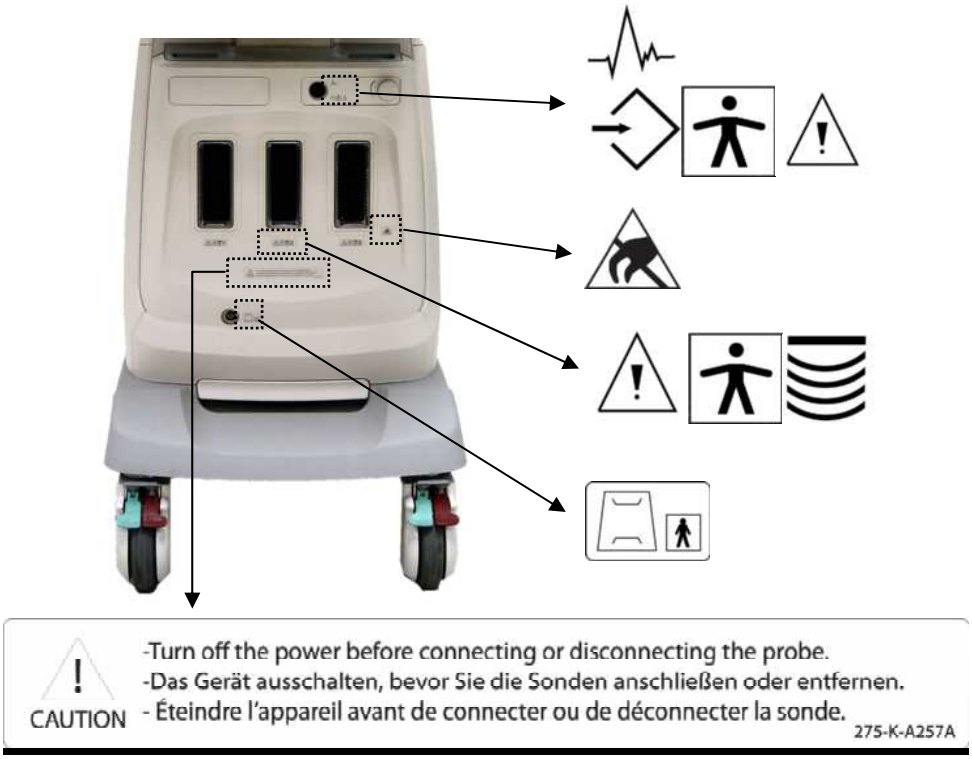
Symbols	Description
	Isolated patient connection (Type BF applied part).
	Power switch (Supplies/cuts the power for product)
	Indicates a caution for risk of electric shock.
	Indicates dangerous voltages over 1000V AC or over 1500V DC.
	Warning, Caution
	Identifies an equipotential ground.
	Identifies 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.
	Electrostatic discharge
	Data Output port
	Data Input port
	Data Input/Output port

Symbols	Description
	Left and right Audio / Video input
	Left and right Audio / Video output
	Print remote output
	Foot switch connector
	ECG connector
	USB connector
	Microphone connector
	Protection against the effects of immersion.
	Protection against dripping water.
	Probe connector

2.2.2 Labels

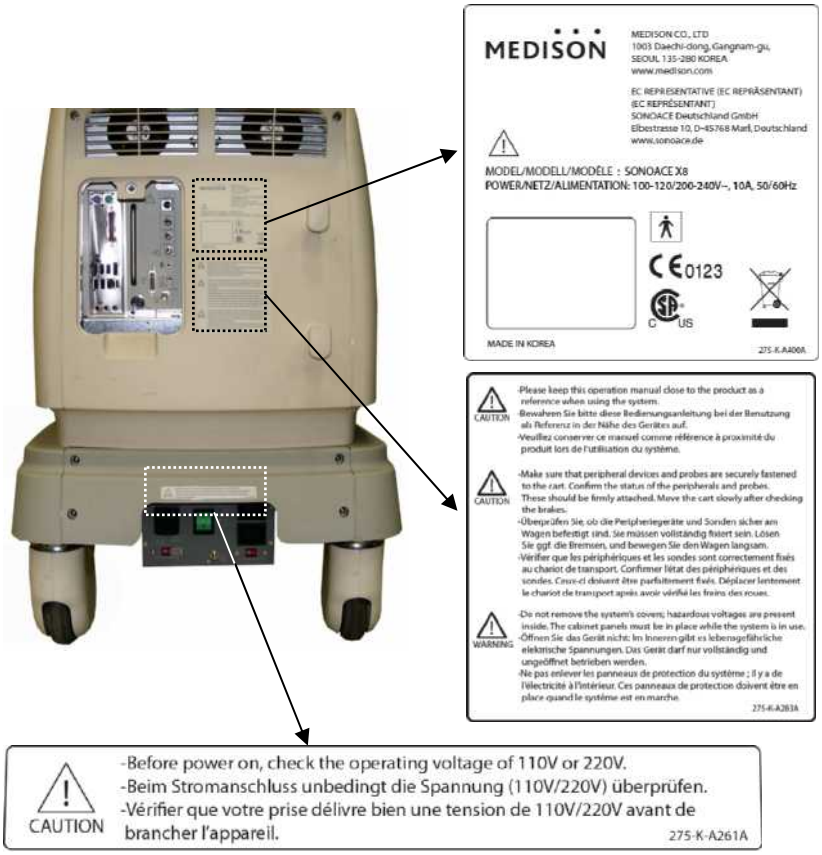
To protect the system, you may see 'Warning' or 'Caution' marked on the surface of the product

1) Front



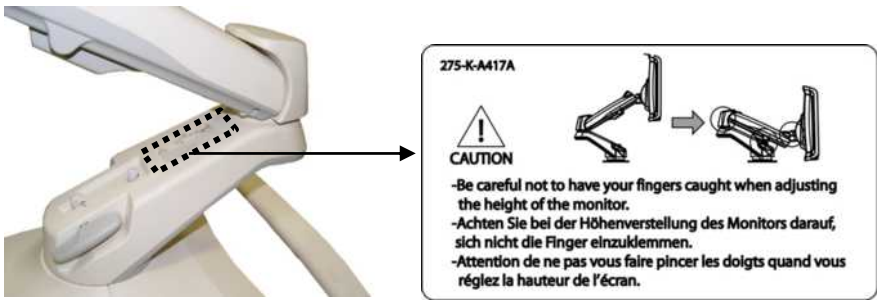
[Figure 2-1] Labels of Front

2) Rear



[Figure 2-2] Labels of Rear

3) Monitor



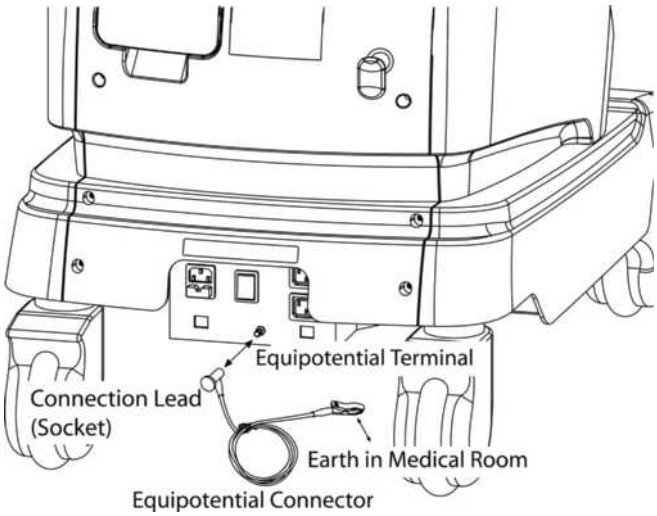
[Figure 2-3] Labels of Monitor

2.3 Electrical Safety

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

2.3.1 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 2-4] 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

2.3.2 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.

2.3.3 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 2-5] 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.

2.3.4 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.

2.3.5 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).

2.3.5.1 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 (Radiation) CISPR 11	Group 1 Class B	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. The Ultrasound System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies building used for domestic purpose.
RF Emission (Radiation) CISPR 11	Group 1 Class B	
Harmonic Emission IEC 61000-3-2	Class A	
Flicker Emission IEC 61000-3-3	Complies	

2.3.5.2 Approved Cables, Transducers and Accessories for EMC

1) 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

2) Approved Transducer for Electromagnetic Compliance

The probe listed in 'Chapter 8. Probes' when used with this product, have been tested to comply with the group1 class B emission as required by International Standard CISPR 11.

3) 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.

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.			

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	3 V/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.

2.3.5.3 Recommended separation distances between portable and mobile RF communications equipment and the SONOACE X8

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 $d = [\frac{7}{E_1}]\sqrt{P}$
	V1=0.01Vrms	E1=3 V/m	E1=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.

2.3.5.4 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.

2.3.5.5 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 System 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.

2.4 Mechanical Safety

2.4.1 Moving the Equipment

Before transporting the product, check that the brakes on the front wheels are unlocked. Also, make sure to retract the monitor arm completely so that it is secured in a stationary position.

Always use the handles at the back of the console and move the product slowly.

This product is designed to resist shocks. However, excessive shock, for example if the product falls over, may cause serious damage.

If the system operates abnormally after repositioning, please contact the MEDISON Customer Service Department.

WARNING

The product weighs more than 100kg. Be extra careful when transporting it. Careless transportation of the product may result in product damage or personal injury

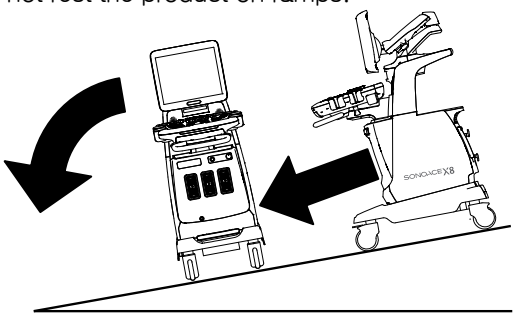
2.4.1.1 The Brakes

Brakes are mounted to the front wheels of the console only. To lock the brakes, press the top part of the brake with your foot. To unlock them, press the part labeled Off at the bottom of the brake with your foot.
You can use the brakes to control the movement of the product. We recommend that you lock the brakes when using the product.

2.4.1.2 Precautions on Ramps

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

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.



[Figure 2-6] Precautions on Ramps

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

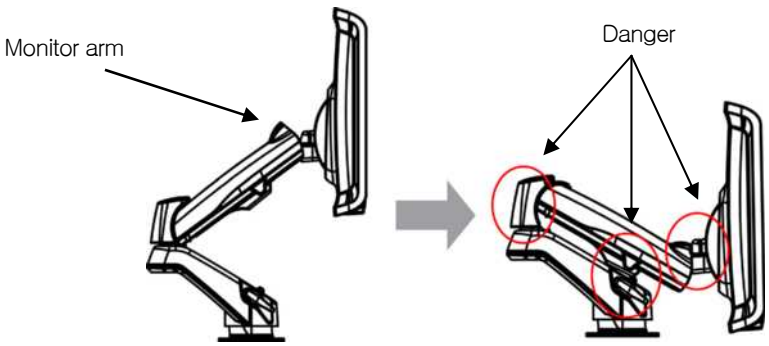
2.4.2 Safety Note

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.

2.4.3 Safety Note for Monitor

When adjusting the height or position of the monitor, be careful of the space in the middle of the monitor arm. Having your fingers or other body parts caught in it may result in injury.



[Figure 2-7] Safety Note for Monitor

2.5 Biological Safety

Verify the alignment of the Probe before use. See the "Chapter 9. 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.

2.5.1 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.

2.5.1.1 Applying ALARA

The system-imaging mode used depends upon the information needed. 2D-mode and M-mode imaging provide anatomical information, while Doppler, Power, and Color imaging provide information about blood flow. Scanned modes, like 2D-mode, Power, or Color, 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.

2.5.1.2 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.

2.5.1.3 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, color sensitivity, 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.

2.5.1.4 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.

2.5.1.5 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.

2.5.1.6 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), bone (TIb) and cranial bone (TIc). 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.

1) 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

2) 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.

3) 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.

2.5.1.7 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.

1) 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 Color, 2D-mode and pulsed 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.

2.5.1.8 2D Mode Controls

1) 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.

2) 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.

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

4) 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.

5) 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.

2.5.1.9 Color and Power Controls

1) Color Sensitivity

Increasing the color sensitivity may increase the TI. More time is spent scanning for color images.

Color pulses are the dominant pulse type in this mode.

2) Color Sector Width

Narrower color sector width will increase color frame rate and the TI will increase. The system may automatically decrease pulse voltage to stay below the system maximum. A decrease in pulse voltage will decrease the MI. If pulsed Doppler is also enabled then pulsed Doppler will remain the dominant mode and the TI change will be small.

3) Color Sector Depth

Deeper color sector depth may automatically decrease color frame rate or select a new color focal zone or color pulse length. The TI will change due to the combination of these effects. Generally, the TI will decrease with increased color sector depth. MI will correspond to the peak intensity of the dominant pulse type, which is a color pulse. However, if pulsed Doppler is also enabled then pulsed Doppler will remain the dominant mode and the TI change will be small.

4) Scale

Using the SCALE control to increase the color velocity range may increase the TI. The system will automatically adjust pulse voltage to stay below the system maximums. A decrease in pulse voltage will also decrease MI.

5) Sec Width

A narrower 2D-mode sector width in Color imaging will increase color frame rate. The TI will increase. MI will not change. If pulsed Doppler is also enabled, then pulsed Doppler will remain as the primary mode and the TI change will be small.

2.5.1.10 M mode and Doppler Controls

1) Speed

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

2) 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.

3) 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.

2.5.1.11 DOPPLER, CW, M MODE, and COLOR 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.

1) 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.

2) 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.

3) 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.

2.5.1.12 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.

2.5.1.13 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)

2.5.1.14 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:

$$\text{In Situ} = \text{Water}\ [\, e^{-(0.23alf)} \,]$$

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:

$$\textit{In Situ}\ (\textit{derated}) = \text{Water}\ [\, e^{-(0.069lf)} \,]$$

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.

2.5.1.15 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 ranges 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 plane (centimeters).

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

2.5.1.16 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 %

1) 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.

2.6 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

NOTE 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.

3 Installing the Product

3.1 Overview

Chapter 3 contains the information necessary to plan the installation of SONOACE X8 and install it.
This chapter describes the requirements for the transportation and installation environment for the product, so that the product is installed in the best condition. Also included are product installation and set up procedures and electrical security check procedures. In addition, procedures for connecting probes and external equipment are included.

Contents Installing the Product

3.2 Transportation

SONOACE X8 is a sensitive piece of electronic medical equipment. Take care when moving it.

3.2.1 Precautions for Transportation

1) The box packaging is designed to diminish the effects of any impact to the product. However, take care not to subject the product to any external impact.

2) If the box is subjected to an impact or is dropped, the shock sensor as illustrated below will indicate that a shock has occurred. In this case, contact the customer care department of MEDISON Co., Ltd. or an authorized engineer immediately.

NOTE Direct impact to the shock sensor may cause an error.

[Figure 3-1] Shock Sensor to identify damage during transportation

3.2.2 Temperature and Humidity

The following [Table 3-1], “Temperature and Humidity Requirements” shows the required temperature and humidity for the transportation, care, and operation of the product.

Type	Temperature [°C]	Humidity [%]
Transportation	-25 ~ 60	20 ~ 90
Care	-10 ~ 50	20 ~ 90
Operation	10 ~ 35	30 ~ 75

[Table 3-1] Temperature and Humidity Requirements

3.2.3 Transportation of the Product

1) Moving the product package by forklift, or with not less than 4 persons, is recommended.

2) The product should be delivered to the end user without removing the packaging, to avoid external shocks to the product.

3.3 Unpacking

3.3.1 Unpacking the Box.

1) Remove the box strap.

2) Lift the top side of the box up and remove it.

3) Lift the box body up and remove it.

4) Remove the protective plastic packaging.

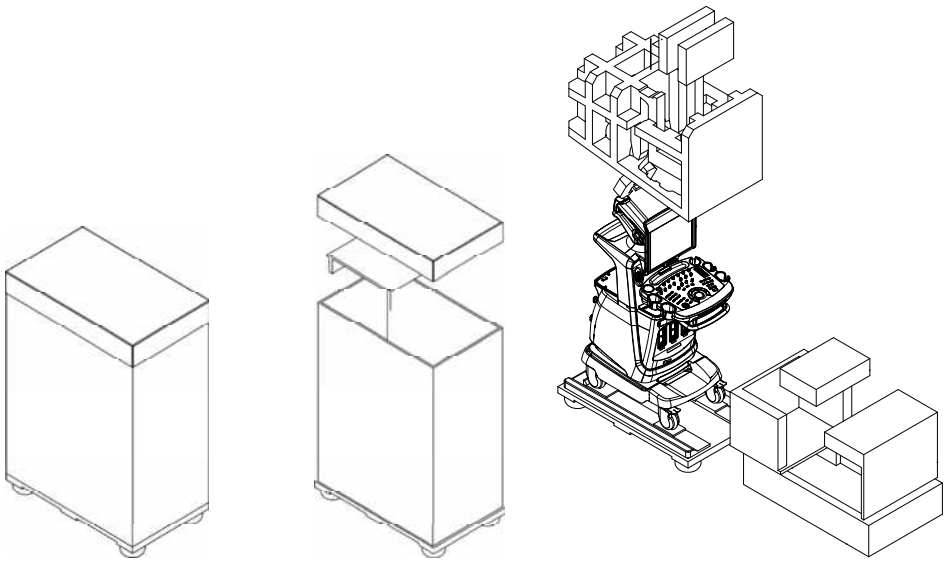
5) Take the probe and accessory boxes out and put them in a safe place.

6) Fix the panel for carrying the product.

7) Unlock the wheel.

8) Hold the rear handle and move the product to its installation location, pulling it gently by the handle.

9) It is recommended to use two persons when wheeling the product.



[Figure 3-2] Unpacking the Box

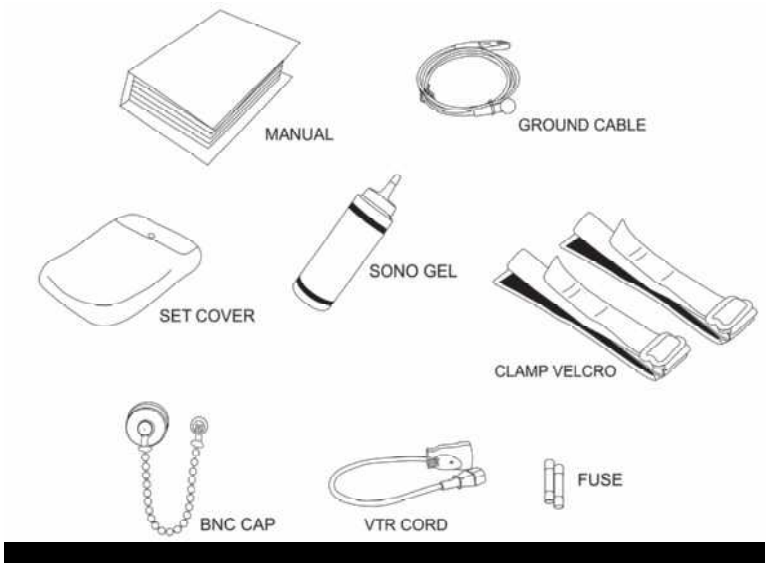
CAUTION

When moving the product up a steep incline or over a long distance, there is a danger of injury.

3.3.2 Checking Package Contents

Unpack the product's packaging and check the package contents.

If there are any missing parts, contact your dealer.



[Figure 3-3] Contents of SONOACE X8 Package

3.4 Precautions for Installation

3.4.1 Precautions

Please follow the precautions below.

1) Avoid installing the product where water may get into it.
2) Avoid installing the product in direct sunlight.
3) Avoid installing the product in places where there are high temperature fluctuations.
4) Temperatures of 10°C ~ 35°C and a humidity of 30% ~ 75% are required for normal operation..
5) Avoid installing the product near a heater.
6) Avoid installing the product in a dusty location, or where there is a lack of ventilation.
7) Avoid installing the product in a location subject to vibration.
8) Avoid installing the product where there are chemicals or gas.

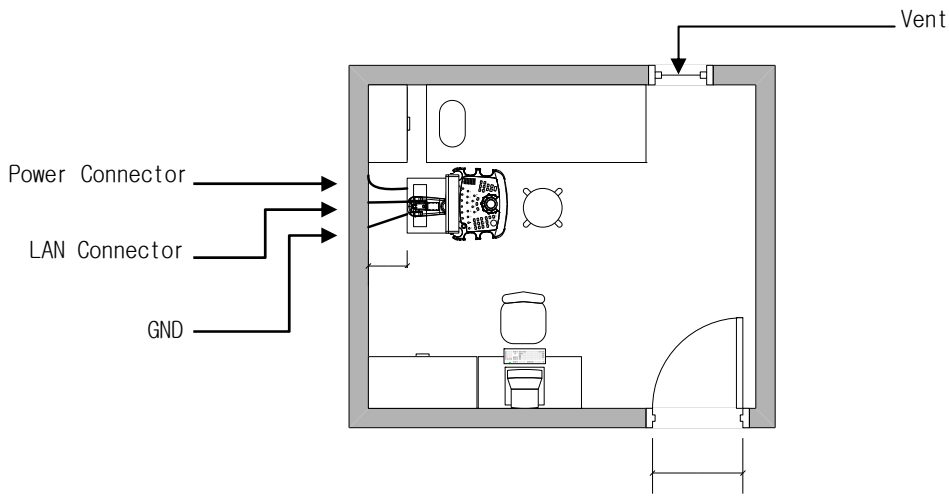
CAUTION

If you use the product near a generator, X-Ray equipment, or a broadcasting transmission cable, the screen may not work normally due to interference.

In addition, sharing the same wall outlet with other electric equipment may cause noise.

3.4.2 Installation Location

1) The width of the door must be at least 70cm for the product to pass through.
2) The distance between the wall and the product must be at least 30cm.
3) The wall outlet, grounding terminal and LAN connector (Ethernet Connector or LAN Connector) should be within 1m of the product.
4) The illumination should be capable of being brightened or dimmed.
5) There must be sufficient ventilation in the room.



[Figure 3-4] Installation location

30cm

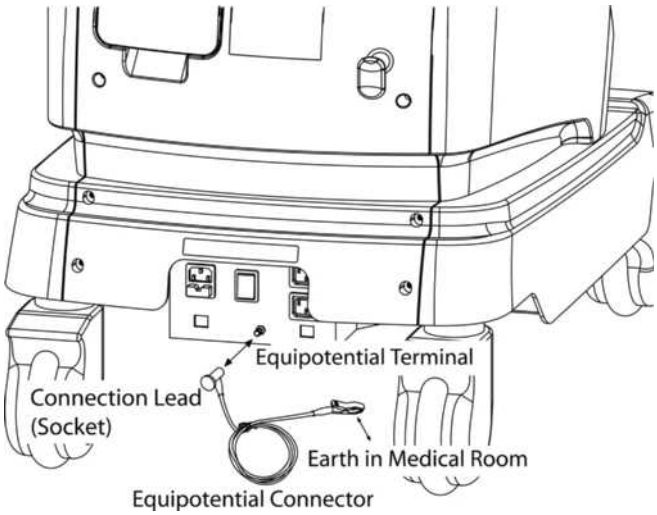
3.5 Installation Procedure

3.5.1 Installation Safety

DANGER

If you use the product near a generator, X-Ray equipment, or a broadcasting transmission cable, the screen may not work normally due to interference.

In addition, sharing the same wall outlet with other electric equipment may cause noise.



[Figure 3-5] Equal Electric Potential Terminal (Ground) Connection

CAUTION

When moving or storing the product for a long time, you should check the temperature and humidity of the environment.

Turn the power on after referring to the information in the following [Table 3-2] "Product Operation Temperature".

Sudden temperature change causes dew and may generate problems in the product.

Temperature	-20	-15	-10	-5	0	5	10 ~ 40	45	50	55	60
Time to Wait	16	10	8	6	4	2	Immediate	2	4	6	10

[Table 3-2] Product Operation Temperature

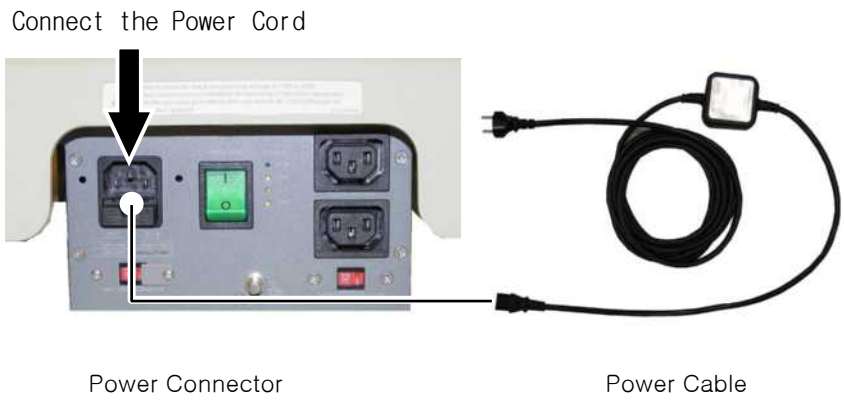
3.5.2 Connecting the Power Cord

Make sure to check the output voltage of the wall outlet in the installation location.

For the stable operation of SONOACE X8, use it within the voltage range specified in the following [Table 3-3] "Product Voltage".

Connect the power cord to the power port on the rear panel of SONOACE X8.

NOTE The product and the power cord may be connected before shipping.



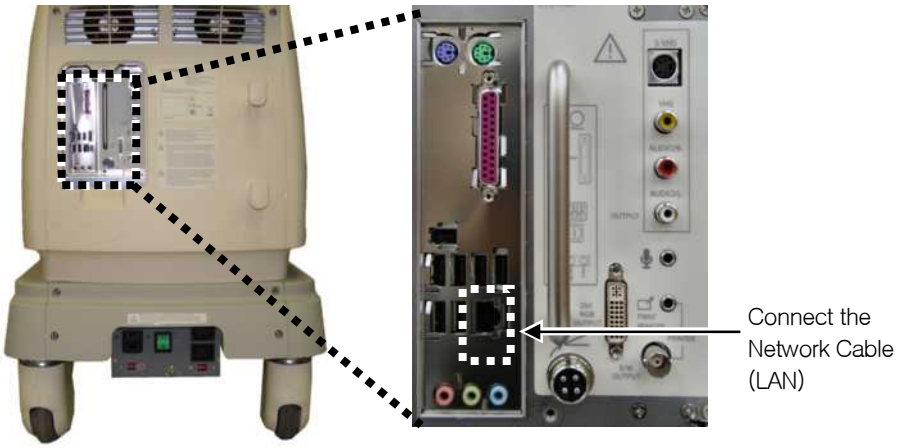
[Figure 3-6] Product Power

Voltage	Allowable Voltage Range	Current	Frequency
100-120VAC	+/- 10%	10A	50~60Hz
200-240VAC	+/- 10%	10A	50~60Hz

[Table 3-3] Product Voltage

3.5.3 Connecting the Network Cable

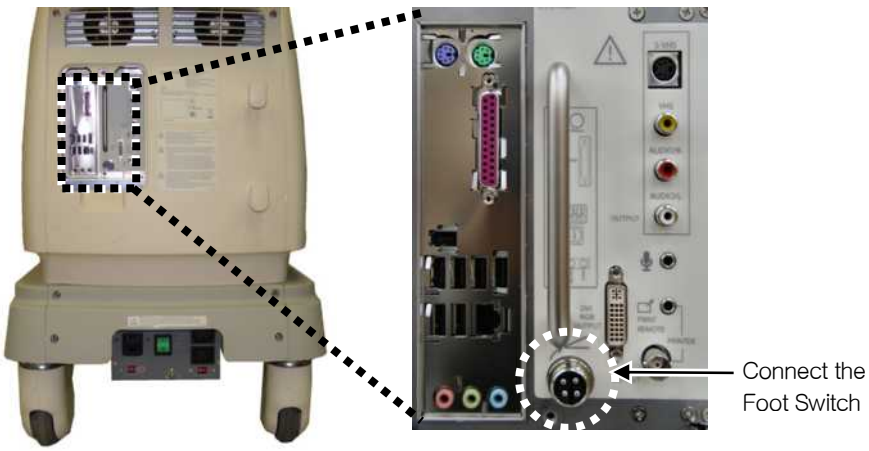
Connect the network cable to the LAN port on the rear panel of SONOACE X8.



[Figure 3-7] Network Cable Connection

3.5.4 Connecting the Foot Switch

Connect the foot switch to the port on the rear panel of SONOACE X8.



[Figure 3-8] Foot Switch Cable Connection

3.5.5 Connecting the Probe

SONOACE X8 provides 3 probe connections on its front panel.

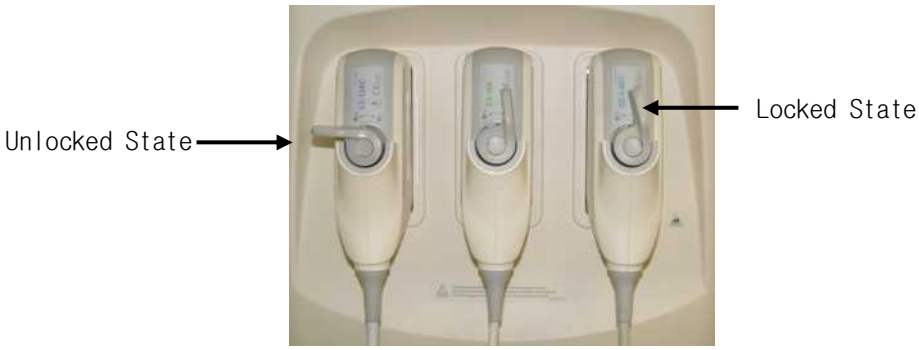
The probe connections are numbered 1, 2, and 3 from the left . SONOACE X8 can be connected to any of these probe connections.

Place a probe in the probe holder and connect it up.

CAUTION

Do not connect with excessive force, to prevent damage to the probe connection pin and the connector PCB.

1) Connect probes when the probe handle is unlocked (when the knob is turned counterclockwise).
2) Connect probes with the probe cable pointing downwards.
3) Turn the probe handle clockwise until it is fixed at the opposite direction of the cable.



[Figure 3-9] Probe Connections

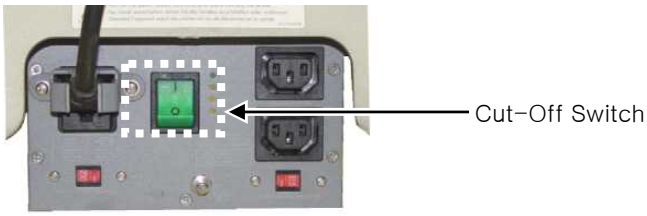
CAUTION

Although you can connect a probe when the power is on, do not connect or disconnect a probe during the booting sequence of the product.

3.6 Starting the Product

Check again if the power capacity is compliant with SONOACE X8 and connect the power cord to the wall outlet.

Check if the SONOACE X8 power cord is properly connected and switch on the cut-off switch for the AC power.



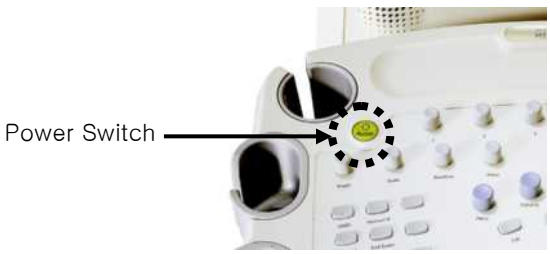
[Figure 3-10] AC Power

CAUTION

- The product should be turned on about 10 seconds after the AC power switch at the back of the product is turned on.
- If you turn on the power after turning off forcibly, the system can turn on and off momentary. It is one of the character of Intel® PC main board, not system error.

To start SONOACE X8, press the On/Off switch at the right side of the control panel (keyboard).

1) A "beep" sound is generated 3 times and you will be able to hear the fan start inside the product.
2) The booting sequence is displayed on the LCD monitor. As the Windows XP logo disappears, the SONOACE X8 logo and loading bar appear.
3) The loading bar fills with color. This represents data being copied to the system by the PC software.
4) When software data copying is complete, the ultrasound picture appears and the system becomes ready. The booting sequence of the product takes approximately 1 minute.

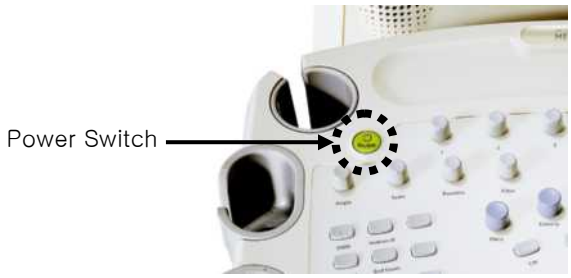


[Figure 3-11] Power Switch

3.7 Shutting down the Product

You can shut down SONOACE X8 by either turning the system off or switching off the cut-off switch.

1) Turning the system off: Press the On/Off switch at the right side of the control panel (keyboard). The system will shut down after the message.



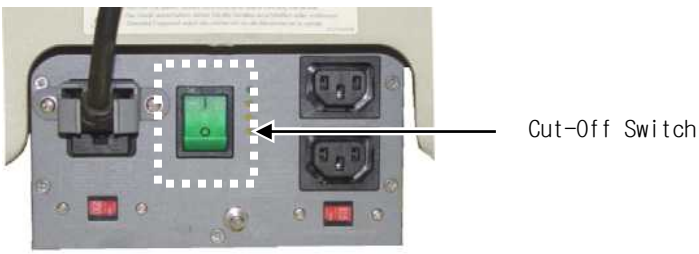
[Figure 3-12] Power Switch

CAUTION

- Pressing the On/Off button over five seconds turn off the power forcibly. It can cause hard disk damage.
- If this problem repeats, contact the customer care department of MEDISON Co., Ltd. or an authorized engineer.

2) Switching off the cut-off switch : You can cut off the power by switching off the cut-off switch after turning the system off.

3) Cut the power off in the event of storing the product for a long period of time, or when repairing the product.



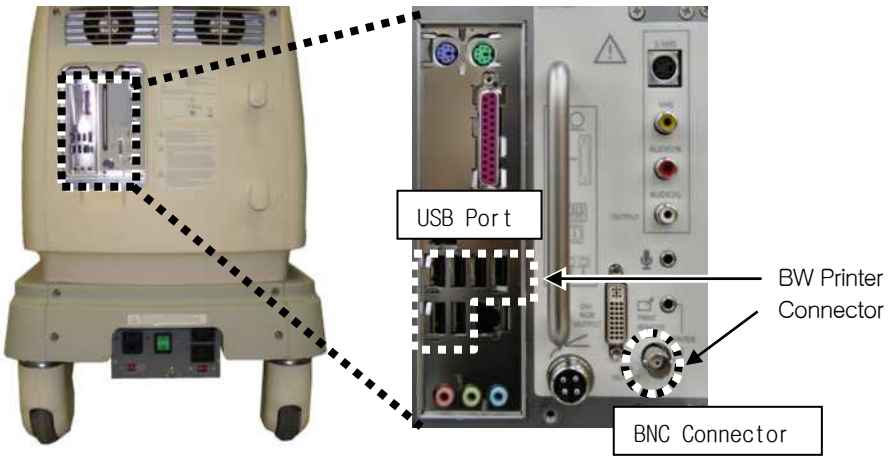
[Figure 3-13] AC Power

3.8 Connecting the Peripherals

SONOACE X8 provides various connectors so that various external devices can be connected. Peripherals can include a mono printer, color printer, line printer, USB storage device, and VCR.

3.8.1 BW Printer

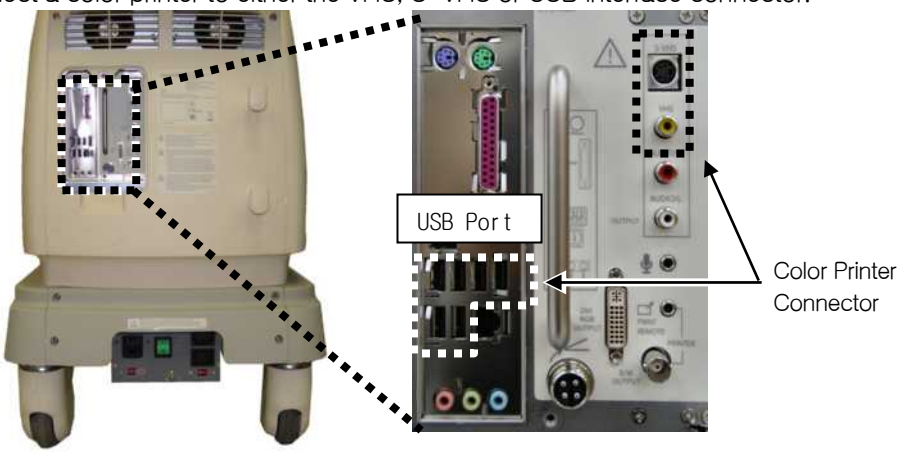
Connect a mono printer to either the BNC or USB interface connector.



[[Figure 3-13] BW Printer Connector

3.8.2 Color Printer

Connect a color printer to either the VHS, S-VHS or USB interface connector.

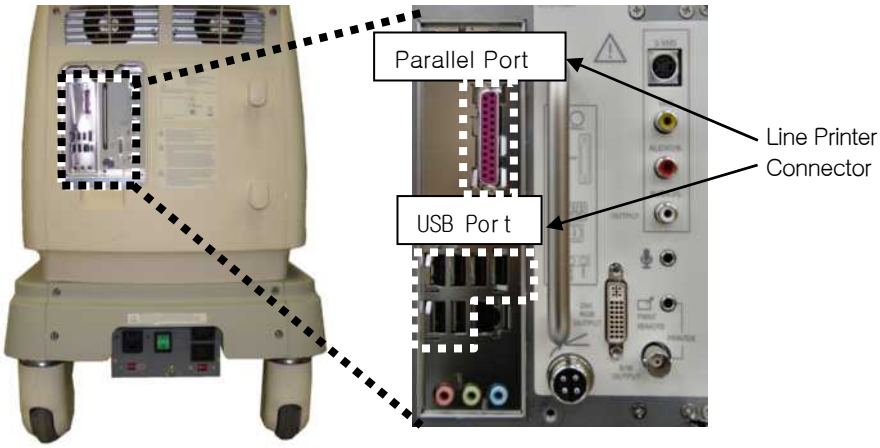


[Figure 3-14] Color Printer Connector

3.8.3 Line Printer

Connect a line color printer to either the Parallel or USB port.

'Line printer' means an Inkjet Printer or a Laser Printer.

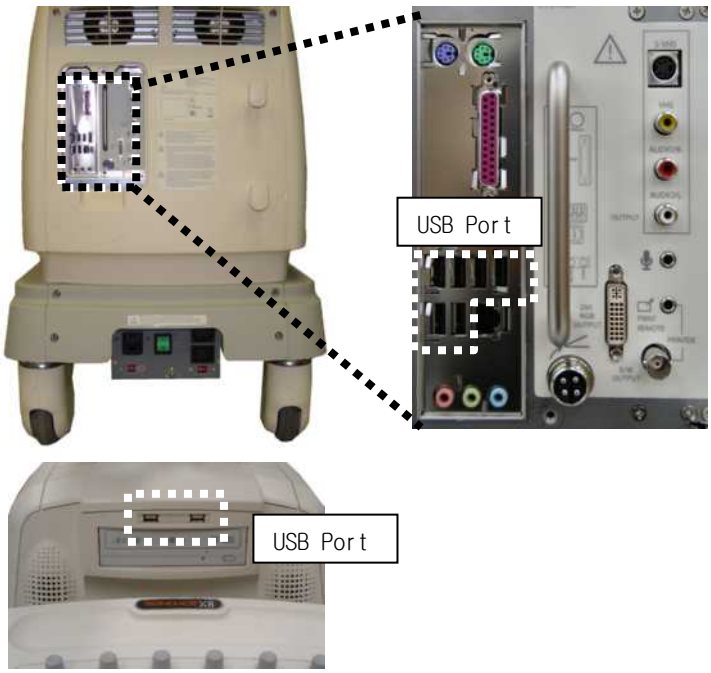


[Figure 3-15] Line Printer Connector

3.8.4 USB Storage Device

You can use USB port on both of the front and rear side of the system to connect a USB storage device.

USB Storage Device: USB Flash Memory Media, USB MO Driver or EXT USB HDD.



[Figure 3-16] USB Port

NOTE If you use the USB 1.1 flash memory, the system cannot recognize it. In the case of this, delete the flash memory from the console and quip again.

3.9 System Settings

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 **Utility** button on the control panel and select **Setup** in the menu.

2) The **Setting** screen will appear. Select a tab that has items to specify.

> ※ Tips! – Selecting a tab
>
> You can select a tab in either of two ways as desired.
>
> – Use the **Trackball** and the **Set** button to select a tab.
>
> – Rotate the **Menu** dial-button to select a tab.

3) Specify settings for each item.

4) Press **Close** to finish the setup. Press the **Exit** button on the control panel to cancel.

3.9.1 General System Setting

Select the **General** tab in the *Setting* screen. You can specify general settings such as title settings.

3.9.1.1 Title

You can specify information displayed in the title area on the screen.

1) Institution

Enter the name of the hospital/institution where the product is installed.

2) Date

The current date is displayed. To change the date, press 

NOTE You cannot change the date and time when a patient ID is registered. To change the date and time, you should finish the current diagnosis by pressing **End Exam** on the control panel

3) Date Format

Specify the date format. Select a desired date format by pressing the combo button. The date format that you specify will be applied to various date fields in *Patient Information*.

4) Time

The current time is displayed.

5) Time Format

Specify the time format. Select a desired time format by pressing the combo button.

※ Tip! How to set the date and time

① Press  in the **Date** (or **Time**) button.

② Set the date and time by using the **Trackball** and the **Set** button on the control panel.

③ If it is properly set, press Apply to apply changes. Press OK to close the Date & Time window. To cancel, press **Cancel** or the **Exit** button on the control panel.

[Figure 3-17 Date & Time]

3.9.1.2 Display

Specify display-related options.

1) Option

You can specify more than one item. Use the **Trackball** and the **Set** button to select a desired item and check or uncheck it.

- Auto Freeze: If the product is unused for 10 minutes, the scan mode will be automatically stopped

NOTE In Live 3D Mode, if the product is unused for 20 minutes, the Auto Freeze function is applied.

- Post Map: This sets whether to display the Post Map in the feedback area on the screen.
- TGC Line: This sets whether to display the TGC line.
- VCR Counter: This sets whether to show the VCR Counter on the screen when a VCR is connected to a serial port. When the counter interferes with an image and is turned off, it will appear during recording only.
- Image Info: This sets whether to display image information. When the image information interferes with an image and is turned off, it will not be displayed.
- Name + Age: This sets whether to display the patient ID, name and age.

2) Display

TI (Thermal Index) Display: Specify the TI to display on the screen as TIs (Soft tissue Thermal Index), TIb (Bone Thermal Index) or TIc (Cranial bone Thermal Index).

3) Simultaneous Mode

This determines whether to enable simultaneous mode in Spectral Doppler Mode.

- Off: Select this if you do not wish to use simultaneous mode.
- Allow B/PW: Select this if you do not wish to use simultaneous mode in 2D/C/PW modes but do wish to use it in 2D/PW mode.
- Allow B/C/PW: Select this if you wish to use simultaneous mode for both 2D/PW and for 2D/C/PW.

4) Doppler Axis

Select the axis scale unit in Spectral Doppler Mode.

- Velocity: Specify the Doppler axis scale unit in cm/s (mm/s).
- Frequency: Specify the Doppler axis scale unit in KHz.

5) 2D/C DualLive Color Position

Select the location of Color Doppler Mode in 2D/C Live Mode. In the 2D menu, you can select from Up/Down if **Horizontal Dual** is on, or from Left/Right if it is off.

- Left/Up: Color Doppler Mode is located in the left or upper part.
- Right/Down: Color Doppler Mode is located in the right or lower part.

3.9.1.3 Clip store Setting

1) Clip Store Method

Specify the method and range in which an image is acquired and saved.

You can select ECG Beat, Time or Manual. Note that ECG Beat can be selected only when ECG is on.

- ECG Beat: Specify the heart beat as 1 – 8 beats.
- Time: Specify it as 1 – 8 seconds.
- Manual: Save images automatically for 8 seconds after pressing the **Clip Store** button.

2) Prospective

When **Store Clip** is pressed during scanning, the subsequent images are saved.

3) Retrospective

When **Store Clip** is pressed during scanning, the previous images are saved.

3.9.1.4 Control

You can specify display-related options

1) Track Ball Speed for Management

Specify the Trackball speed as Slow, Normal or Fast. Slower speed allows more precise measurement

[Figure 3-18] Setting-General

3.9.2 Peripherals Setup

Select the **Peripherals** tab in the *Setting* screen. You can configure keys, buttons and the peripheral devices connected to the product.

3.9.2.1 Peripherals

1) VCR Model

Select the type of VCR Model from Panasonic MD835 or Sony SVO 9500MD.

You should reboot the system before you can use the configured VCR.

2) COM

Configure a device to connect to a serial port. Available devices are VCR and Open Line Transfer. If you select **Reserve**, the COM port will not be used

3) Printer

Configure a printer to use. After connecting a printer to the USB port or parallel port of the system, select the printer type on the screen and click **Ok**. The printer can then be used immediately. Press the printer-shaped button to view the printer settings.

[Figure 3-19] Setting-Peripherals

NOTE The printing format for a report is optimized to Portrait. When printing a report, please set the page format to Portrait.

3.9.2.2 Key Setup

1) Set / Exit Key Switch

If this checkbox is checked, the roles of the **Exit** button and the **Set** button on the control are reversed. Therefore, the **Exit** button does what the **Set** button does and vice versa.

2) Printer2 Key

Configure the **Print 2** button on the control panel. You can set it to either Local Printing or Record.

3) Local Printing Area

Configure the local printing area. The following two options are provided.

- Full Screen (1280*1024): The entire screen is printed.
- Video Out (1024*768): Only the image area is printed.

3.9.2.3 Foot Switch

Specify the left/right pedal of the foot switch to Freeze, Update, Record, Print, Store, or Volume Start.

NOTE The left and right pedals cannot be configured to provide the same function

3.9.3 System Information

Select the **Information** tab in the *Setting* screen. Information about the system S/W version will be displayed.

Press **Detail** to view more detailed information on the product version

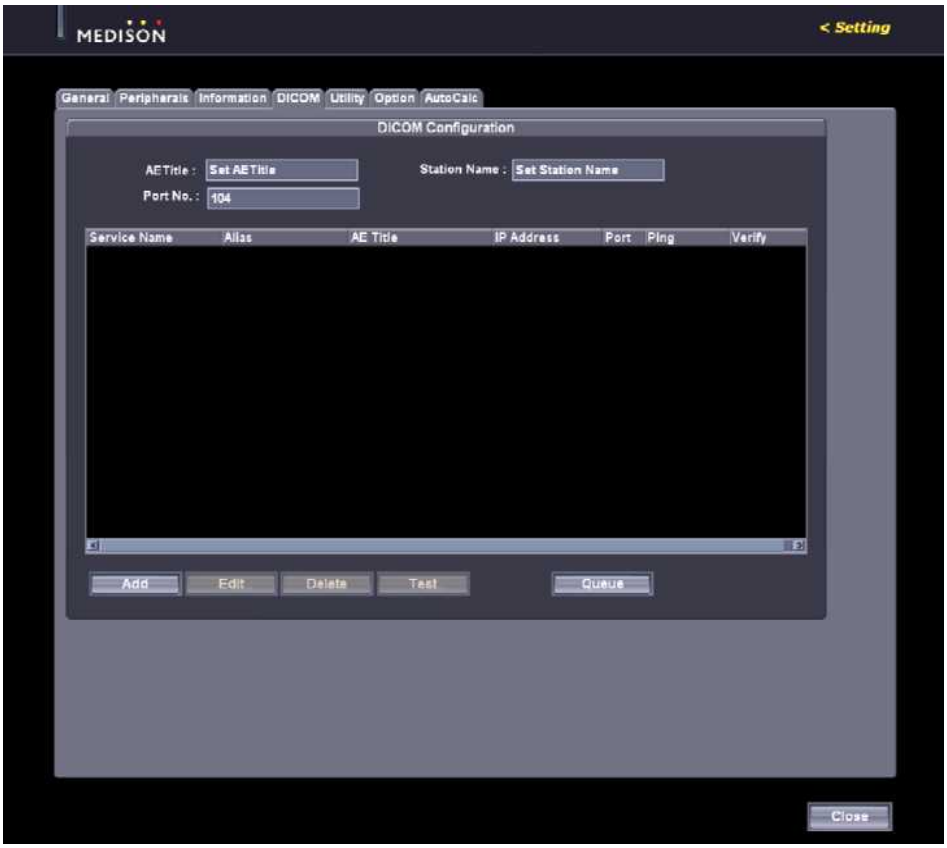
[Figure 3-20] Setting-Information

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

3.9.4 DICOM Setup (Option)

Select the **DICOM** tab in the *Setting* screen. You can configure the DICOM (Digital Imaging and Communication in Medicine) operation and the DICOM server.

NOTE For more information, please refer to the user manual for the server equipment or the DICOM Conformance Statement.



[Figure 3-21] Setting-DICOM

3.9.4.1 DICOM Configuration

The information on the DICOM server used by the system is displayed.

You can change the information, or add or delete a server. The server information is used to identify DICOM for the system in a network. It is also used to transfer data between other DICOM servers.

NOTE Please consult your network administrator to set **IP Address**, **AE Title** and **Port No.**

1) AE Title

Enter the name of the DICOM AE (Application Entity). The title is used to identify devices that use DICOM in a network. (E.g. US1, US2, etc.)

2) Station Name

Enter the name of the system. Along with **AE Title**, it is often used to identify the system in the DICOM network. (E.g. X81, X82, etc.)

3) Port No.

Enter the port number of the server being used.

3.9.4.2 Adding DICOM Service

Press **Add** on the screen. The system is switched to a screen where you can enter a DICOM service to add. After adding a service, press **Save** to save the information. Press **Cancel** to cancel

1) Services

Select the type of service to use via DICOM. The supported DICOM servers are Storage, Print, Worklist, Modality PPS, SC and Storage SR.

2) Alias

Enter the name of the DICOM server.

3) AE Title

Enter the AE title of the DICOM server. Consult your network administrator before specifying this option.

4) Transfer Mode

Select a transfer method:

- Batch: Send all saved images when you click the **End Exam** button.
- Send As You Go: Send an image whenever you press the **Save** button to save it.
- Manual: Send the specified image in Exam List or SonoView

5) Connect Timeout

Specify how long the system will wait until it receives a response from the DICOM server. You can specify it in seconds.

6) IP Address

Enter the IP address of the server being used. Consult your network administrator before specifying this option.

7) Port

Enter the port number of the server being used. Consult your network administrator before specifying this option

8) Retry Interval

Specify how long the system will wait before it retries when transmission fails. You can specify it in seconds.

9) Maximum Retries

Specify how many times the system will retry when transmission fails.

3.9.4.2.1 Storage Server Information

Select **STORAGE** under **Services**. Configure the Image Storage Service using DICOM.

[Figure 3-22] DICOM Configuration-Storage

1) VOI LUT Setup

Configure VOI LUT (Value Of Interest Look Up Table). Adjust the brightness and contrast of a DICOM image when saving it. The saved image can be viewed with any PACS device that has DICOM VOI LUT implemented.

- Window Centre: Enter a value for the DICOM Tag (0028, 1050) setting. The

setting value indicates the brightness of an image that is displayed by the Storage service. Relative to 128, a higher value results in a darker image. Note that this function can be used only when it is supported by the Storage service.

- Window Width: Enter a value for the DICOM Tag (0028, 1051) setting. The setting value indicates the brightness of an image that is displayed by the Storage service. Relative to 256, higher values result in lower contrast. Note that this function is available only when it is supported by the Storage service.

2) Include 3D Volume

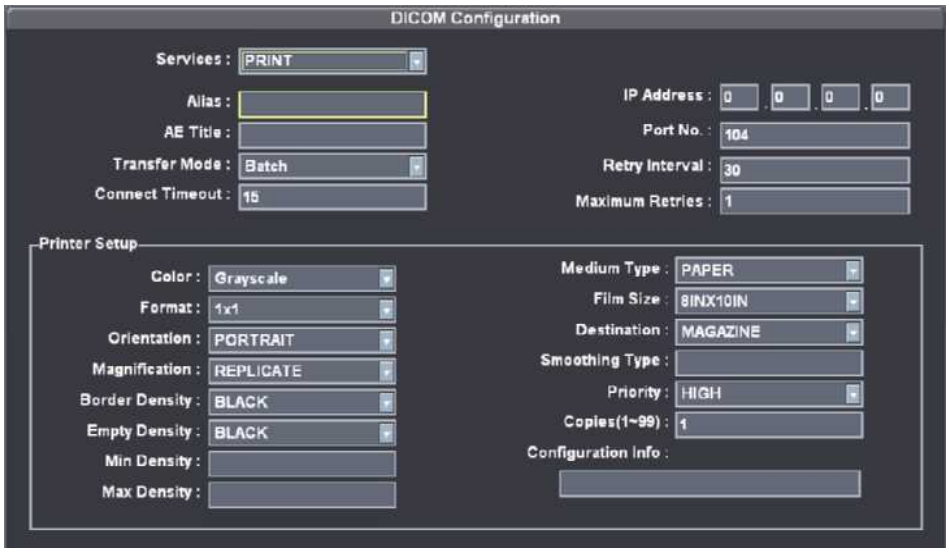
When selected, the 3D volume data is transferred when a 3D image is saved. You should select this option only when the Storage service supports MEDISON 3D volume data.

3.9.4.2.2 Print Server Information

Select **PRINT** under **Services**. Configure the Print Service using DICOM

NOTE

- You can configure a printer connected to the DICOM network only.
- Depending on the printer, some of the following functions may not be available. Before configuring a printer service, please refer to the user manual for the printer or the DICOM Conformance Statement.



[Figure 3-23] DICOM Configuration-Storage

1) Color

Specify whether to use colors. Select **Grayscale** or **RGB**.

2) Format

Specify the paper layout. Select from 1 x 1, 1 x 2, 2 x 2, 2 x 3, 3 x 3, 3 x 4, 3 x 5, 4 x 4, 4 x 5 and 4 x 6.

3) Orientation

Specify the paper orientation. Select Landscape or Portrait.

4) Magnification

When resizing an image to print, specify the interpolation. Select from Replicate, Bilinear, Cubic and None.

5) Border Density

Specify the border density of an image to print. Select Black or White.

6) Empty Density

Specify the background color of an image to print. Select Black or White.

7) Min Density

Specify the minimum brightness of an image to print. If this option is not specified, the default value is applied.

8) Max Density

Specify the maximum brightness of an image to print. If this option is not specified, the default value is applied.

9) Medium Type

Specify the paper type. Select from Paper, Clear Film, Blue Film, Mammo Clear Film and Mammo Blue Film.

10) Film Size

Specify the paper size. Select from 8 inch x 10 inch, 5 inch x 11 inch, 10 inch x 12 inch, 10 inch x 14 inch, 11 inch x 14 inch, 11 inch x 17 inch, 14 inch x 14 inch, 14 inch x 17 inch, 24cm x 24cm, 24cm x 30cm, A4 and A3.

11) Destination

Specify the paper pathway. Select Magazine or Processor.

12) Smoothing Type

This option is available only when **Magnification** is set to **CUBIC**. Enter a value specified in the DICOM Conformance Statement for the printer.

13) Priority

Specify a priority for the print command. Select from High, Med and Low.

14) Copies

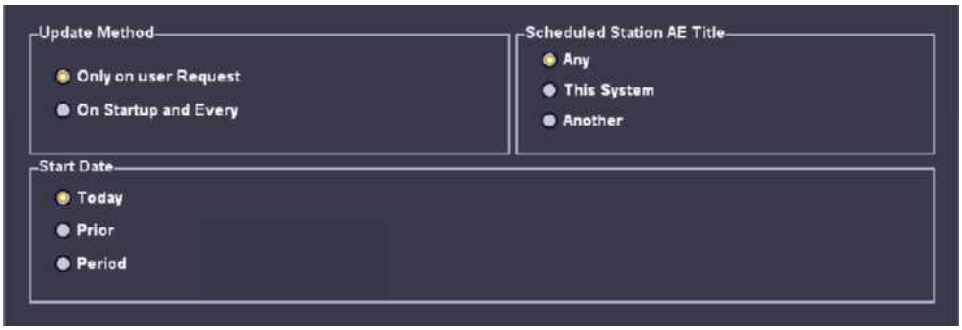
Enter the number of copies between 1 and 99.

15) Configuration Info

Specify the unique value for a printer. Please refer to the DICOM Conformance Statement for the printer.

3.9.4.2.3 Worklist Server Information

Select **WORKLIST** under **Services**. Configure the Modality Worklist Service using DICOM.



[그림 3-24] DICOM Configuration-Worklist

1) Update Method

Specify the update method for Worklist.

- Only on user Request: Update only when asked by the user.

> ※ TIP!
>
> To update a worklist, in the **Search** tab on the *Patient Information* screen, select **Worklist** for Search Source and press **Search**.

- On Startup and Every : Update automatically at a specified interval after the system boots and Worklist is updated.

2) Scheduled Station AE Title

Specify the range of AE Title to retrieve from the Worklist server in a hospital.

- Any: Retrieve the patient list stored in all AE Titles in the server.
- This System: Retrieve the patient list specified under the DICOM tab.
- Another: Retrieve the patient list stored in the AE Title specified by the user.

NOTE This option is available only when the Worklist server is enabled.

3) Start Date

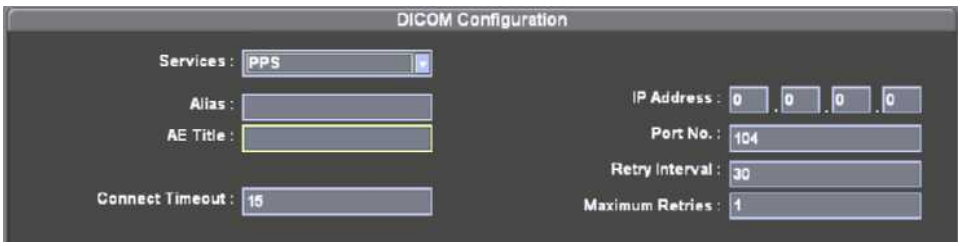
Specify the range of dates to search.

- Today: Retrieve the patient list for the current date.
- Prior_days, Next_days: Retrieve the patient list for n days before and n days after the current date.
- Period: Retrieve the patient list for the period specified by the user.

3.9.4.2.4 PPS Server Information

Select **PPS** (Performed Procedure Step) under **Services**. Configure the Modality Performed Procedure Step Service using DICOM.

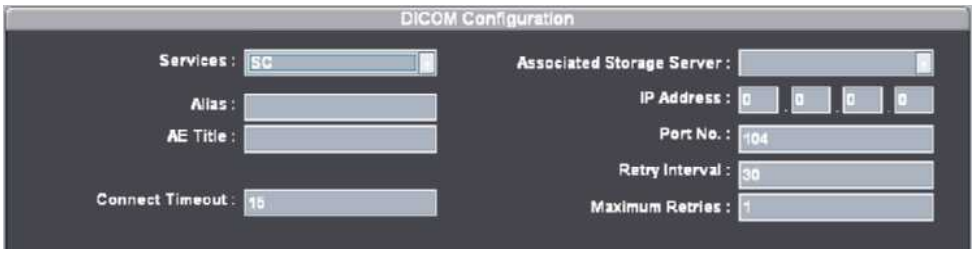
It can be configured in the same way as for the Storage server.



[Figure 3-25] DICOM Configuration-PPS

3.9.4.2.5 SC Server Information

Select **SC** (Storage Commitment) under **Services**. Configure the Storage Commitment Service using DICOM. The Storage Commitment Service is used after a diagnosis is finished and all saved images and reports are transferred.



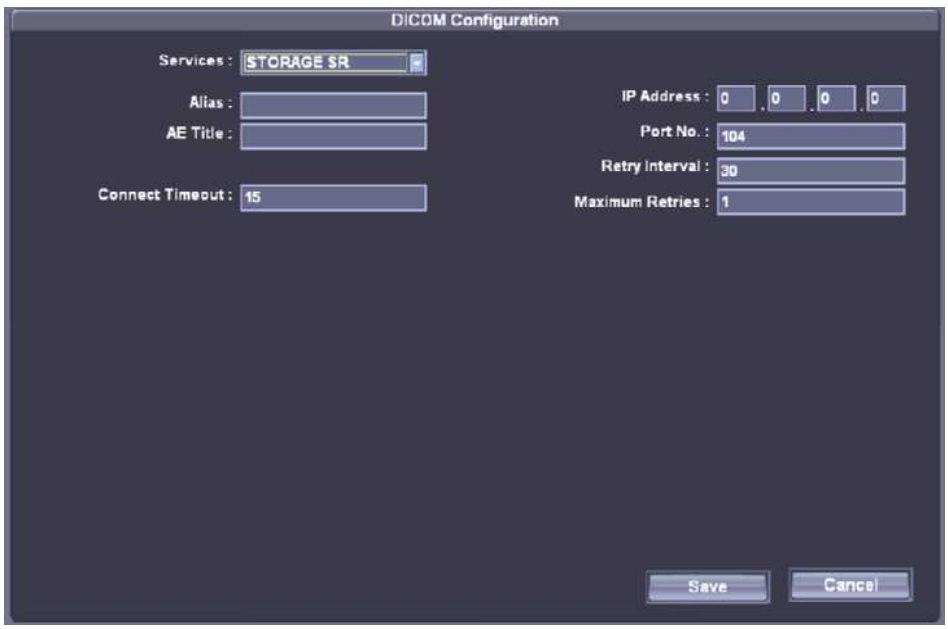
[Figure 3-26] DICOM Configuration-Storage

1) Associated Storage Server

- Select an image storage server to connect.

3.9.4.2.6 Storage SR Server Information

Select **Storage SR** (Storage Structured Report) under **Services**. Configure the Report Storage Service using DICOM.



[Figure 3-27] DICOM Configuration-Storage SR

3.9.4.3 Changing DICOM Information

Select a service and press **Edit** on the screen. The information on the selected service will appear.

After changing the information, press **Save** to save the changes. Press **Cancel** to cancel.

3.9.4.4 Deleting DICOM Service

Select a service and press **Delete** on the screen. A message appears asking whether to delete it. Press **Ok** to delete the selected service. Press **Cancel** to cancel

3.9.4.5 Testing DICOM Server

Select a service and press **Test** on the screen. The connection with the selected service is tested and the results are shown under the **Ping** and **Verify** items. If the result is Normal, it indicates that the connection is normal.

3.9.4.6 Managing DICOM

Press **Queue** on the screen and then the system will switch to the **DICOM Job Status** screen. In this screen, you can manage service operations and the history of services performed.

The DICOM Manager provides two major functions: a Job Monitor that allows you to check the operation of the DICOM Service, and a Log Manager that allows you to manage the history of services performed.

3.9.4.6.1Job Monitor

Press the **Job Monitor** tab.

A job indicates a patient diagnosis. Therefore, under the **Job Monitor** tab, you can view and manage diagnoses performed or in progress using the product and the relevant DICOM services.

Job shows the status of the current exam. If you select a list of patients, all related DICOM services and their operation status are shown under **Service**.

[Figure 3-28] Job Monitor

1) Delete Job

Under **Job**, select a list of patients and press **Delete Job**. Note that patients can be deleted only when an exam is finished and its **Status** is set to COMPLETED or FAILED.

2) Restart Job

Under **Job**, select a list of patients and press **Restart Job**. The DICOM service will be restarted for the selected list of patients. Note that it can be restarted only when the DICOM service has failed and its **Status** is set to FAILED.

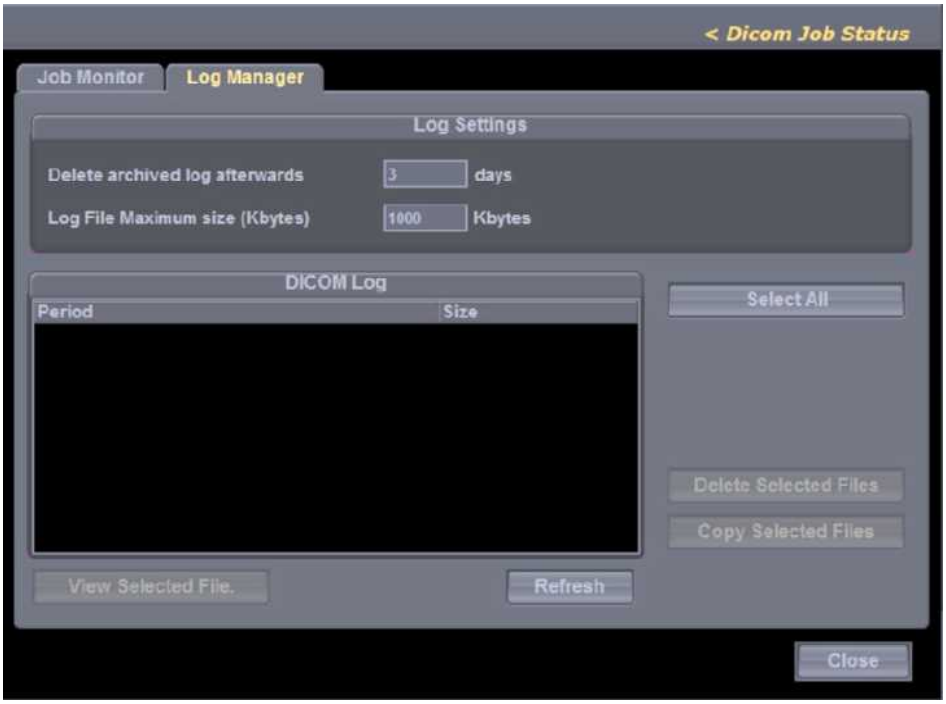
3) Restart Service

Under **Service**, select a service and press **Restart Service**. The selected DICOM service will be restarted. Note that it can be restarted only when the DICOM service has failed and its **Status** is set to FAILED.

3.9.4.6.2 Log Manager

Press the **Log Manager** tab.

A log indicates the DICOM history and is saved in a file. Under the Log Manager tab, you can manage the history of all the DICOM services performed using the product.



[Figure 3-29] Log Manager

1) Specify Log File Management Method

Under **Log Settings**, you can specify how log files are managed.

- Delete archived log file after: Specify how long a log file will be archived. Enter a number in days. If the specified time has elapsed after the log file was created, the file is deleted from the system.
- Log File Maximum Size: Specify the maximum size of a log file that can be archived. Enter a number in Kb. A log file that is larger than the specified size is not archived on the system and deleted immediately.

2) Manage Log File

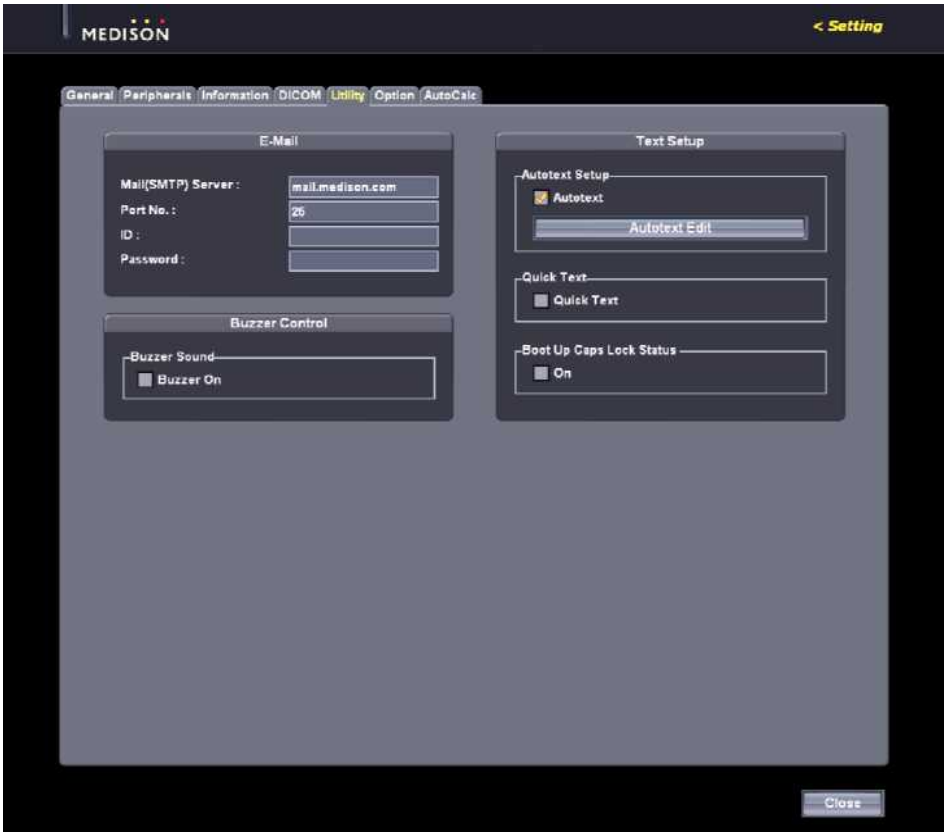
DICOM Log shows information on log files.

- Select All: Select all log files.
- Delete Selected Files: Delete the selected log file.
- Copy Selected Files: Copy the selected log file to an external storage media.
- View Selected File: Display the details of the selected log file on the screen.

Refresh: Update the information of a log file.

3.9.5 Utilities Setup

Select the **Utility** tab in the *Setting* screen. You can configure settings for e-mail, text and network status.



[Figure 3-30] Utility

3.9.5.1 E-Mail

You can specify a server through which you will send and receive e-mails.

1) Mail (SMTP) Server

Specify the e-mail server.

2) Port No.

Enter a port number.

3) ID

Enter an ID for the e-mail server.

4) Password

Enter a password for the e-mail server.

3.9.5.2 Text Setup

1) Autotext Setup

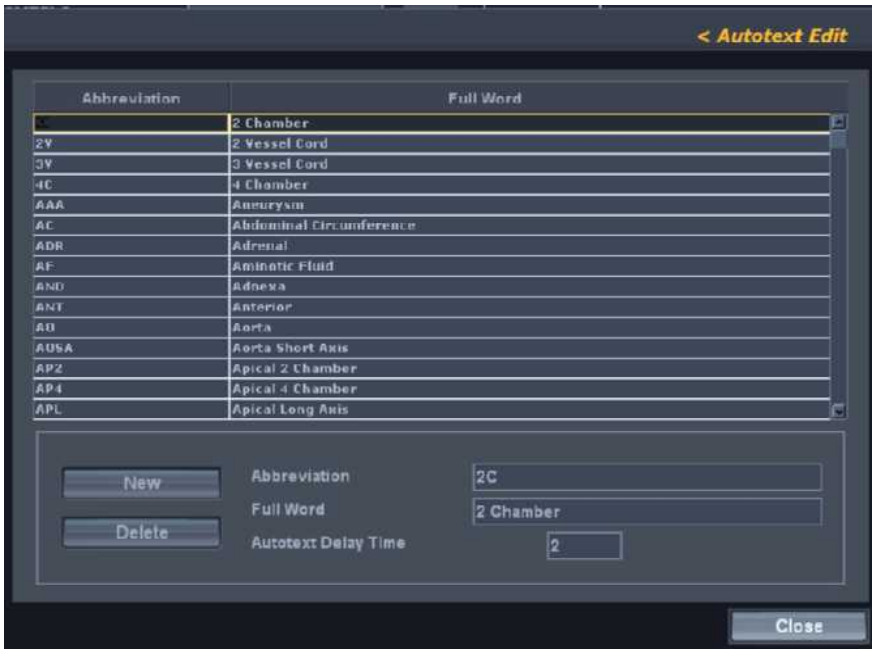
If an abbreviation is entered, the system retrieves and enters a full word automatically. When this option is selected, you can enter text more easily and quickly.

For example, to enter the text 'Abdominal Circumference', you only need to enter 'AC' and the system will search the full word from the abbreviation list and automatically enter it.

To enable Autotext, check the **Autotext** checkbox with the **Trackball**. Otherwise, uncheck the checkbox.

If this option is selected, the abbreviation list appears on the screen when text is entered.

The system has a built-in abbreviation list for this function. You can add a new abbreviation or edit the existing abbreviation as desired.



[Figure 3-31] Autotext Edit

※ Editing Abbreviation List

To enable the abbreviation list stored in the system, press the **Autotext Edit** button. The system will switch to the **Autotext Edit** screen.

To save the changes and finish editing, press the **Close** button.

1) Modify Word

- Use the **Trackball** and the **Set** button to select a word to modify in the list. An abbreviation for the selected word and its full word are displayed under the **Abbreviation** and **Full Word** fields at the bottom of the screen.
- Modify words in the **Abbreviation** and **Full Word** fields. The abbreviation list is updated in real time.

2) Add Word

- Press the **New** button.
- Enter words to add in the **Abbreviation** and **Full Word** fields at the bottom of the screen. The entered words are added to the abbreviation list.

3) Delete Word

- Use the **Trackball** and the **Set** button to select a word to delete from the list. An abbreviation for the selected word and its full word are displayed under **Abbreviation** and **Full Word** at the bottom of the screen.
- Press the **Delete** button, and the following warning message will appear.
- To delete the selected word, press **Ok.** The selected word will be deleted from the abbreviation list. Press **Cancel** to cancel.

4) Specify Word Input Delays

- Specify the time taken by the system to convert an abbreviation to a full word and enter it. In the **Autotext Delay Time** field at the bottom of the screen, enter the input delay time in seconds.

[Figure 3-32] Warning

5) Quick Text

If the checkbox is selected, the Quick Text function is enabled. Quick Text switches the system to the text input mode immediately after a character key in the Alphanumeric Keyboard is pressed.

NOTE You can still enter text if this option is not enabled. If this is the case, press the F2 key in the Alphanumeric Keyboard to switch to the text mode.

6) Boot up Caps Lock Status

If this checkbox is checked, Boot up Caps Lock Status is turned on. When text is entered, it is entered in capital letters.

3.9.5.3 Buzzer Control

Generate a buzzer sound when a button or dial-button is used.

1) Buzzer Sound

If **Buzzer On** is selected, the buzzer sound is turned on. A buzzer sound is generated whenever a button or dial-button is used.

3.9.6 Option Setup

Select the **Option** tab in the *Setting* screen. You can enable or disable optional software and hardware.

[Figure 3-33] Options

3.9.6.1 Option

The list of optional software is displayed on the screen.

Options: Shows the types of optional software that can be installed on the product. The following table shows the list of optional software that is available with SONOACE X8 :

3D	Dynamic MR™
3D XI™	DICOM
CW Function	DICOM SR
Cardiac Measurement	Spatial Compound

Status: Shows the current status of optional software.

Lock_Not Installed: No hardware is connected.

Lock_Unregistered: The software is not registered.

Lock_Installed: Hardware is installed but not registered.

Unlock_Permanent: Ready for use without any time limitation.

Unlock_Restricted: Ready for use for a certain period.

NOTE To purchase optional software, please contact the distributor for the software.

3.9.6.2 HW Configuration

The list of optional hardware is displayed on the screen. Currently, only ECG is supported.

Check the checkbox for hardware that will be used. Reboot the system to finish settings.

4 Checking the Product

4.1 Overview

Chapter 4 describes how to check SONOACE X8 and how to check if its major functions and the power supply are working properly.

Contents Checking the Product

4.2 Power On/Boot up

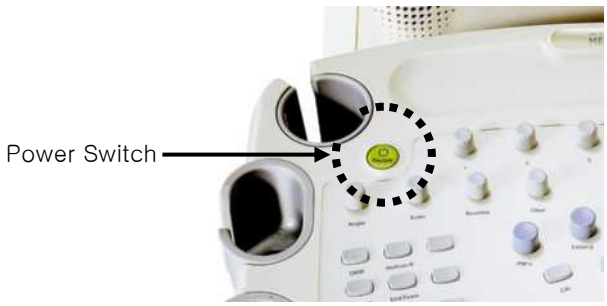
Check if the SONOACE X8 power cord is properly connected and switch on the cut-off switch for the AC power.

To start SONOACE X8, press the ON/OFF switch at the right side of the control panel (keyboard).

CAUTION

Do not repeatedly operate the Cut-Off switch. It may cause damage to the product circuit board, and may cause a problem.

1) A "beep" sound is generated 3 times and you will be able to hear the fan start inside the product.
2) The booting sequence is displayed on the LCD monitor. As the Windows XP logo disappears, the SONOACE X8 logo and loading bar appear.
3) The loading bar fills with color. This represents data being copied to the system by the PC software.
4) When software data copying is complete, the ultrasound picture appears and the system becomes ready. The booting sequence of the product takes approximately 1 minute.

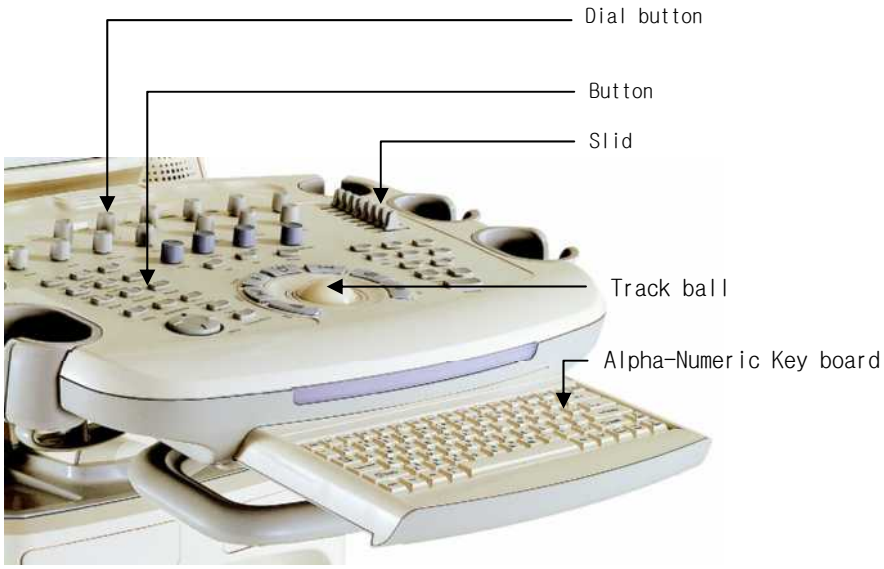


[Figure 4-1] Power Switch

4.3 Control Panel

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

1) Function keys for mode selection and scanning, located on the right side of the control panel.
2) Function keys for annotation and measurements, located around the Trackball.
3) Menu selection buttons, located on the left side of the control panel.
4) An alpha-numeric keyboard, located under the control panel.



[Figure 4-2] Control Panel

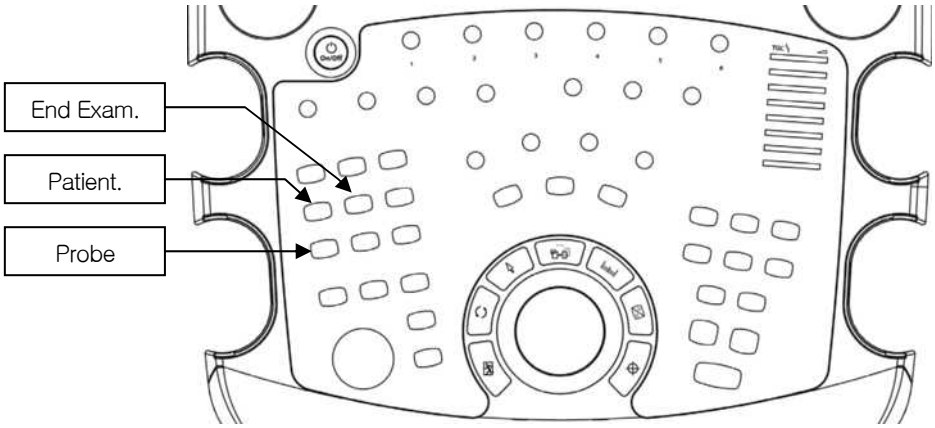
[Figure 4-3] Detail Control Panel

4.3.1 Detail Control Panel

The following are descriptions and instructions for the controls on the control panel. For more information on the buttons with multiple functions, see Chapter 3 and later of this Operation manual.

1) Power On/Off
Powers the product On/Off.

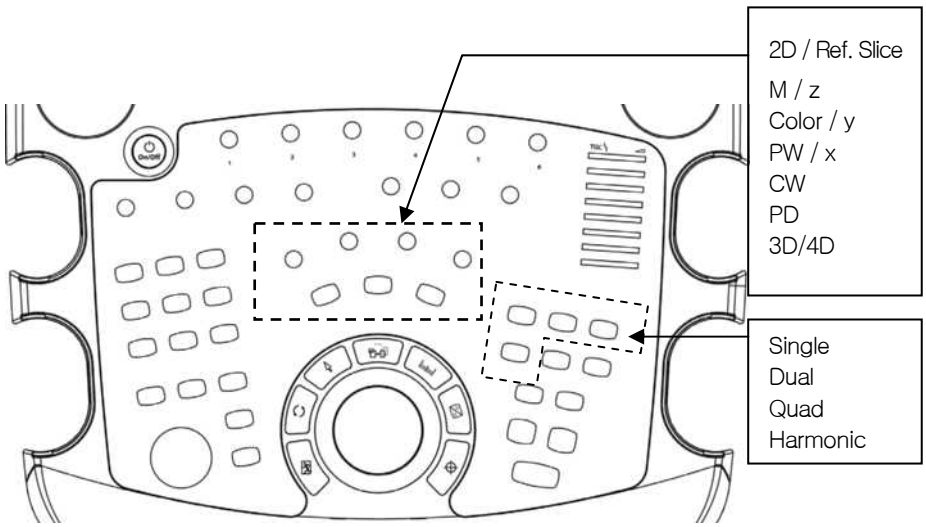
2) Starting and Finishing Exam



[Figure 4-4] Starting and Finishing Exam

End Exam.	This is used to appear the Probe Selection window to select /change probes and applications.
Patient	This is used to appear the Patient Information window for patient selection and information entry.
Probe	This is used to finish the exam of the currently selected patient and reset the related data.

3) Selecting Diagnosis mode and Gain Control

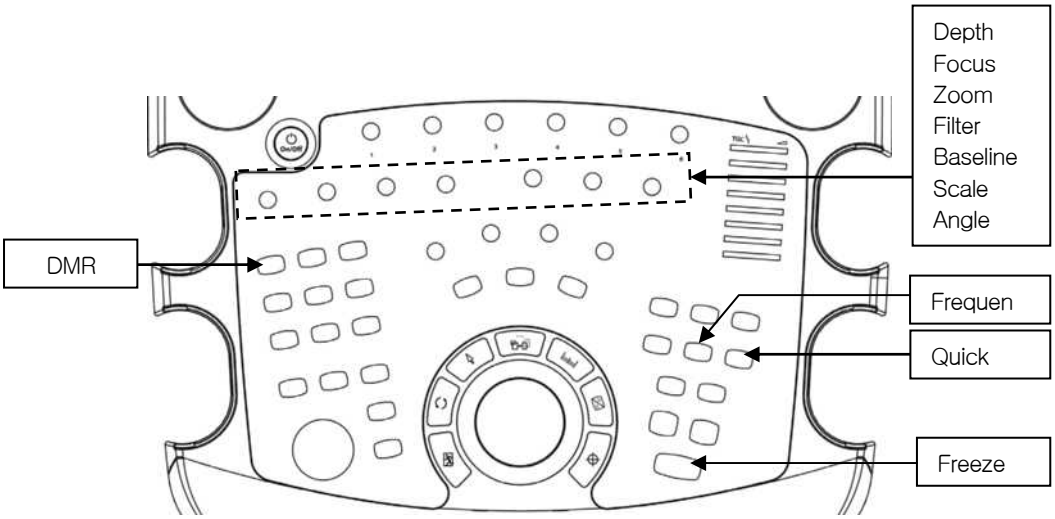


[Figure 4-5] Selecting Diagnosis mode and Gain Control

2D/Ref. Slice	Pressing this dial-button while in other single image modes will return the system to 2D Mode from other image modes. However, pressing this again while in 2D mode does not turn it off. Pressing this button while in combine modes will return the system to single image modes. Turning this dial-button again when in 2D mode adjusts the 2D Gain. Also, turning this dial-button when in 3D View adjust the reference slice of the image.
M / z	Press this dial-button to turn M Mode on / off. Turning this dial-button adjusts the M Gain. Also, turning this dial-button when in 3D View rotates the image along the Z-axis.
Color / y	Press this dial-button to turn Color Doppler Mode on / off. Turning this dial-button when in Color Doppler mode adjusts the Color Doppler Gain. Also, turning this dial-button when in Power Doppler mode adjusts the Power Doppler Gain. Turning this dial-button when in 3D View rotates the image along the Y-axis.

PW / x	Press this dial-button to turn PW Spectral Doppler Mode on / off. Turning this dial-button adjusts the Spectral Doppler Gain. Also, turning this dial-button when in 3D View rotates the image along the X-axis.
CW	Press this button to turn CW Spectral Doppler Mode on / off. This mode can only be activated when using the Phased Array Probes or Static CW Probes.
PD	Press this button to turn Power Doppler Mode on / off. Use [Color / y] dial-button to control power Doppler gain.
3D/4D	Press this button to turn 3D / 4D Mode on / off. This function is available under 2D mode.
Single	Press this button in Dual or Quad Mode to switch to Single Mode, in which only a single diagnosis mode is available.
Dual	Press this button to turn Dual Mode on.
Quad	Press this button to turn Quad Mode on.
Harmonic	Press this button to turn Harmonic Imaging on / off.

4) Image Adjustment

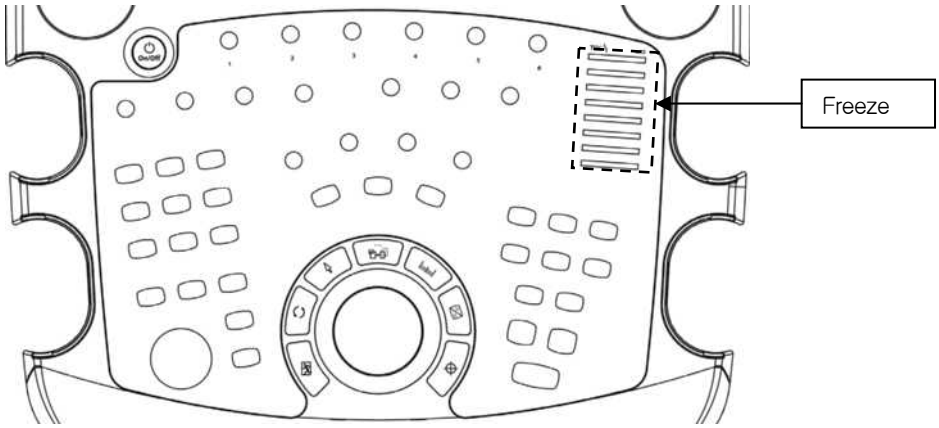


[Figure 4-6] Image ADujustment

Freeze	Press this button to stop/start scanning.
Dynamic MR™ (Optional)	Press this button to turn Dynamic MR™ mode on / off. The 'DMR' mark is displayed on the top of the image. Dynamic MR™ is not available in 3D mode and CW probe.
Quick Scan	Press this button to turn Quick Scan function on. The 'Q' mark is displayed on the top of the image. This button is activated for specific diagnostic applications with specific probes only. Press the Exit button to exit Quick Scan Mode.
Frequency	Press this button to change the frequency setting of the probe. This button is activated for multi-frequency probes. Whenever user press this button, the sign of 'Gen' (general), 'Res'(resolution), and 'Pen'(penetration) are displayed respectively on the title area.

Depth	This dial is used to adjust the scanning depth of an image. Turn this dial clockwise / counter clockwise to decrease / increase the scanning depth.
Focus	This dial is used to focus on the area of interest. Turn this dial clockwise / counter clockwise to rise / lower the focusing point.
Zoom	Press this button to turn Zoom mode on. To exit Zoom Mode, press the Exit button or adjust the scan depth with the Depth dial.
Filter	This is used to adjust Wall Filter values in Color Doppler Mode, Power Doppler Mode and Spectral Doppler Mode. Turn this dial clockwise / counter clockwise to increase / decrease the Wall Filter values.
Baseline	This is used to raise/lower the baseline in Color Doppler Mode, Power Doppler Mode and Spectral Doppler Mode. Turn this dial clockwise / counter clockwise to rise / lower the baseline.
Scale	This is used to adjust the speed of blood flow (or frequency) range in Color Doppler Mode, Power Doppler Mode and Spectral Doppler Mode. Turn this dial clockwise / counter clockwise to expands / reduces the speed range (frequency).
Angle	This is used to adjust the angle of sample volume in Spectral Doppler Mode. It is also used to adjust the Indicator angle or the Body Marker Probe angle.

5) TGC (Time Gain Control)

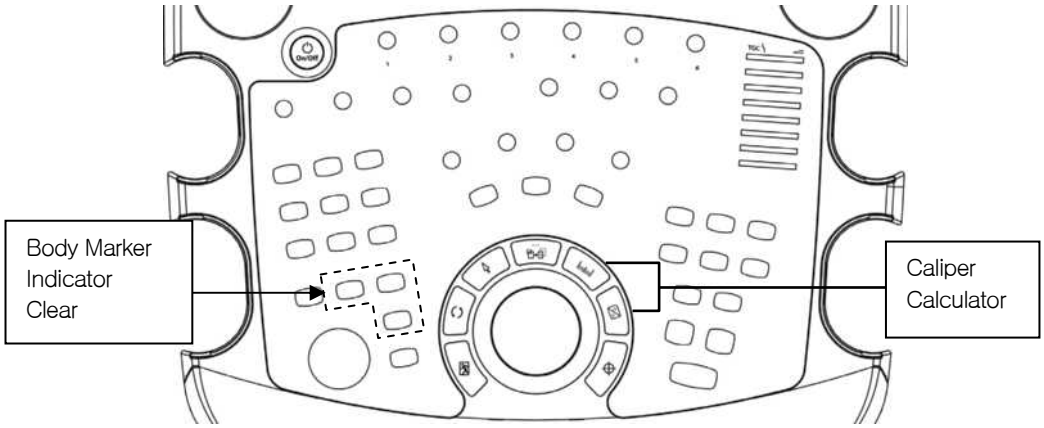


[Figure 4-7] TGC

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

CAUTION Too large a difference in the gain value settings of two adjacent slides may lead to inaccurate image generation.

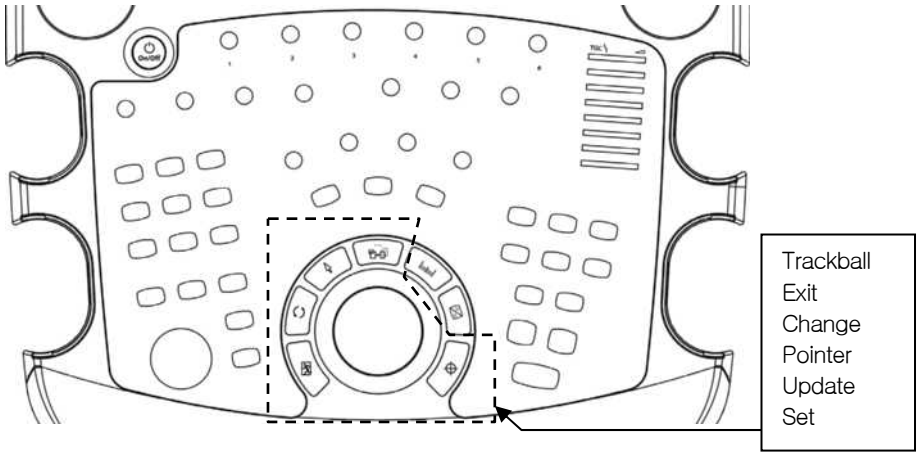
6) Measurement and Annotation



[Figure 4-8] Measurement and Annotation

Caliper	This button is used to measure distance, circumference, area, and volume. Press the button repeatedly to cycle through all the available measurement methods.
Calculator	A different measurement menu appears, depending on the examination subject and diagnosis mode. The examination subject changes each time the button is pressed.
Body Marker	When this is pressed, a Body Marker list appears. Select a specific Body Marker, and it appears on the selected display.
Indicator	When this is pressed, an arrow marker appears to point to the parts of the displayed image.
Clear	When this is pressed, the text, Indicator, Body Marker, and measurement data are erased from the displayed image.

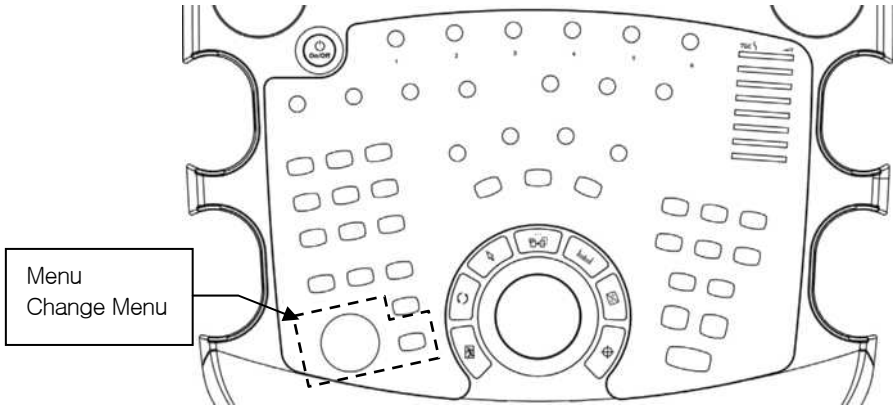
7) Trackball and its related control



[Figure 4-9] Trackball and its related control

Trackball	This is used to move the cursor on the display and to scroll through CINE images.
Exit	This is used to exit the current mode and return to initial settings.
Change	This is used to change the current Trackball function. For example, you can reset the position of the last point specified during measurement or change the position of the cursor during text input.
Pointer	In Scan mode, an arrow-shaped pointer appears on the screen. Press this button again to disappear pointer.
Update	When this is pressed in a diagnosis mode. Press this button in PW or CW Spectral Doppler Mode to enter D Only Mode.
Set	This is used in conjunction with the Trackball to set a specific item or value.

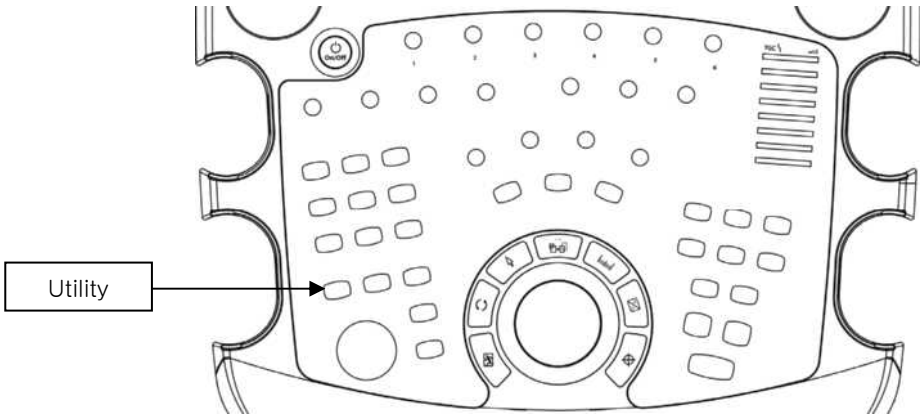
8) Menu



[Figure 4-10] Menu

Menu	Rotate the dial button to the right/left to move up/down a menu. Press the dial-button to execute the selected menu item.
Change Menu	Switch menus when using more than one menu. Each time the button is pressed, the menu is toggled.

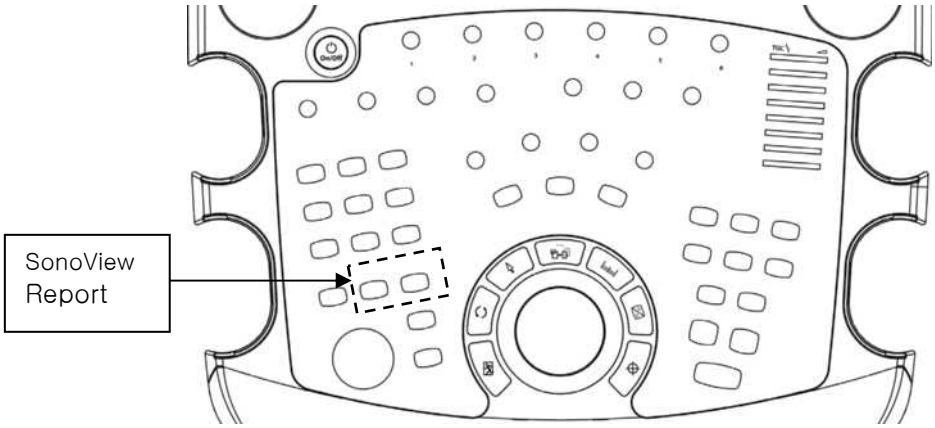
9) Utility



[Figure 4-11] Utility

Utility	This is used to appear the utility menu.

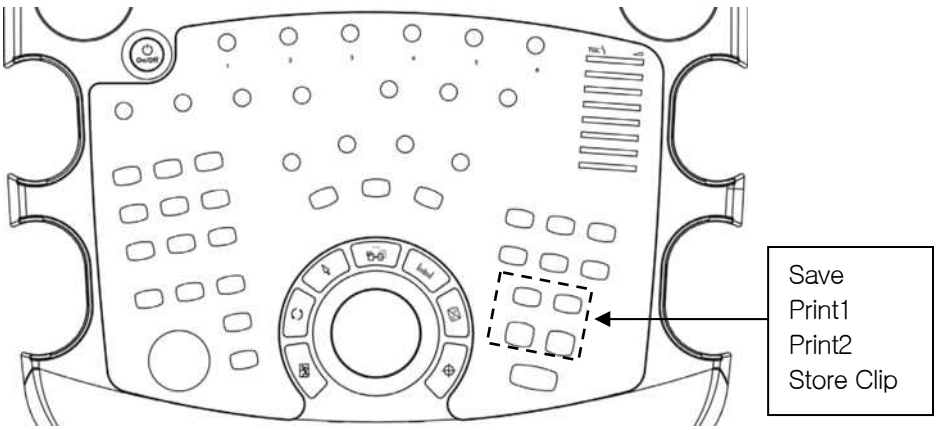
10) SonoView and Report



[Figure 4-12] SonoView and Report

SonoView	This is used to activate SonoView™, the Image Filing program.
Report	This is used to appear a report program containing measurement results from the current diagnosis mode.

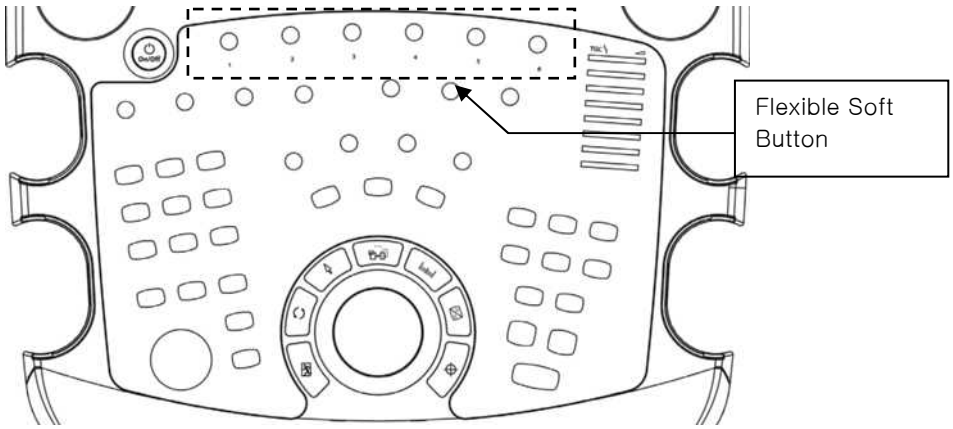
11) Save and Print



[Figure 4-13] Save and Print

Save	This is used to save a currently displayed image or measurement report in the system database.
Print1	This is used to print out the current image via an Echo printer.
Print2	Print the current image with the local printer connected. When this option is set to “Record” in Peripherals Setup, the current image is recorded with the specified VCR.
Store Clip	This is used to save CINE images. The user can manage the saved CINE images in the SonoView™ or in the scan mode.

12) Flexible Soft Button

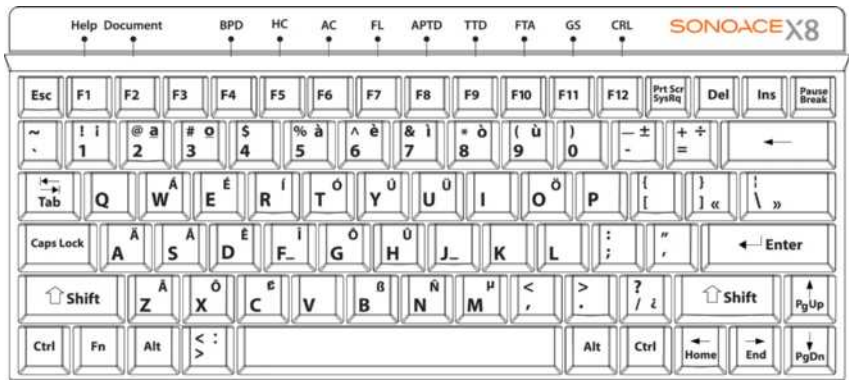


[Figure 4-14] Flexible Soft Button

Flexible Soft Button 1 ~6	Press or turn the dial-button to execute the respective Flexible soft menu indicated at the bottom of the screen, depending on the system settings.

13) Alpha-numeric Keyboard

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



[Figure 4-15] Alphanumeric keyboards

F1	This button is used to appears Help manual on the screen.
F2	This button is used to enter text on the displayed image. However, when the Quick Text checkbox under Setup is checked, you can enter text by using the Alphanumeric keyboards without pressing the button
F4~F12	This button Starts measurement for the corresponding obstetrics measurement item.
Space bar	This button is used to hide the image information on the screen. Pressing it again show the image information.

NOTE If you press [Restore] + [Alt] + [₩] key combination by using the keypad of the keyboard, a problem may occur in Alpha-numeric keyboard.

4.4 Checking the Performance

4.4.1 Basic Check

1) Monitor

Check the screen color, focus, dots, residual image, spot, blurring, etc.

Check the screen status when a shock is applied to the monitor and check t he signal when you shake the cable.

2) Keyboard Key Pad and LED Status

Press an alphanumeric key and check if the corresponding character is displayed on the screen.

Check if the Keyboard LED is turned on.

3) Body Mark Key

Check if the Body Mark [Body Mark Key] is properly displayed and if the key works properly.

4) Indicator Key

Check if the trackball works properly by moving it up, down, left and right.

5) Clear Key

Check if TEXT and measurement data is erased properly when this key is pressed.

6) Zoom Operation Examination

Check that the Zoom works properly.

7) SONO VIEW Examination

Save an IMAGE and CINE IMAGE in each mode.
Check if the images are properly saved.

Check if Backup & Restore works properly.

8) Measure

Check if DISTANCE, CALIPER, and CALC works properly.

9) Patient

Enter information in PATIENT and check if the entered contents appear in the report or Sono View.

10) End Exam

Measure for a New Patient and check if the measured data is cleared when End Exam is selected.

11) Probe Key

Check if it works properly when the probe is changed.

4.4.2 Detail Check

1) B Mode

① Check if there is any missing line in an image by doing a Knife Test.

② Check if the image is displayed properly through Phantom.

③ Check if Freeze Cine (Broken Image, Auto run, Auto run Speed and Track ball Cine) and its related functions work properly.

④ Check if there is an image brightness change when the Gain is adjusted.

⑤ Check if there is an image brightness change when the TGC Gain is adjusted.

⑥ Check if the image is flipped horizontally or vertically and left or right when the Left/Right Flip, Up/Down Direction and Rotation keys are pressed.

⑦ Check if the image select menus (EE, DR, View Area, Tissue, Frame Rate) work properly.

⑧ Check if the frequency (Phantom, Res, Pen, Gen) is normal.

⑨ Check if the image changes according to Depth change.

⑩ Check if the image changes according to Depth change when the focus is changed.

⑪ Check if the image compensation modes (FSI, Harmonic, DMR, SRF, Quick Scan, Spatial Compound Imaging) work properly.

2) Dual Mode

① Check if the image is displayed properly through Phantom.

② Check if the image is flipped horizontally or vertically and left or right when the Left/Right Flip, Up/Down Direction and Rotation keys are pressed.

③ Check if the image select menus (EE, DR, View Area, Tissue, Frame Rate, Sane angle, Power) work properly.

④ Check if the frequency (Phantom, Res, Pen, Gen) is normal.

⑤ Check if the image changes according to Depth change.

⑥ Check if the image changes according to Depth change when the focus is changed.

⑦ Check if the left or right image Cine (number of pages, Auto run, Auto run Speed and Track ball Cine) and its related functions work properly.

3) M Mode

① Check if the image is displayed properly through Phantom.

② Check if the information on M Line is displayed in the Image area.

③ Check if there is an image brightness change when the GAIN is adjusted.

④ Check if the image select menus (EE, DR, View Area, Tissue, Frame Rate, Sane angle, Power) work properly.

⑤ Check if image changes according to Depth change.

⑥ Check if image changes according to Depth change when focus is changed.

⑦ Check if the speed change and information is correct according to the SPEED conversion step.

⑧ Check if an image is reversed when Negative operates.

⑨ Check if the Top Down Format and Side by Side Format Image Image are correct when Loop Format is selected.

⑩ Check if there is a size change in the DISP.FORMAT B-MODE and M LINE area.

⑪ Check if the Freeze Cine (Broken Image, Auto run, Auto run Speed and Track ball Cine) and its related functions work properly.

4) C Mode & PD Mode

① Check if image is displayed properly through Phantom.

② Check if the image select menus (Balance, Sensitivity, Color Mode, Display) work properly.

③ Check if image changes according to Depth change.

④ Check if the Freeze Cine (Broken Image, Auto run, Auto run Speed and Track ball Cine) and its related functions work properly.

⑤ Check if there is image brightness change when the Color Gain is adjusted.

⑥ Check if an image is broken or if there is noise (B or C Mode Noise) when ROI Box is moved.

⑦ Check if an image is broken or if there is noise (B or C Mode Noise) when ROI Box is resized.

⑧ Adjust the Scale up and down and check if the frequency is converted and blood flow speed range is controlled. (Check with directly scan)

⑨ Operate the filter and check if small signals are removed by step.

⑩ Check if the Color Bar is reserved when the Invert key is pressed.

⑪ Move the Baseline up and down and check if the blood flow range moves to + or – part.

5) D Mode

① Check if image is displayed properly through Phantom.

② Check if the Doppler PRF value changes as the Simultaneous is turned on or off.

③ Check if the Doppler spectrum works properly.

④ Change the Scale and check the speed range change.

⑤ Move the Baseline up and down and check if the blood flow range moves to + or – part.

⑥ Operate the filter and check if small signals in the spectrum are removed.

⑦ Operate the Invert and check if the Doppler waveform is reversed.

⑧ Operate the Angle.

⑨ Move the SV or Size and check if it works properly.

⑩ Change the Spectrum Type and check if the spectrum video changes.

⑪ Check if Sound Volume works properly.

⑫ Check if the line when appears when Auto Calc runs is continuous and if the subsequent calculations are automatically done correctly.

⑬ Check if the Top Down Format and Side by Side Format Image are correct when LOOP FORMAT is selected.

⑭ Check if the CINE/LOOP (Broken Image, Auto run, Auto run Speed and Track ball Cine) and its related functions work properly.

6) 3D Mode

① Check if the loading is normal when Free Hand 3D Scan runs and it is skipped by Freeze, check if the image is fragmented and if there is any noise during the operation.

② Check if the loading is normal when Static 3D Scan runs, check if the image is fragmented and if there is any noise during the operation.
Check if the probe and motor sounds are normal.

③ Check if the loading is normal when Live 3D Scan runs, check if the image is fragmented and if there is any noise during the operation.
Check if the probe and motor sounds are normal.

④ Check if the ROI 3D, ABC 3D, and Full images are normal.

⑤ Check if a 3D image changes according to the selected angle.

⑥ Check if the contrast of 3D images changes according to the selected value.

⑦ Check if images are displayed properly according to image size changes.

⑧ Check if the Display Format Image is normal. (ABC, Volume CT Image)

⑨ Select Step Angle, Rotation Angle, and Rot. Axis and check if Cine Loading is done according to the settings made during Cine operation. Check if images are properly displayed during the Cine operation.

5 Product Structure

5.1 Overview

Chapter 5 describes the internal structure and operation mechanism of SONOACE X8. This chapter must be read for the product maintenance and upgrade.

SONOACE X8 is Software DSC-applied ultrasound video analyzer.
It not only adopted 17 inch LCD monitor and provides high resolution ultrasound video, but also provides the premium grade system functions. To improve the processing speed, MEDISON Co., Ltd. developed new interface to connect a latest PC and the ultrasound system with its proprietary technology. The enhancement of processor speed makes the system operations faster and reduces diagnosis time.

SONOACE X8 can use up to 128 Element probes and adopted Digital Beamforming of TX 64 Channels. Ultrasound image is displayed on the LCD through the Front End Part and Back End Part (including PC Part).
The resolution of the LCD monitor is 1280 X 1024 pixels and various image formats are provided. The wide view angle of the LCD panel provides convenient work environment for diagnosis. In addition, the arm-type monitor controller enables users to control the monitor easily.

The DVD RW drive and USB port are placed on the front panel of the system for easier image backup and software service. Since this system supports various external storage devices such as USB MO, USB Flash Memory and external-type USB HDD, upgrade becomes more easier.

SONOACE X8 consists of the following major components.

1) Ultrasound System Part : PSA, BF Board, CW Board, BE Board, DC to DC Power Module

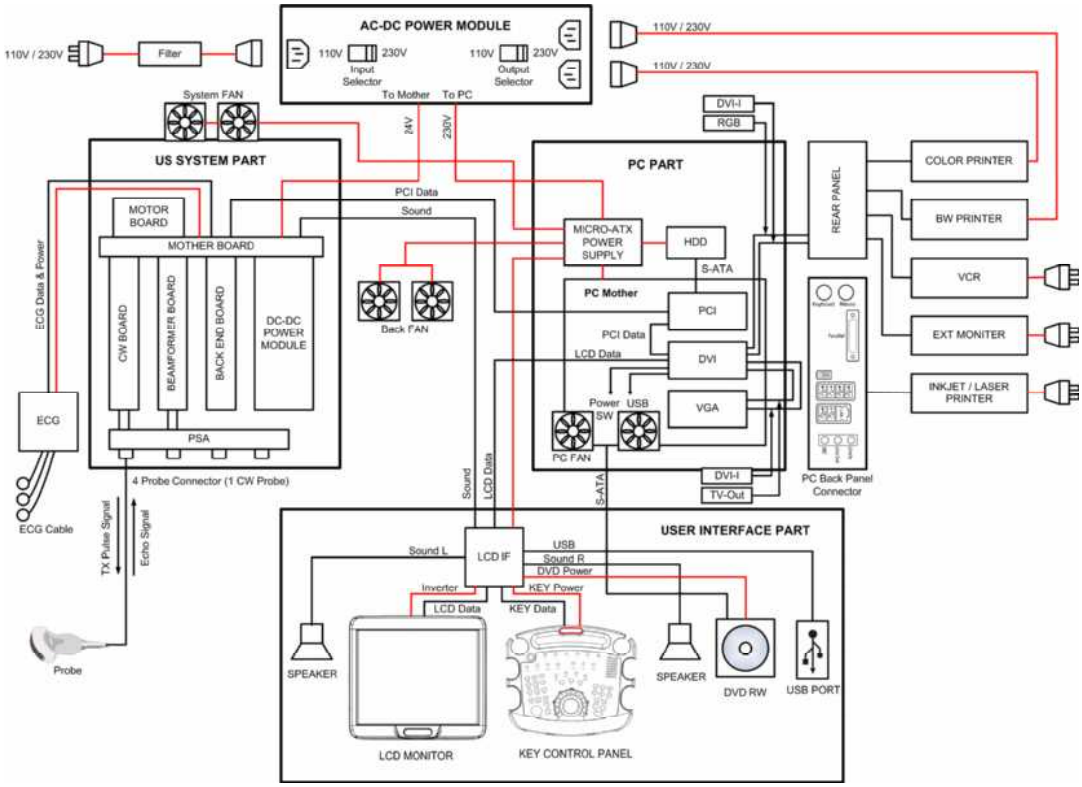
2) PC Part : PCI, DVI, VGA, PC Mother Board, Rear Panel, PC Power Supply

3) User Interface Part: LCD Monitor, Key Matrix Board, Key Interface Board, Track Ball, Alpha Numeric Key Board, LCD IF Board

4) AC to DC Power Module

Contents Product structure

5.2 System Block Diagram



[Figure 5-1] System Block Diagram

5.3 Basic Structure of SONOACE X8

5.3.1 Overview

SONOACE X8 consists of Ultrasound System Part, PC Part, User Interface Part and Power Part. However, it consists of Front End Part, Back End Part, User Interface Part, and Power Part from the electronical view point.

The following is the description of electronical structure of SONOACE X8.

Front End Part refers to the CW (Continuous Wave) Board, PSA (Probe Select Assembly), and BF (Beamformer) Board of the Ultrasound System Part. The Front End Part delivers High Voltage Pulser to the probe so that ultrasound is generated, amplifies the returned echo signal and processes Digital Beamforming. The RF signal generated here is delivered to the Back End Part.

Back End Part refers to the BE(Back End) Board and PC of the Ultrasound System Part. The RF signal generated in the BF(Beamformer) Board is processed to diagnosis image such as BW, Color Doppler, PW Doppler, CW Doppler, and Power Doppler and displayed on the monitor so that users can see it. In addition, new technologies such as SCI, DMR and AIO are applied to provide various diagnosis.

User Interface Part refers to the LCD monitor and control panel.

Power Part consists of AC-DC Power Module and DC-DC Power Module. AC-DC Power Module converts AC to DC voltage and supplies power to the DC-DC Power Module and the PC Power of the PC Part. The DC-DC Power Module supplies voltage to the boards of the Ultrasound System Part and the PC Power supplies voltage to the PC Part.

5.3.2 Ultrasound System Part

The major function implements the ultrasound data before the prior step of the Scan Converter.
It plays the roles of the Front End Part and Back End Part (including some).

It recognizes probes and delivers system and application information depending on the user environment to each board. Based on the information, TX Focusing and RX Focusing are done. When high-voltage Pulser is delivered to probe along through the TX Focusing, ultrasound is generated and the echo signal returned from human body is amplified by the amplifier circuit and then is processed by Digital Beamforming. The RF signal generated here is delivered to the PC Part to process it to provide diagnosis image such as BW, Color Doppler, PW Doppler, CW Doppler, and Power Doppler and display it on the monitor.

DC-DC Power module supplies power to the power of Ultrasound System Part.

Ultrasound System Part consists of the components.

- CW(Continuous Wave Board)
- PSA(Probe Select Assembly)
- BF(Beamformer Board)
- BE(Back End Board)
- DDM (DC to DC Power Module)

5.3.3 PC Part

PC Part consists of Scan Converter and video output circuit so that the ultrasound information generated by the Ultrasound System Part is displayed on the monitor. In addition, it provides interface with the control panel.

The ultrasound information output from the Ultrasound System Part is connected to the PC Part using the DMA mode of the PCI interface. The ultrasound image is implemented by software DSC and VGA.

While conventional ultrasound system used Hardware DSC, SONOACE X8 used software DSC and displayed ultrasound image on the LCD monitor.

PC Power Supply is Micro ATX and supplies power to the PC Part.

The PC Part consists of the following components.

- PCI(Peripheral Component Interconnect)
- DVI(Digital Video Interface)
- VGA(Video Graphics Array)
- PC Mother Board
- Rear Panel
- PC Power Supply

5.3.4 User Interface Part

User Interface Part enables users to view ultrasound image on the LCD monitor and control SONOACE X8 through the control panel.
The image output from the PC Part is transferred to the LCD monitor and external device. Image output interface includes VGA, S-VGA, Composite, and DVI. In addition, the control panel enables users to easily operate the system through various interfaces.

The User Interface Part consists of the following components.

- LCD Monitor
- Key Matrix Board
- Key Interface Board
- Track Ball
- Alpha Numeric Key Board
- LCD IF Board

5.3.5 AC to DC Power Module

It converts 110/220V AC voltage from external into DC voltage and supplies power to the DDM (DC to DC Power Module) of the Ultrasound System Part and supplies stable AC power to the PC Power Supply of the PC Part. It provides power cut-off switch and fuse to prevent problem due to over-voltage.

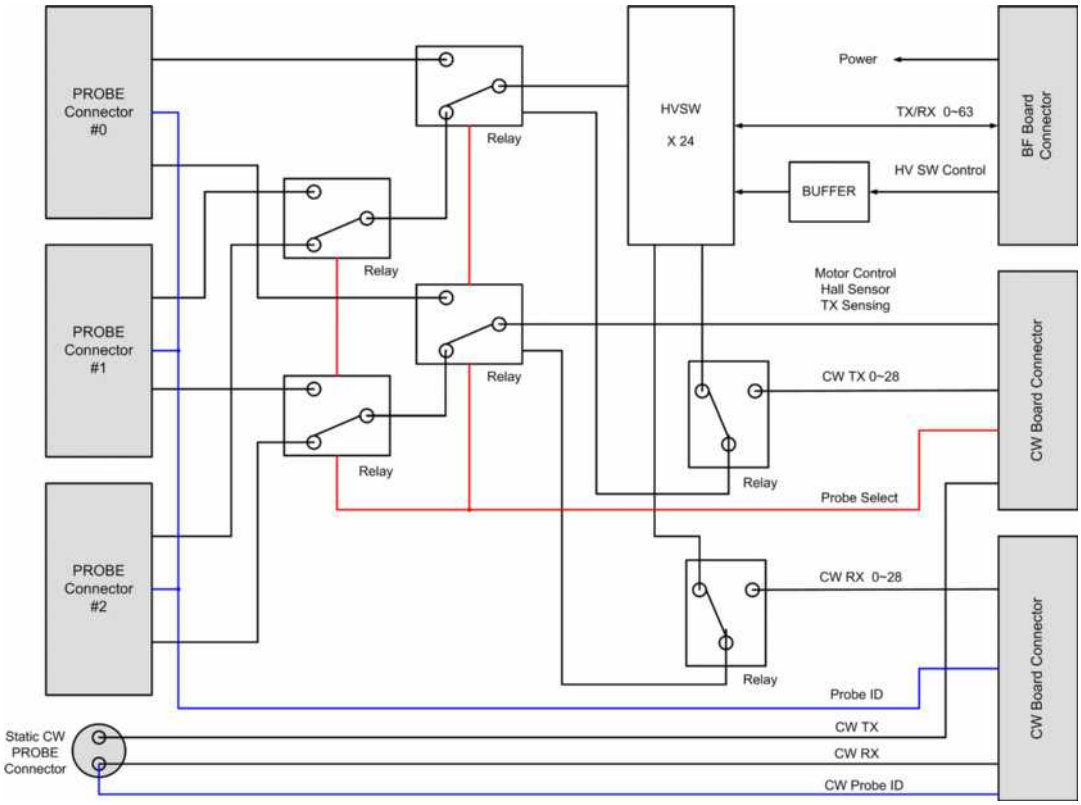
5.4 PSA

5.4.1 Major Function

PSA (Probe Select Assembly) connect the system and probe.

It has 3 260-Pin Array Probe Connector and 1 Static CW Static Probe Connector. The pins of Probe Connector are defined for Probe ID and HV-MUX control functions and consist of Relay circuit to select one of 3 Array Probes. In addition, High Voltage Switching is applied so that the BF (Beamformer Board)'s 64 Channel Signal and Probe's 128 Element are switched.

5.4.2 Block Diagram



[Figure 5-2] PSA Diagram

5.4.3 Specification

- 260 Pin Array Probe Connector 3ea
- Static CW Probe Connector 1ea
- High Voltage Switching (64 Channel : 128 Element)
- Probe Switching (from CW)
- Probe ID Reader (to CW)
- Board Version Reader

5.4.4 Operation Mechanism

5.4.4.1 High Voltage Switching Process

SONOACE X8 supports 64 Channels and 128 Element Probes.
Since the BF(Beamformer Board)'s Pulser and Receiver circuit consists of 64 channels only, additional Element Selection is necessary. Element Selection uses 24 High Voltage Switches and switches based on the Control Signal output from the BF(Beamformer Board)'s Control Logic. Control Signal is connected through the Mother Board Connector.

High Voltage Switch consists of the Shift Register and High Voltage FET.

5.4.4.2 Probe Switching

It consists of circuit to select one of 3 probes. It can select a probe selected by the user by using Latched type relay. It drives the Relay with the Probe Select signal transmitted from the CW(Continuous Wave Board)'s Control Logic(CPLD). The Probe Select signal is connected through Mother Board Connector.

5.4.4.3 CW Probe Switching

Since Steered CW and Static CW are not done by BF(Beamformer Board) and CW(Continuous Wave Board) constructs Pulser and Receiver circuit, do Selecting by constructing an additional circuit when Steered CW and Static CW are used.

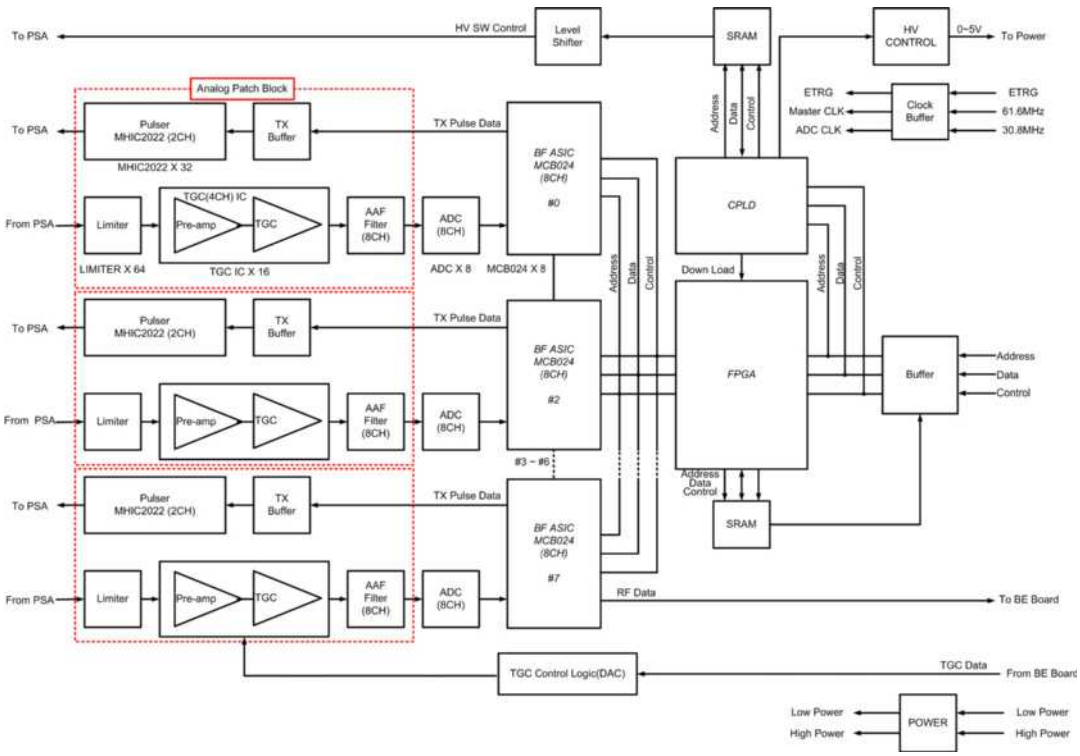
5.5 Beamformer Board

5.5.1 Major Function

Beamformer Board (hereafter, BF Board) delivers High Voltage Pulser to a probe, generates ultrasound, amplifies the returned echo signal and does Digital Beamforming.

Active aperture is in charge of 64 channel and supports up to 128 Element Probes. It consists of TX Pulser circuit, Receiving circuit and 8 Beamformer ASICs(MCB024) to construct the Active aperture 64 channels and does the Dynamic Apodization, Multi Beam Receiving, and TGC functions to enhance ultrasound image.

5.5.2 Block Diagram



[Figure 5-2] Beamformer Board Diagram

5.5.3 Specification

- TX Pulser 32ea (MHIC2022 : 2 Channels)
- Limiter 64ea
- TGC amp 16ea (4 Channels)
- AD converter 16ea (8 Channels)
- BF ASIC 8ea (MCB024)
- RX Dynamic Aperture Function
- RX Apodization Function
- Board Version Reader
- BFIC Operation Control Support
- PSA Probe Selecting Function
- Synthetic Aperture Support
- Trapezoidal Imaging Support
- Multi-Line Receiving Support
- TX Focal Point Support

5.5.4 Operation Mechanism

5.5.4.1 TX Pulser

The Exciting pulse data provided by BF ASIC(MCB024) is applied to TX Pulser (HIC2022) via TX Pulse Buffer. TX Pulser(HIC2022) generates Bipolar Pulser using the Exciting pulse data and the High Voltage from the DC-DC Power Module. Bipolar Pulser is sent to the Probe element by using the PSA (Probe Select Assembly) to generate ultrasound.

TX Pulser is a Hybrid IC. HIC2022 developed by MEDISONMEDISON Co., Ltd. is used as TX Pulser. 32 Blocks are applied in total.

Since Active aperture 64Channel provides up to 128 Elements, additional Element Selection is necessary. For this purpose, High Voltage Switch is used. High Voltage Switch is constructed in PSA (Probe Select Assembly).

5.5.4.2 Receive Channel

Receive Channel amplifies echo that is penetrated through the medium of human body and the reflected, and does the role of Analog Digital Converter so that Beamforming can be conducted. It consists of Limiter and Pre-Amp, TGC-Amp, Low-Pass Filter and A/D Converter.

1) Limiter

It removes unnecessary signal from the Echo returned through the PSA (Probe Select Assembly)'s High Voltage Switch. Up to 180 Vpp Tx Pulses and a few mV

Echo signals are mixed. Since actually necessary RX data is the echo signal of a few mV, Tx Pulse should be removed before the signal to the Pre-Amp. Limiter removes signal of higher than approximately 0.6V and transfers the echo signal to the Pre-Amp.

2) Pre-Amp

Pre-Amp amplifies echo signal of a few mV that is not processed.

3) TGC-Amp

Each TGC(Time Gain Compensation) Amp consists of 4 channels. Since the echo signal that is penetrated and reflected by medium diminishes as it traverses, it compensates the attenuation of the signal.

4) Low Pass Filter

Low-Pass Filter filters noise in Stop Band that is out of ultrasound band. In addition, it does the role of Anti-aliasing Filter that minimizes the Aliasing Effect that may appear in a high frequency probe such as 7.5MHz probe. The Aliasing of high frequency probe occurs due to the limitation of the Sampling Clock in the BF ASIC.

5) A/D Converter

It converts the digital signal to be used in the Digital Beamforming into analog.

5.5.4.3 Digital Beamforming

The ultrasound generated by a probe takes channel mode that uses a number of elements for TX Focusing. The ultrasound generated by channel is penetrated through medium and reflected as echo signal. However, since echo signals do not return to Probe Element simultaneously, but they return with delay variation. Therefore, a countermeasure against the delays is necessary for RX Focusing and it is very important to construct ultrasound image.

Digital Beamforming samples the echo signal returned to Probe Element and save the sampled data into the memory. The data saved in the memory when the sampling is complete means that time compensation is complete. The time compensation is done by the Sampling Clock itself. RX Focusing becomes complete, just by reading the data saved in memory and adding the data. Since this method requires different Sampling Clock for each element, VSCG(Variable Sampling Clock Generator) is necessary. VSCG(Variable Sampling Clock Generator) uses 61.6Mhz that is the same as A/D Sampling Clock and generates data necessary for BF ASIC(MCB024A).

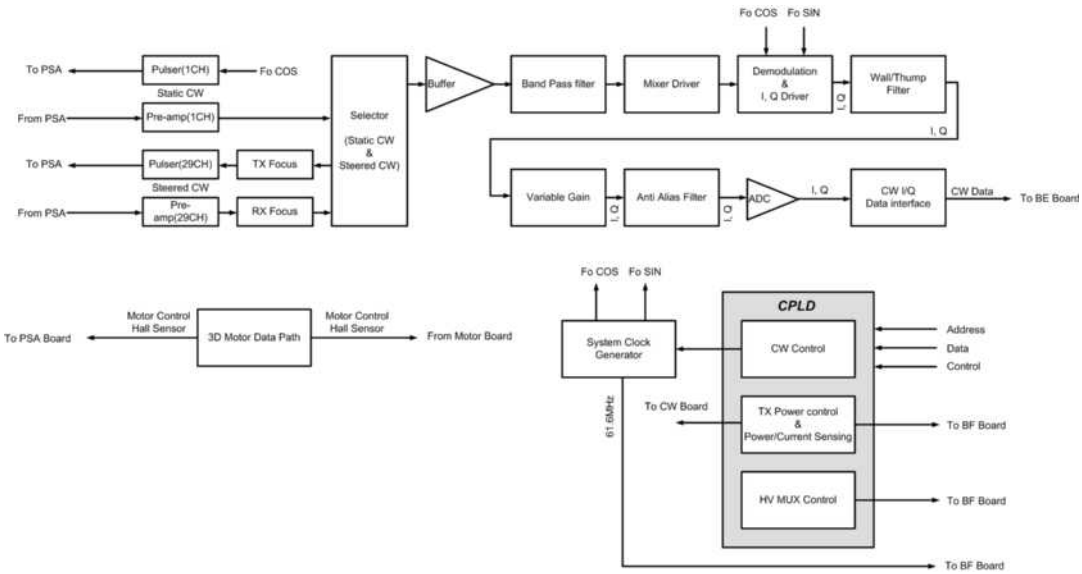
5.6 CW Board

5.6.1 Major Function

CW(Continuous Wave Board) is classified into CW Board that includes Continuous Wave Doppler function and Non CW Board that includes no Continuous Wave Doppler function. Continuous Wave Doppler function is optional. A product equipped with Non-CW should be replaced.

Non-CW(Continuous Wave Board) function provides System Clock Drive, Beamformer Sensing function, High Voltage Sensing function and PSA related signal.

5.6.2 Block Diagram



[Figure 5-4] CW Board Diagram

5.6.3 Specification

- Master Clock : System Clock Drive
- Beamformer Sensing
  Beamformer High Voltage(+) Sense
  Beamformer High Voltage(−) Sense
  Beamformer High Current(+) Sense
  Beamformer High Current(−) Sense
- Beamformer TX Control
- PSA related
  Probe ID Read
  Probe Insert Check
  Probe Port Select
- 3D Probe Path
  Sine Drive/Return
  Cosine Drive Return
  Hall Signal
- Continuous Wave Doppler (CW Option)
  Static CW Doppler TX/RX
  Steered CW Doppler TX/RX
- CW Sensing (CW Option)
  CW TX Voltage Sense
  CW TX Current Sense
- CW TX Control (CW Option)

5.6.4 Operation Mechanism

5.6.4.1 Master Clock

It provides 61.6Mhz Master Clock of the Ultrasound System Part to the CW(Continuous Wave Board), BF(Beamformer Board), and BE(Back End Baord) so that the boards can be synchronized.

5.6.4.2 Beamformer Sensing

Beamformer Sensing controls the TX voltage and current of is BF(Beamforming Board). This function is executed in CPLD.

1) Beamformer High Voltage(+) Sense and Beamformer High Voltage(−) Sense
   If the voltage of the TX Pulser used by BF(Beamformer Board) fails to satisfy the specification, the system stops with an error message.

2) Beamformer High Current(+) Sense and Beamformer High Current(−)Sense
   If the current of the TX Pulser used by BF(Beamformer Board) fails to satisfy the

specification, the system stops with an error message.

5.6.4.3 Beamformer TX Control

It controls the voltage of the TX Pulser of the BF(Beamformer Board). This function is executed in CPLD.

5.6.4.4 PSA Related

PSA related control functions Also are executed in CPLD.

1) Probe ID Read
   Reads Probe ID from the PSA(Probe Select Assembly) and check the probe information.

2) Probe Inset Check
   Identifies if a probe is installed from PSA(Probe Select Assembly).

3) Probe Port Select
   Selects a probe according to the Probe Select signal when a command is issued to select a probe connected to PSA(Probe Select Assembly).

5.6.4.5 3D Probe Path

Although 3D Probe and CW(Continuous Wave Board) is not related, information necessary for 3D Probe passes through CW(Continuous Wave Board).

3D Probe Path is Motor Moard, System Mother Board, CW, PSA, and 3D Probe in order.

NOTE "5.6.4.1 ~ 5.6.4.5" described Non-CW(Continuous Wave Board). Continuous Wave Doppler function is a function added to CW(Continuous Wave Board).

5.6.4.7 Continuous Wave Doppler

Continuous Wave Doppler processes TX and RX continuously and detects Doppler signal that cannot be detected by Pulse Wave Doppler.
SONOACE X8 does this function in the CW(Continuous Wave Board) and constructs Static CW and Steered CW circuit.

1) Static CW Doppler Circuit (TX/RX 1Channel)

- CW Pulser that drives Transducer
- RF Pre-Amplifier for signal reception
- Mixer to convert RF signal into vertical phase (0 degree, 90 degree) baseband signal of 50KHz bandwidth
- Thump Filter
- Variable Wall Filter
- Variable Gain
- Variable Low Pass Filter
- 16bit Analog-To-Digital Converters

2) Steered CW Doppler Circuit (TX/RX 29 Channel)

- 16 Channel CW Pulser that drives Transducer.
- 16 Channel RF Pre-Amplifier for signal reception
- TX/RX Beamformer for TX and RX Focusing
- Mixer to convert RF signal into vertical phase (0 degree, 90 degree) baseband signal of 50KHz bandwidth
- Thump Filter
- Variable Wall Filter
- Variable Gain
- Variable Low Pass Filter
- 16bit Analog to Digital Converters

5.6.4.8 CW Sensing

It controls the TX voltage and current of CW(Continuous Wave).

1) CW TX Voltage Sense
If the voltage of the TX Pulser used by CW(Continuous Wave) fails to satisfy the specification, the system stops with an error message.

2) CW TX Current Sense
If the current of the TX Pulser used by CW(Continuous Wave) fails to satisfy the specification, the system stops with an error message.

5.6.4.9 CW TX Control

Controls the voltage of the CW(Continuous Wave)'s TX Pulser.

5.7 Back End Board

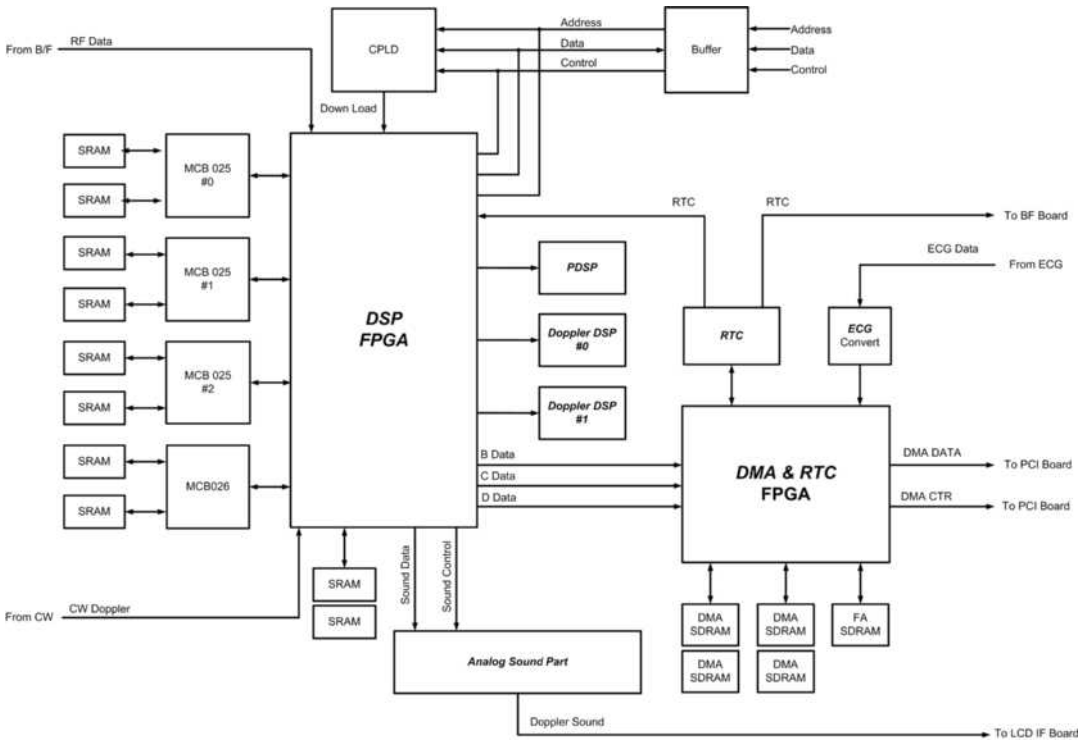
5.7.1 Major Function

Back End Board (hereafter, BE Board) consists of DSP(Digital Signal Processing) Part, DMA & RTC Part, and Analog Sound Part.

DSP Part receives RF Data and CW I/Q Data from the BF Board and CW Board respectively, processes the data and outputs the data as image data such as BW Image, PW Doppler, CW Doppler, Color Doppler, and Power Doppler. The image data pass through the Frame Average of the BE Board's DMA & RTC Part, are sent to the PC Part through the PCI BUS and are processed by the Software DSC. Analog Sound Part processes the Doppler Sound Data from the DSP Part, with the Digital Analog Converter, amplifies the signal and sends it to the speaker.

BE Board consists of MID processor(MCB025A), Color processor(MCB026A), DSP FPGA, DMA FPGA, DSP processor, and CPLD.

5.7.2 Block Diagram



[Figure 5-5] Back End Board Diagram

5.7.3 Specification

- BW mode (B-mode) Image Data Processing
- Motion mode (M-mode) Image Data Processing
- Color Motion mode (CM-mode) Image Data Processing
- Directional Power Doppler Image Data Processing
- Pulsed wave (PW) spectral Doppler Image Data Processing
- Multi frequency Doppler Image Data Processing
- Spatial Compound Imaging (SCI) Support
- Tissue Harmonic Imaging Support
- Pulse Inversion Harmonic Imaging Support
- Power Pulse Inversion Harmonic Imaging Support
- Trapezoidal Imaging Support
- Synthetic Aperture Support
- Tissue Doppler Imaging Support
- Extreme High Dynamic Range (170db)
- Full Spectrum Imaging (FSI) Support
- High Pulse Repetition Frequency (HPRF) Support
- Interface between Ultrasound System Part and PC Part
- Frame Average Function
- Real Time Controller (RTC) Function
- ECG Interface

5.7.4 DSP Part Operation Mechanism

5.7.4.1 BW Mode and M Mode Image Data Processing

RF data generated in the BF Board in Input to the DSP FPGA.

The input RF data in converted into RF data, which can be processed by the MID Processor (MCB025A), and Input to the MID Processors (MCB025A #0, #1, #2).

The 3 MID Processors (MCB025A #0, #1, #2) generate BW mode image data (hereafter, BW Data) and send the data to the DSP FPGA. The 3 MID Processors (MCB025A) are used to implement FSI(Full Spectrum Image) function that has 3 bands. The final processing of FSI(Full Spectrum Image) function is done in the DSP FPGA.

MID Processors (MCB025A #0, #1, #2) not only generate BW data but also do the functions of FSI(Full Spectrum Image), Spatial Compound Imaging (SCI), Trapezoidal Imaging, and Synthetic Aperture.

Especially, BW data is generated using the received RF data and through the DTGC(Digital Time Gain Compensation), Decimation, Quadrature mixer, Envelope

detection, Log compression and various filters.

The BW data generated by MID Processors (MCB025A#0, #1, #2) as described above are input to the DSP FPGA again. The data are processed by FSI(Full Spectrum Image) and Lateral filter, which is used to remove Multibeam artifact, and sent to the DMA & RTC Part.

For your reference, BW data can also be used as Motion Mode Image Data.

5.7.4.2 Doppler Image Data Processing

The RF data generated in the BF Board is Input to the DSP FPGA.

The input RF data is converted into RF data that can be processed by the MID Processor (MCB025A) and Input to the MID Processor (MCB025A) #1.

MID Processor(MCB025A) #1 receives RF data and does the DTGC(Digital Time Gain Compensation), Decimation, and Quadrature mixer processing for the RF data . The RF data becomes I/Q data (In-phase & Quadrature Data). I/Q data are input to the DSP FPGA again.

I/Q data are processed by the DSP FPGA and Doppler DSP and become Doppler Data and are sent to the DMA & RTC Part. Detailed descriptions are given below. The DSP FPGA that received the I/Q Data, sends the data to the Doppler DSP via filtering. At this time, the CW I/Q Data from the CW Board also sends final Doppler Data to the DMA & RTC Part through the same process as above. Since both PW and CW data cannot be processed simultaneously, all commands follow internal control process.

I/Q Data passes through the Clutter Filter in the Doppler DSP to remove the Wall (blood vessel wall) Noise after the data are filtered by the DSP FPGA. After that, the Doppler Sound is generated through the Hilbert transform that separates sound directions. The data are input to the DSP FPGA again and is sent to the Analog Sound Part of the BE Board.
In addition, I/Q Data are sent to the FFT (Fast Fourier Transform) circuit to generate the Doppler Spectrum, after passing through the Clutter Filter. By extracting the basic Doppler components of Power, Velocity, and Variance components, the Doppler Data are generated. The data are input to the DSP FPGA again and is sent to the DMA & RTC Part of the BE Board.

5.7.4.3 Color Image Data Processing

RF Data generated in the BF Board are input to the DSP FPGA.

The input RF data is converted into RF data that can be processed by the MID Processor (MCB025A) and input to the MID Processor (MCB025A) #0.

MID Processor(MCB025A) #0 receives RF data and does the DTGC(Digital Time Gain Compensation), Decimation, and Quadrature mixer processing for the RF data . The RF

data becomes I/Q data (In-phase & Quadrature Data). I/Q data are input to the DSP FPGA again.

I/Q Data generates Color Data through the processing in the Color Processor(MCB026A) and the data are sent to the DMA & RTC Part. Detailed descriptions are given below.
The DSP FPGA receives the I/Q Data, sends the data to the Color Processor(MCB026A) to extract color components. However, since the color component include Wall(blood vessel wall) Noise, the data are sent to the DSP FPGA again and passes through the Rejection, Smooth Filter, and Post Filter. Color Data are completed in the process and sent to the DMA & RTC Part of the BE Board.

5.7.5 Analog Sound Part Operation Mechanism

Processes the Doppler Sound and outputs to the speaker.

Doppler Sound is generated in the Doppler Part and is sent to the Analog Sound Part. Doppler Sound passes through Audio Digital Analog Converter because the speaker requires analog signal. In addition, the control of the Audio Digital Analog Converter is supported by the DMA & RTC Part.
After that, the noise is removed and Doppler Sound is amplified and sent to the speaker via the LCD IF Board.

5.7.6 DMA & RTC Part Operation Mechanism

The DMA Part of the DMA & RTC Part (Direct Memory Access & Real Time Controller Part) temporarily saves the Image Data (BW, Doppler, Color) that is signal-processed in the DSP Part and the ECG Data from the ECG Module and sends Image Data to the PC Part through PCI Bus according to the purpose of the data. The RTC Part also determines base signal and operation sequence of all Image Modes, and controls the Audio Digital Analog Converter.

5.7.6.1 DMA Part

DMA(Direct Memory Access) consists of FA(Frame Average), DMA and ECG In/Out Part.

FA(Frame Average) processes the BW, Doppler, Color Data with the average of the current Frame's Scanline Data and the previous Frame's Scanline Data. DMA temporarily saves the Frame-Averaged BW, Doppler, and Color Data and send them through the PCI BUS upon request of the PC Part. In addition, ECG Data are also saved and transferred in the same way as above.

Since DMA processes data using the DMA path with the PC Part, it plays key role to improve the product performance.

5.7.6.2 RTC Part

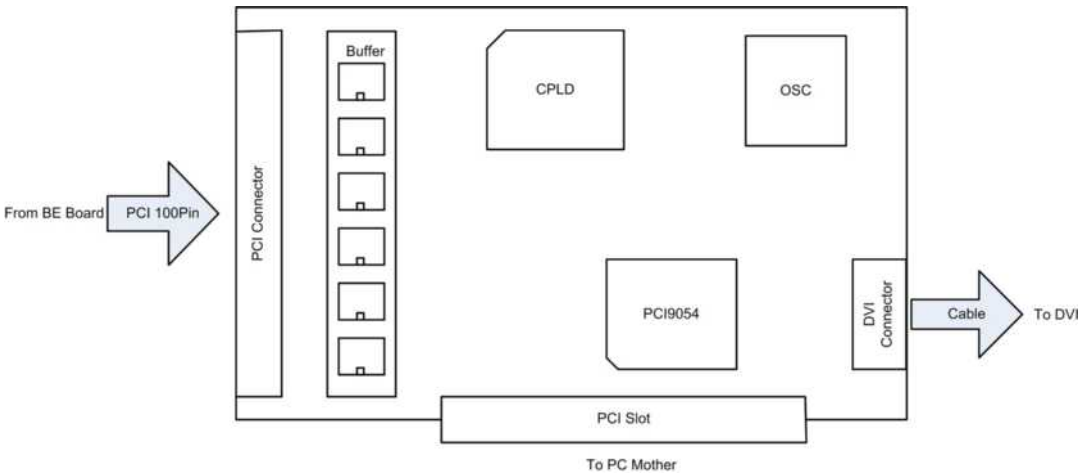
RTC(Real Time Controller) generates base signal necessary for entire system operation in real-time and controls the system operations. It generates and controls the PRF(Pulse Repeat Frequency), OF(One Frame), RP(Rate Pulse), LineType, and ScanLine signals necessary for the BF Board and BE Board's DSP Part. In addition, it internally controls the data flow in the DMA FPGA.

5.8 PCI Board

5.8.1 Major Function

Peripheral Component Interconnect Board (hereafter, PCI Board) interconnects the Ultrasound System Part and the PC Part. It is used as a DMA path to control and initilize the Ultrasound System Part and to handle the BW, Color, Doppler Data using the Software DSC (Software Digital Scanconversion).

5.8.2 Block Diagram



[Figure 5-6] Back End Board Diagram

5.8.3 Specification

- Interface between Ultrasound System Part and PC Part
- PCI Clock Generation
- 100 Pin Fast PCI Cable Connector
- Rear Board Cable Connector

5.8.4 Operation Mechanism

It interconnects the Ultrasound System Part and the PC Part and provides interface function.
The Ultrasound System Part's Mother Board and the PC Part's PCI Board are connected by 100 Pin PCI Cable. Through the PCI cable, Control Address bus, Control Data bus, Select signal, DC to DC Power Unit On/Off signal, and Analog Audio Data are transferred.

CPLD decodes the address and data of the PC Part to interface the Ultrasound System Part and the PC Part, and processes the Interrupt signal for DMA. PCI9054 interfaces the Ultrasound System Part and PC Part.

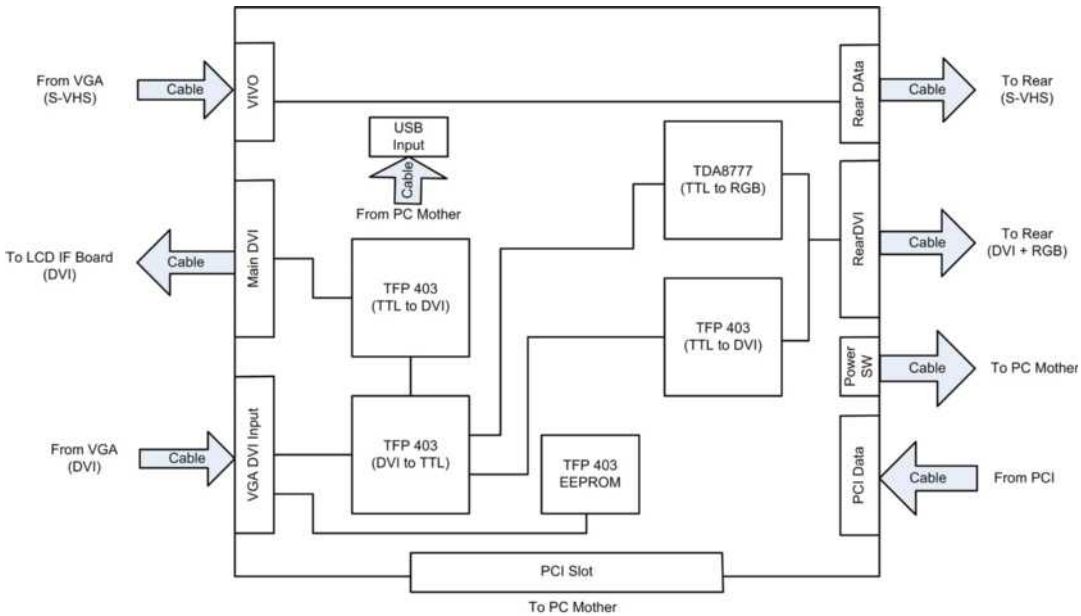
OSD is PCI built-in Clock Generation to secure the stability of the data sent to PCI and the Rear Board Cable Connector is connected to the DVI Board with the DC to DC Power Unit's On/Off signal.

5.9 DVI Board

5.9.1 Major Function

Digital Video Interface Board (hereafter, DVI Board) enables high-quality video processing without connecting a VGA Card to the LCD Monitor. In addition, the circuit with LCD IF Board is constructed for the User Interface of Power Control and USB Port.

5.9.2 Block Diagram



[Figure 5-7] Back End Board Diagram

5.9.3 Specification

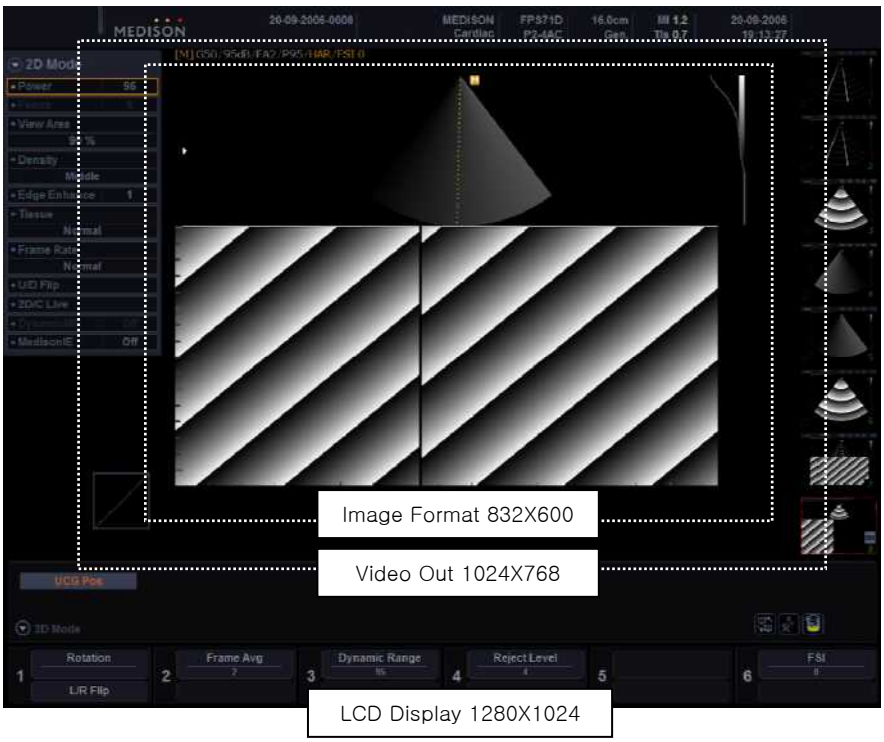
- LCD Monitor Data Transmission
- DVI 1 Port Input 2 Port Output
- Analog RGB 1 Port Output
- USB 2.0 1 Port to LCDIF
- Power Control Interface

5.9.4 Operation Mechanism

If DVI is input from the VGA Card, it processes the data to send the data to the LCD Monitor. This circuit has been implemented to provide high-quality image because multiple data with User Interface are processed simultaneously, it may affect the quality of the resultant image.

The DVI and S-VHS are input from the VGA Card and the output of DVI Board is connected to the Main LCD Monitor and the Rear Panel.

The PC internal signals such as USB Signal and Key Interface Control Signal are connected to the DVI Board, and the PCI Board's Power Control Signal is also connected to the LCD IF Board through the DVI Cable.



[Figure 5-8] LCD Display

5.10 VGA Card

5.10.1 Major Function

VGA Card is a card to display the final ultrasound image such as Software DSC and PC Overlay on the monitor. A commercial VGA card has been used. VGA Out is not directly connected to the LCD Monitor and image is displayed through the DVI Board.

nVIDIA GeForce 7600GS used as VGA Card is equipped with 7600GS graphic chipset and provides the best graphic performance. The VGA Card has GDDR2 type 256MB memory optimized for graphic and provides sufficient graphic buffer. To cool the heat from the CPU and memory, the best cooling system has been implemented through the low-noise high-performance cooling fan and high-capacity heat sink.

5.10.2 Picture

[Figure 5-9] VGA Card

5.10.3 Specification

Item	Contents
Product Name	nVIDIA GeForce 7600GS
Interface	PCI-Express X 16
Memory Type	DDR2
Memory Capacity	256MB
Memory Bus	126bit
Core Clock	400MHz
Memory Clock	800(400)MHz
RAMDAC	400MHz
Cooling System	Cooling Fan & Heat Sink
Video Out	TV-OUT, D-SUB, DVI

5.11 PC Mother Board

5.10.1 Major Function

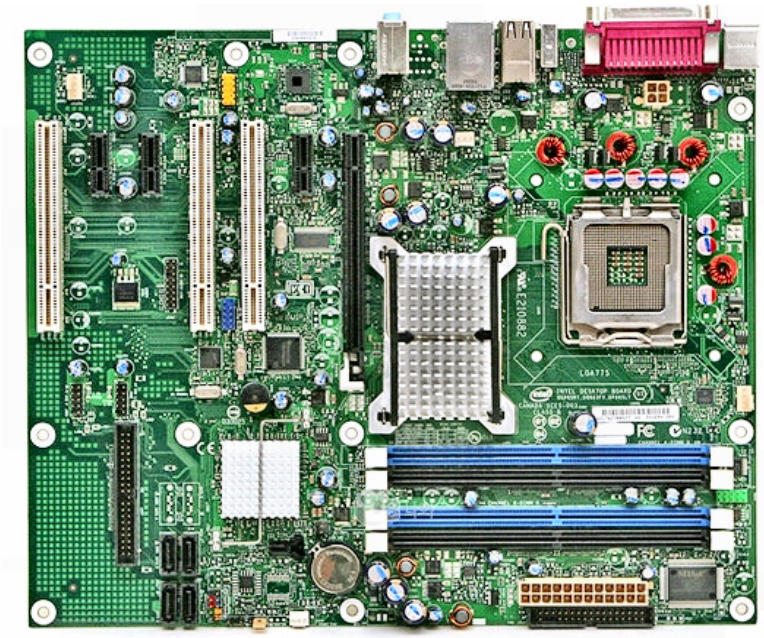
SONOACE X8 adopted commercial PC Mother Board as the PC Mother Board.

The conventional Hardware DSC Board and Video Manager Board have been implemented in the PC Part. Since the BE Part is implemented as software, the performance of the PC Mother Board is critical. We have designed the system considering further upgrade of the PC Mother Board with a commercial one. However, the performance of the system is not guaranteed if a PC Mother Board other than the board supplied by MEDISON Co., Ltd.

PC Mother Board has the following specifications.

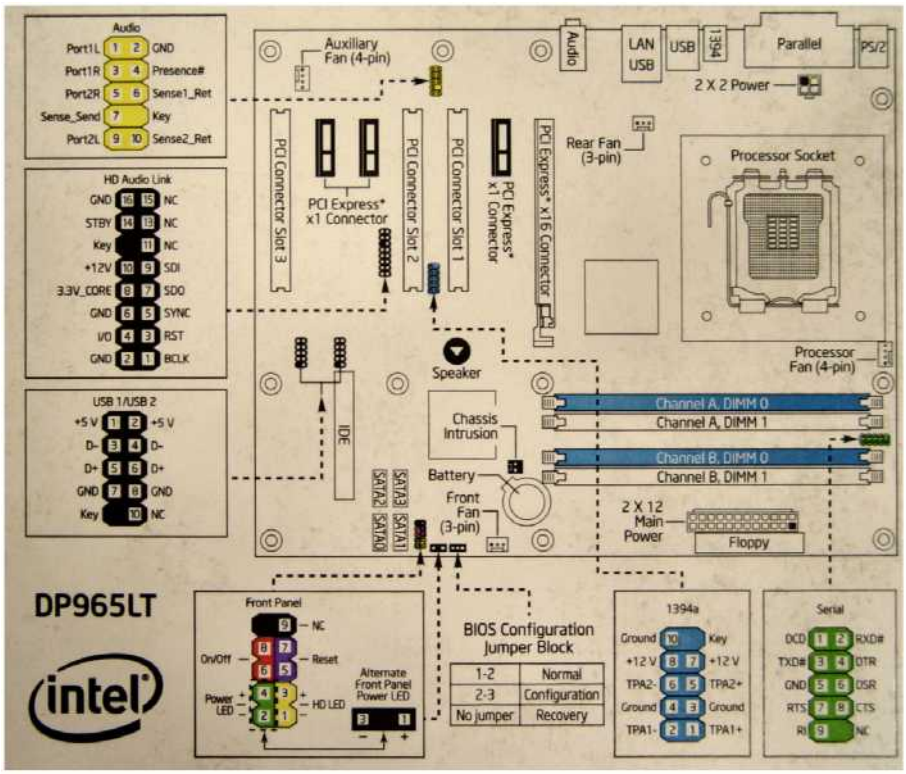
- CPU : Core2 Duo E6320 2GHz
- Main : Mother Board Intel DP965LT
- RAM : DDR2 PC5300 6677MHz 2GB Memory
- PCI Slot : DVI Board, PCI Board
- PCI Express x16 Slot : VGA Card
- Back Panel Connector: User can use it at will.

5.11.2 Picture



[Figure 5-10] PC Mother Board

5.11.3 Specification



Item	Contents
FSB	1066/800/533Mhz
IEEE1394	Supported
PCI Slot	3 PCI, 3 PCI Express x1, 1 PCI Express x16
Serial ATA	4 Ch
USB	USB 2.0
Main Chip set	Intel i965P
Sound	SigmaTel STAC9227* 6Ch
Socket	LGA775
Ethernet	Intel 82566DC Gigabit Ethernet
Memory	Dual Channel DDR2 800/667/533
Max Memory	8GB
Board Type	ATX

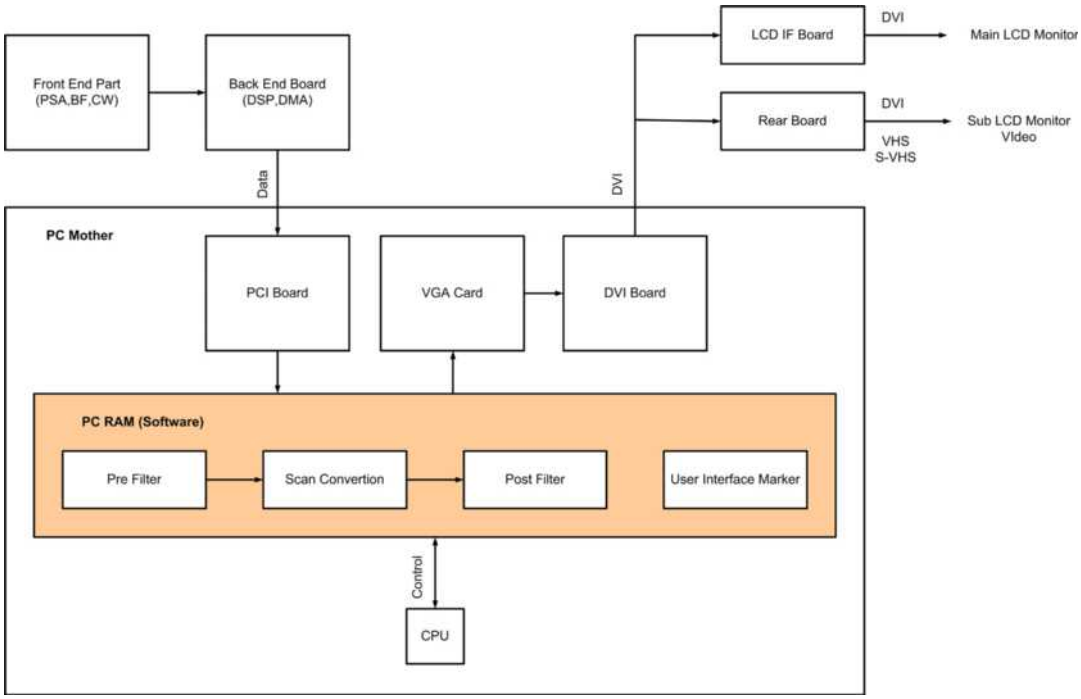
5.12 Software DSC

5.12.1 Major Function

SONOACE X8 does the role of conventional Hardware DSC with Software DSC.

Video signal generated in the BE Board is directly copied to the PC Memory through DMA, processed by Software DSC and ultrasound image processing software, and displayed on the monitor through the VGA Card and DVI Board.

5.12.2 Block Diagram



[Figure 5-11] Software DSC Block Diagram

5.12.3 Specification

- Software DSC
- Cine for 10,000 frame
- Loop Review for 8,192 lines
- Zoom
- Edge Enhancement
- Integrated 3D Imaging Package
- Freehand 3D, Static 3D, Live 4D
- VOCAL
- 3D XI
- Multi-Slice View
- Oblique
- Static Line Oblique
- Dynamic Line Oblique
- Contour Oblique
- Volume CT
- Magic Cut
- Dynamic MR (Optional)
- Quick Scan
- Real-Time Auto Calculation time Doppler Auto Trace
- Free Angle M-Mode
- Post measurement
- Post image optimizing process Arbitrary M mode
- Panoramic View(to be updated)
- Help function

5.12.4 Operation Mechanism

The image data generated in the BE Board's DMA Part are directly copied to the PC Memory in DMA mode through the 100 Pin Cable connecting the Mother Board and the PCI Board.
The data are saved in the Cine Memory through the UCAgency Buffer and processed by the Software DSC and the Image Save.

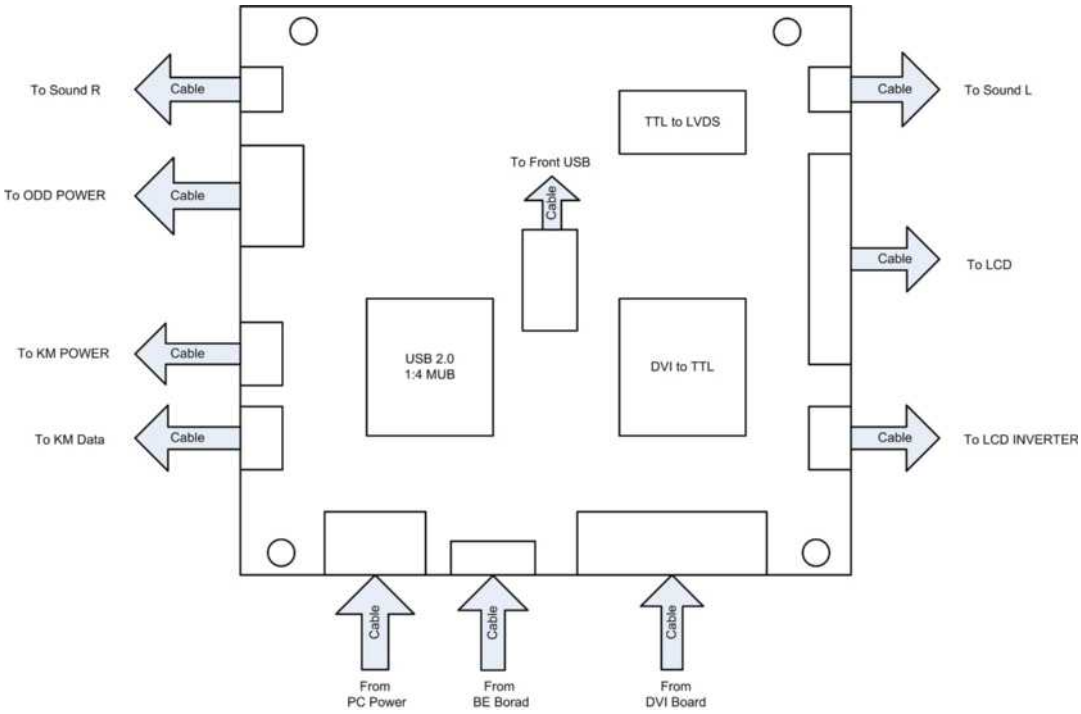
The Software DSC does all the functions can be done by the Hardware DSC. Processes the DSC by the Filter and Rendering and transfers data to the VGA Card. In addition, the delay problem when saving the image into the HDD has been resolved.

5.13 LCD IF Board

5.13.1 Major Function

LCD Interface Board (hereafter, LCD IF Board) supports User Interface.

5.13.2 Block Diagram



[Figure 5-12] LCD IF Board Block Diagram

5.13.3 Specification

- Single DVI Input, Dual LVDS Out (64Mhz)
- Key Matrix Interface
- Front USB 2Port Support
- ODD Power Connection
- Power Control Connection
- Speaker Data Connection

5.13.4 Operation Mechanism

The signal input to the LCD IF Board is the DVI Data from the DVI Board and the Analog Sound Data from the Mother Board. DVI Data or DVI Cable includes Key Interface Control Signal, Power Control Data and USB Signal other than the DVI Data.

LCD IF Board receives input signal and outputs signals to the Key Interface Board, USB Port, and Speaker.

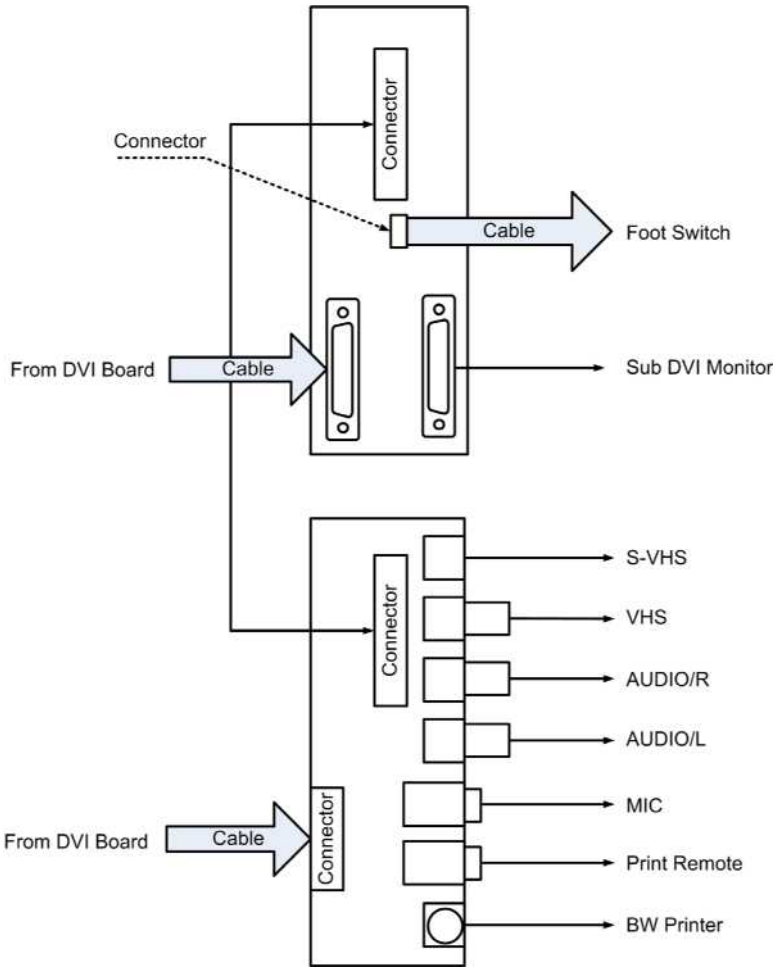
The data of the DVD RW Drive are connected through S-ATA interface and the PC Power Supply's power is used through the LCD IF Board.

5.14 Rear Board

5.14.1 Major Function

Does the Input/Output function with external devices.

5.14.2 Block Diagram



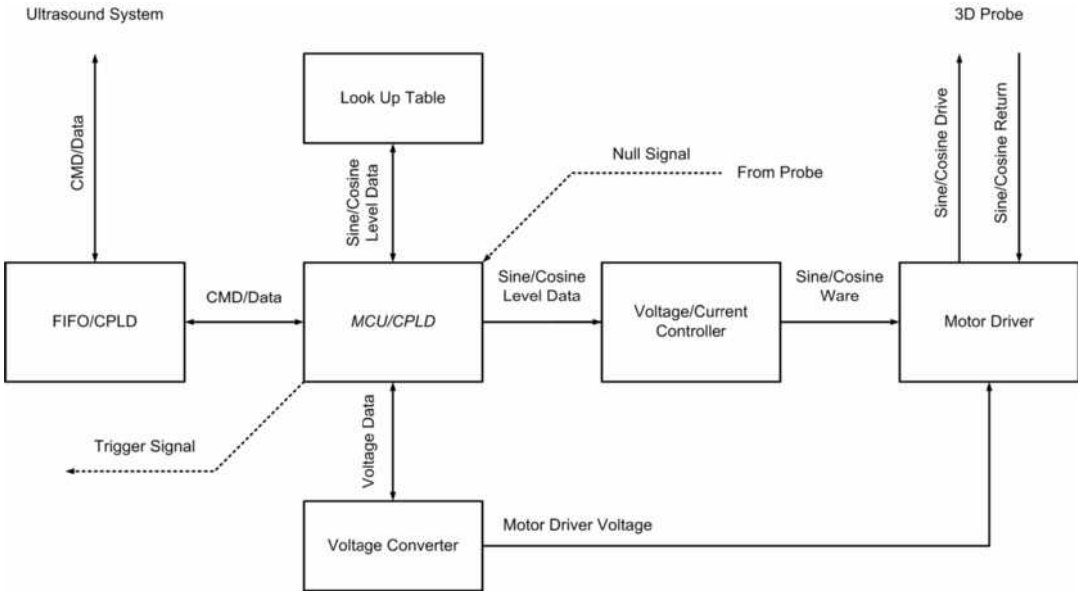
[Figure 5-13] Rear Board Block Diagram

5.15 Motor Board

5.15.1 Major Function

This Motor Board (hereafter, MTR Board) is the Motor Drive Board to drive the 3D Probe.

5.15.2 Block Diagram



[Figure 5-14] Motor Board Block Diagram

5.15.3 Specification

- 3D Probe Motor Drive
- Voltage & Current Control Controller
- Null Position Signal Sensing
- DC Voltage Supply (+12V, −12V, +3.3V, +5V)

5.15.4 Operation Mechanism

3D Probe implements 3D Mode by driving the Stepping Motor. The Motor Board does Feedback Control by using the SIN and COS waveform that has 90^{o} phase difference from the 3D Probe. 3D Probe provides Null Position signal to the Motor Board and the Motor Board provides One Frame signal that is used as basis for 3D image acquisition to the BE Board.

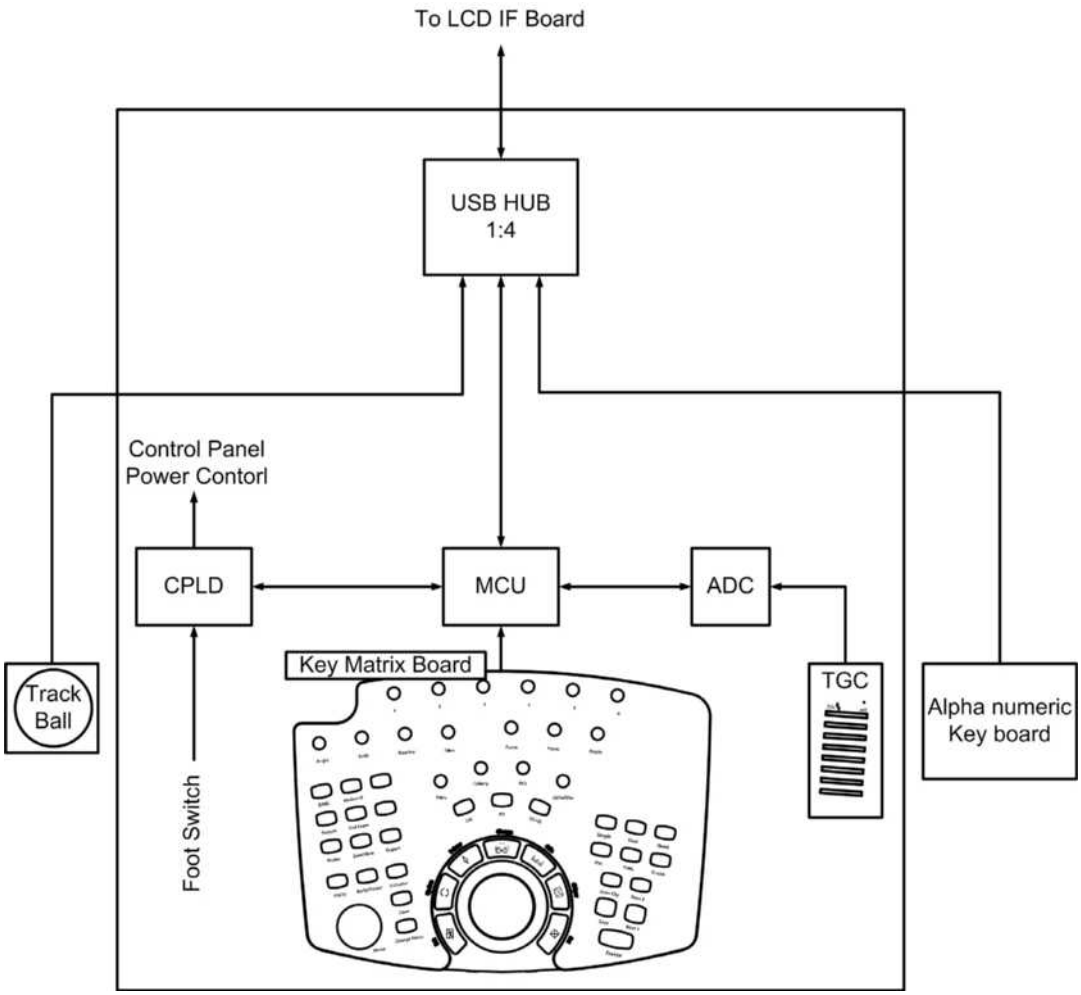
5.16 Control Panel

5.16.1 Major function

It plays the role of the interface between the user and the system.

Key Matrix Board, Alpha Numeric Keyboard, and Track Ball does the role of User Interface.

5.16.2 Block Diagram



[Figure 5-15] Control Panel Block Diagram

5.16.3 Specification

- USB Host Support
- USB Alpha Numeric Board
- USB Track Ball
- USB Key Matrix Board
- TGC Control
- LIMIT Board
- LAMP Board
- Power Control Support
- Printer Remote Support
- Foot Switch Support

5.16.4 Operation Mechanism

It is connected with the Key Matrix Board, Alpha Numeric Board, and Track Ball through the USB HUB and operates according to the user's commands.

Since Power Control is simply connected with the Key Matrix Board through a switch, detailed description will be given in the Operation Mechanism of the Power Module.

5.17 Power Supply

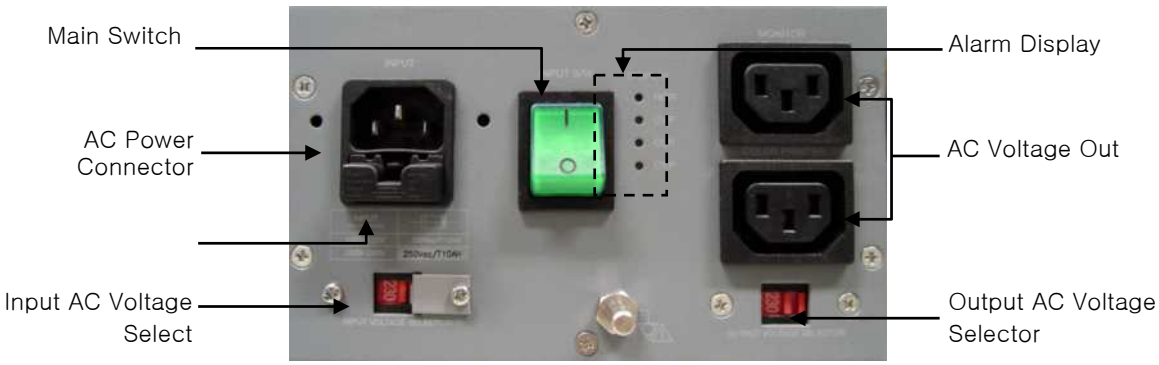
5.17.1 AC to DC Power Module

5.17.1.1 Major Function

SONOACE X8 is designed so that it operates when the input voltage is either 110V or 220V.
You have to select the input voltage selector of the product before using it according to the input voltage to be connected to the product.

The INPUT Voltage Selector is used to determine the power and voltage to be supplied for the product and the OUTPUT Voltage Selector is used to determine the power to be directly supplied to the external devices.

Both AC and DC voltages are output. AC voltage is used for the external devices and PC Power Supply and the DC voltage is used for the power of the Ultrasound System Part.



[Figure 5-16] AC-DC Power Module

5.17.1.2 Input/Output Voltage

1) Input Voltage

Standard Voltage	Input Frequency	Allowed Range
115 V	50 ~ 60 Hz	110 ~ 120 V
220 V	50 ~ 60 Hz	200 ~ 240 V

2) Output Voltage

AC/DC	Output Voltage	Use Range
AC	110 ~ 120 V	External Device
	200 ~ 240 V	
	200 ~ 240 V	PC Power
DC	24 V	Ultrasound System Part

5.17.1.3 Alarm Display

You can identify if the DC to DC Power Module(hereafter, DDM) is working properly by watching the Display LED of AC to DC Power Module (hereafter, ADM).

Alarm LED	LED ON
NOR	Normal
OVP	Over-Voltage
OLP	Over-Current
OTP	Over-Temperature

1) Over Output Current Protection (OLP: Over Current Protection)

If current flows in the Over-Current Range exceeding the standard input and max output current, the OLP is activated and all powers of DDM are cut off.

Output Voltage	Standard Current	Over-Current Range
+ 3.5V	11A	15~25A
+ 5.2V	7A	8~12A
- 5.2V	3A	5~7A
+ 12.2V	4A	8~12A
- 12.2V	1.5A	4.5~6.5A
+ HW (0V ~ + 80V)	0.2A	0.8~3A
- HW (0V ~ - 80V)	0.2A	0.8~3A
+ 97V	0.05A	0.3~0.55A
- 97V	0.05A	0.3~0.55A

2) Over Output Voltage Protection (OVP : Over Voltage Protection)

If current flows in the Over-Voltage Range exceeding the standard input and max output voltage, the protection circuit is activated and all powers of DDM are cut off.

Output Voltage	Over-Voltage Range
+ 3.5V	3.6~3.9V
+ 5.2V	5.5~6V
- 5.2V	5.5~6V
+ 12.2V	13.2~14.4V
- 12.2V	13.2~14.4V
+ HW (0V ~ + 80V)	85~95V
- HW (0V ~ - 80V)	85~95V
+ 97V	105~110V
- 97V	105~110V

3) Over Temperature Protection (OTP)

If the temperature of the DDM Case is equal to or higher than 80℃, all powers of DDM are cut off.

5.17.2 DC to DC Power Module

5.17.2.1 Major Function

DDM receives power from ADM and supplies power to the Ultrasound System Part. Protection circuit within the DDM provides information through the Alarm Display of the ADM when a problem is detected.

5.17.2.2 Input and Output Voltage

Output Voltage	Standard Current	Minimum Current
+ 3.5V	11A	1.1A
+ 5.2V	7A	0.7A
- 5.2V	3A	0.3A
+ 12.2V	4A	0.4A
- 12.2V	1.5A	0.15A
+ HW (0V ~ + 80V)	0.2A	0.02V
- HW (0V ~ - 80V)	0.2A	0.02V
+ 97V	0.05A	0A
97V	0.05A	0A

5.17.3 PC Power Supply

It receives AC 220V from the ADM and uses it for the internal power of the PC Part. In addition, it is also used for the power for the LCD Monitor, DVD RW Drive, System Fan and Back Fan through the connector of the PC Part that is connected to external.

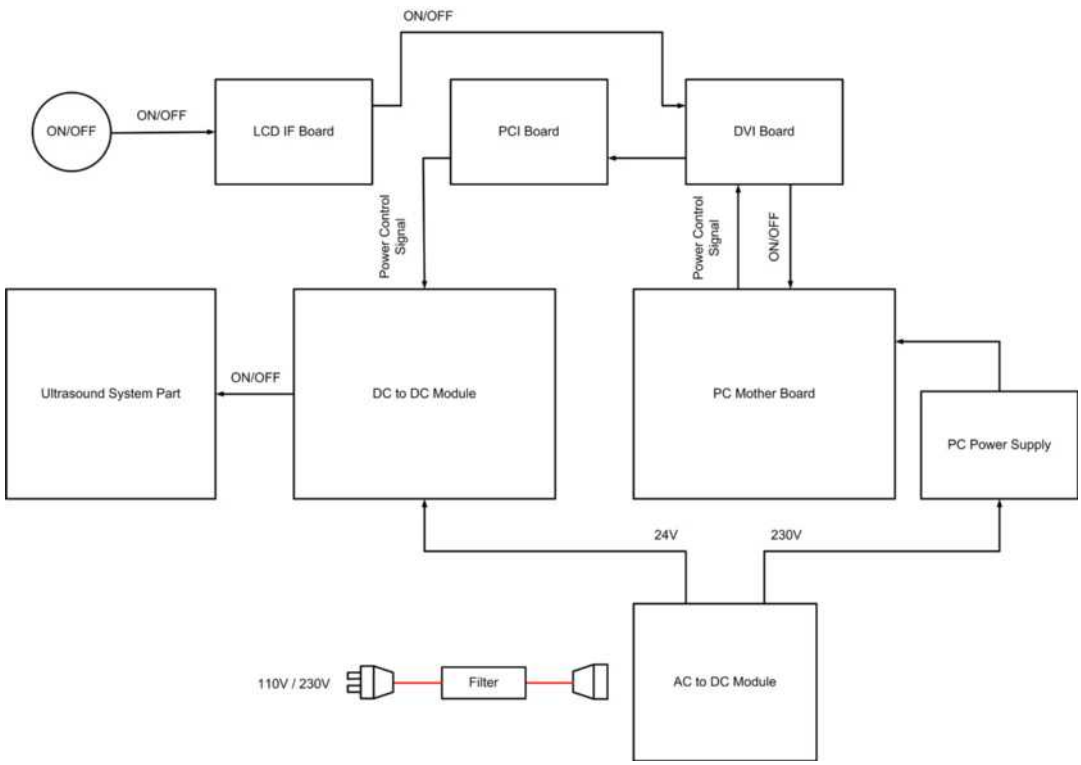
PC Power Supply specification is Micro ATX.

5.17.4 Power Control

The power flow when the power is turned on or off is described below.

If the Power On Switch of the Control Panel is pressed, the power of the PC Part is turned on, and it turns on the power of the Ultrasound System by transferring the Power On Signal over the PCI Board.

If the Power Off Switch of the Control Panel is pressed, the power of the PC Part is turned off, and it turns off the power of the Ultrasound System by transferring the Power Off Signal over the PCI Board.



[Figure 5-17] Power Control

6 Basic Maintenance

6.1 Overview

Chapter 6 describes basic SONOACE X8 maintenance procedures.

How to upgrade and how to use Admin Mode (Service Mode) are described.

Contents Basic Maintenance

6.2 System Information

To view system information, select the [Information] tab in the Setting screen. The software version of the system will be displayed. Press [Detail] to view the detailed version information of the product.

[Figure 6-1] Setting-Information

NOTE The software version number in the above figure may differ from the actual software version of the system.

6.3 Windows Mode

Windows Mode is a mode that switches the ultrasound system to the normal Windows XP Desktop screen and is necessary for software upgrade.

1) Press the [***] + [***] + [***] key combination by using the keypad of the keyboard.
2) When the Windows Password window appears, type "**********" and then press Enter.
3) When the system successfully enters the Windows mode, the Start button appears at the bottom of the screen.

6.4 Upgrade

You can upgrade the software and hardware of SONOACE X8.

Upgrade includes the addition and improvement of functions and improves system performance.

NOTE The installed software should be compatible with the hardware. If the installed software and hardware are not compatible, a problem may occur in functions or operations.
A compatibility table is additionally provided by the customer care department of MEDISON Co., Ltd.

6.4.1 Software Upgrade

6.4.1.1 Software Upgrade Using File

This is the normal software upgrade method. This method uses CD/DVD-ROM or Flash Memory.

1) Prepare the upgrade file provided by the customer care department of MEDISON Co., Ltd.
2) Turn SONOACE X8 on.
3) When system booting is complete, enter Windows Mode and display the Windows XP Desktop screen.
4) Exit the ultrasound program. To exit the program press the "Alt + F4" key combination using the keyboard.
5) Insert the CD/DVD-ROM into the CD/DVD-ROM drive and wait until the CD/DVD-ROM drive LED is turned off. If the upgrade file is in a Flash Memory, connect the Flash Memory to the USB port on the front panel of the system.
6) Click the Start button on the Taskbar of the Windows XP Desktop and select Programs, Accessories and Windows Explorer in that order.
7) Select the drive that includes the upgrade file in My Computer and double-click the upgrade file. Then the software upgrade begins.
8) When the software upgrade begins, click the install button.
9) When the software upgrade is complete, restart SONOACE X8.
10) Check if the software version in the start screen is changed to the new version.

6.4.1.2 Software Upgrade Using Ghost Image CD/DVD-ROM

When upgrading using a file is not available, a Ghost Image CD/DVD-ROM is used for software upgrade. In addition, the Ghost Image CD/DVD-ROM is used to repair the ultrasound program or HDD problems.

The following describes an upgrade using a Ghost Image CD/DVD-ROM with booting and Auto Run function.

1) Prepare the Ghost Image CD/DVD-ROM provided by the customer care department of MEDISON Co., Ltd.
2) Turn SONOACE X8 on.
3) When system booting is complete, insert the Ghost Image CD/DVD-ROM into the CD/DVD-ROM drive.
4) Turn SONOACE X8 off and then on again to restart.
5) Boot with the Ghost Image CD/DVD-ROM instead of the ultrasound program and run the ghost program.
6) In the ghost program, select Local, Disk, and From Image in that order.
7) Select the drive corresponding to the Ghost Image CD/DVD-ROM, select Ghost Image and click the "Open" button.
8) Select the target HDD onto which the Ghost Image will be written and click the "OK" button.
9) If a message appears asking whether to run the Ghost Image, click the "Yes" button. Then the program runs.
10) If the ghost program completes successfully, a message appears. Click the "Restart Computer" button to finish and remove the CD/DVD-ROM .
11) Turn SONOACE X8 off and then on again to restart.
12) Check if the software version in the start screen is changed to the new version.

6.4.2 Hardware Upgrade

This means the replacement or addition of hardware.

NOTE For information on hardware upgrade, refer to the "Chapter 8 Disassembly and Reassembly" of the Service Manual.

6.5 Admin Mode

Admin Mode is also called Service Mode. Admin Mode functions are described below.
Admin Mode is necessary for critical settings and to add or delete options.

6.5.1 Entering Admin Mode

1) While Pressing "*****" and, type "**********".
2) If the entered password is correct, the "Admin Mode" tab appears in the Setup Mode.
3) If you select "Admin Mode" you can enter Admin Mode as shown by [Figure 6-1].

[Figure 6-1] Admin Mode

6.5.2 Admin Mode Functions

6.5.2.1 Language

You can select a language to be used for the system through filter. Supported languages are English, German, French, Spanish, and Italian.

6.5.2.2 Test Pattern

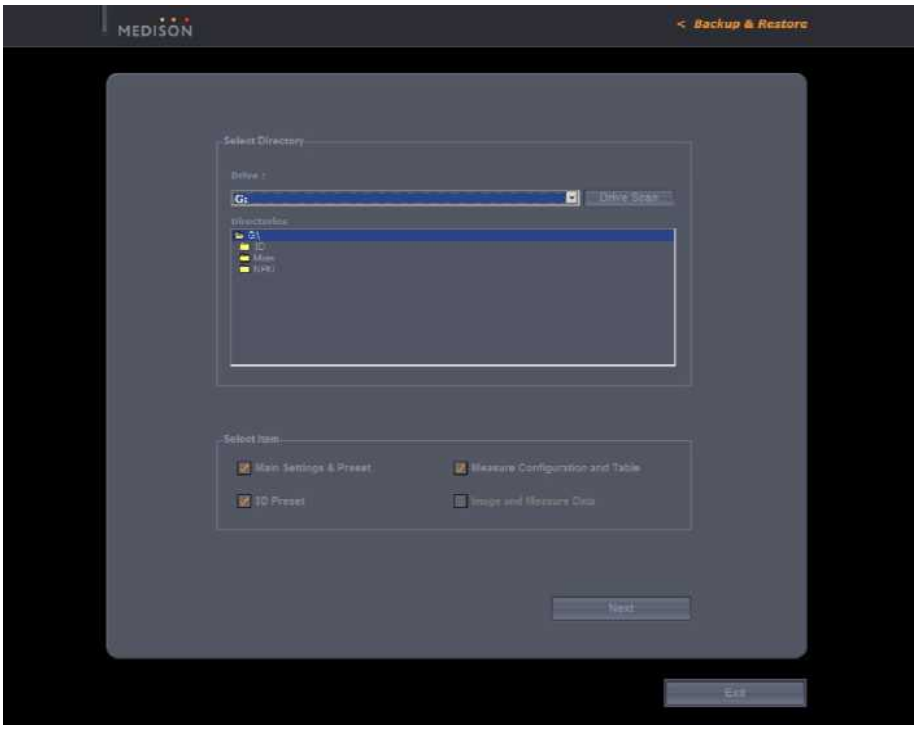
You can test the monitor characteristics. Select [Test Pattern]. Each time you press the [Set] button of the keyboard, one of the 3 test patterns shown by [Figure 6-2] is displayed on the screen in turn.

[Figure 6-2] Test Patterns

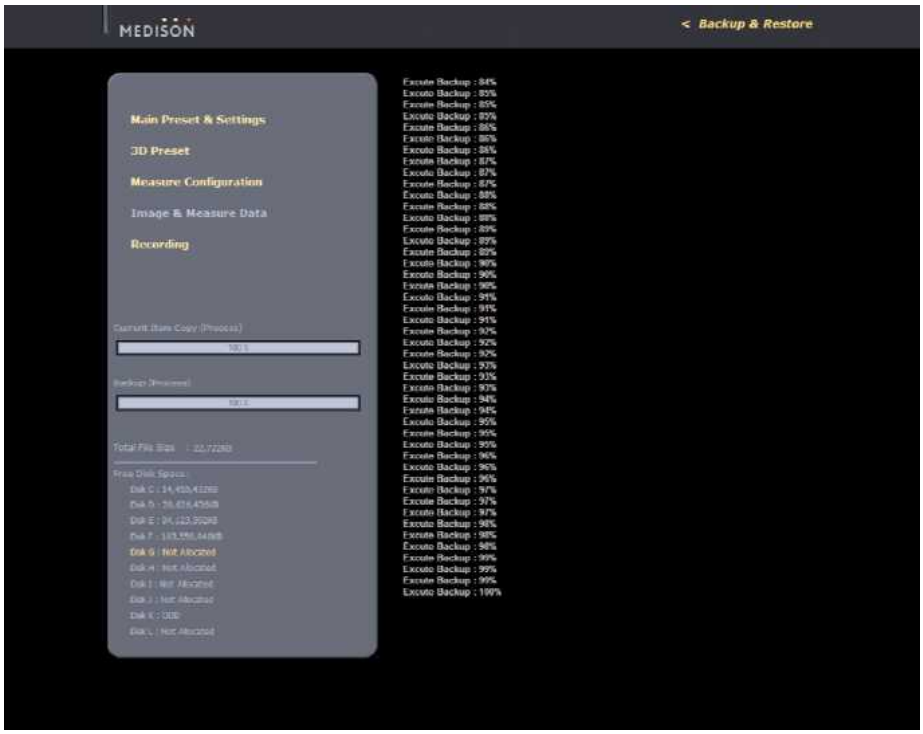
6.5.2.3 Restore

Using this function, you can restore settings with the backed-up user setting values. You can use this function in Admin Mode only.

1) If you press [Restore], the ultrasound program is terminated and the Restore function runs. If a message appears asking whether to exit the ultrasound program before running the Restore function, click [OK].
2) In the [Restore] screen, you can select the User Setting Item and Backup Media.
3) If you press [Next], the Restore function is executed.
4) When the restoration is complete, the system will restart.



[Figure 6-3] Restore Function

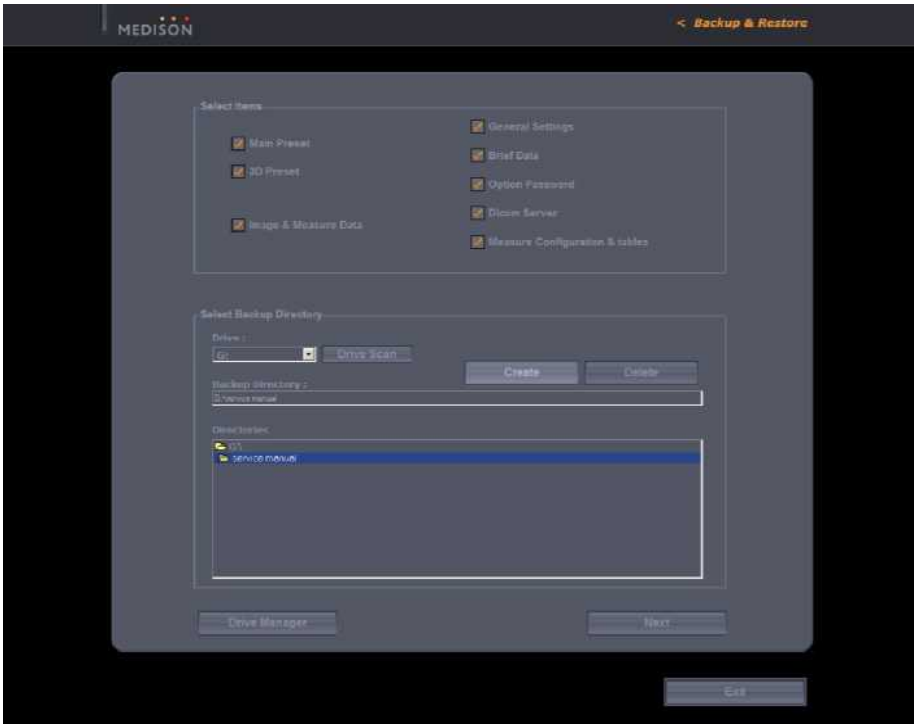


[Figure 6-4] Execution of Restore Function

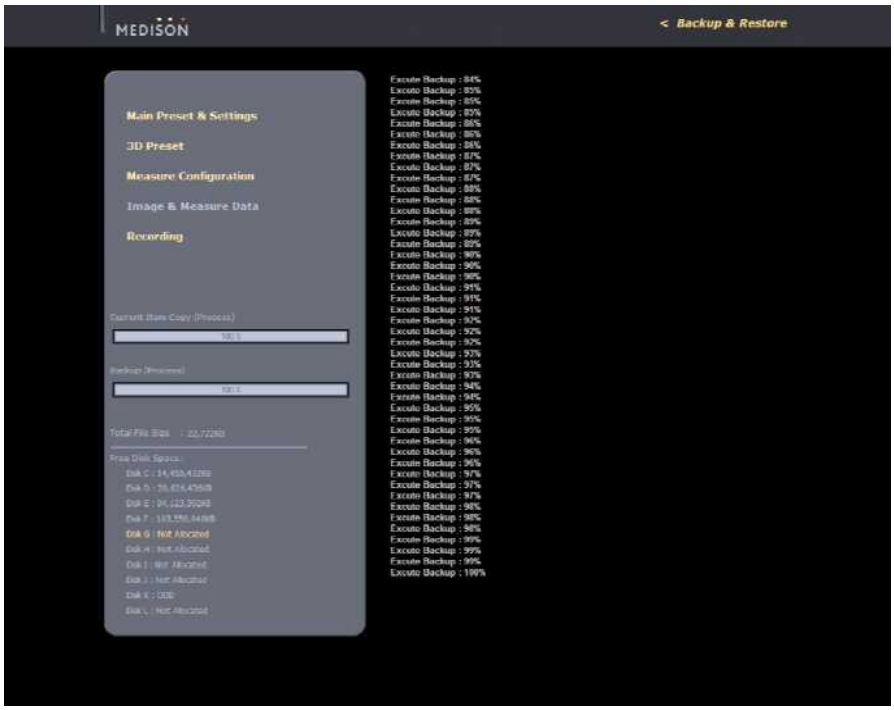
6.5.2.4 Backup

Using this function, you can back up your user settings onto external media. This function is available only in the Admin Mode.

1) If you press [Backup], the ultrasound program is terminated and the Backup function runs. If a message appears asking whether to exit the ultrasound program before running the Backup function, click [OK].
2) In the [Backup] screen, you can select the User Setting Item and Backup Media.
3) If you press [Next], the Backup function is executed.
4) When the backup is complete, the system will restart.



[Figure 6-5] Backup Function



[Figure 6-6] Execution of Backup Function

6.5.2.5 VGA

1) Video Out Format

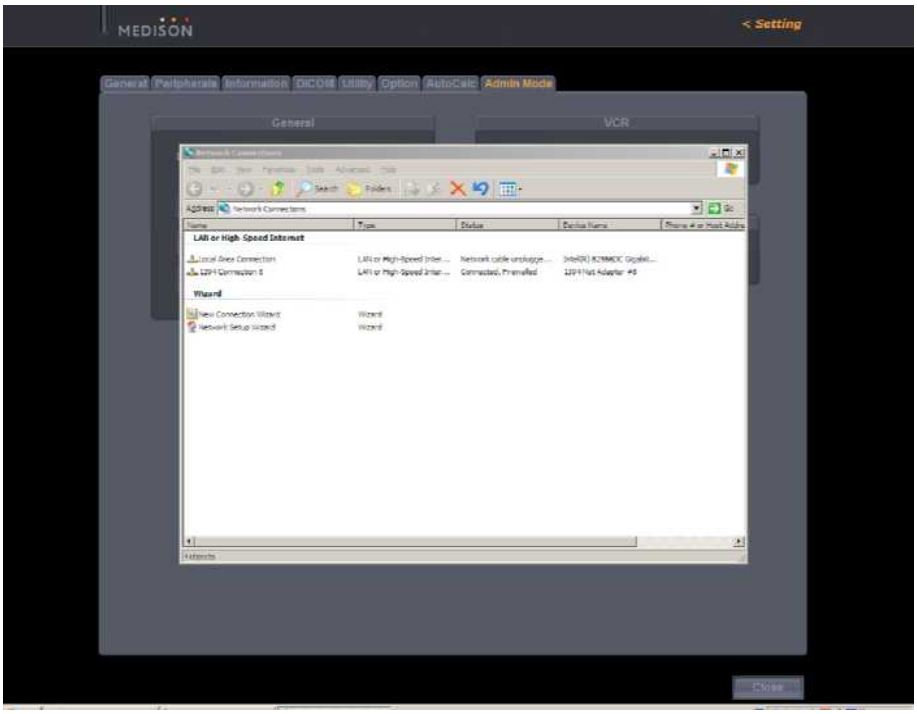
You can select the scan type for Video Out through filter. Supported scan types are NTSC and PAL.

2) Set Graphic Card

You can Set the graphic Card. If you press [Set Graphic Card], the VGA self test function is executed. Do not press button during the VGA Self test function

6.5.2.6 Network Configuration

The Windows XP Network Configuration screen appears.
You can set up Network Settings such as DICOM, etc.



[Figure 6-7] Network Configuration

6.6 Adding and Deleting Options

This section describes how to add and delete options from SONOACE X8.

Adding and Deleting Options consist of Unlock / Lock types. Unlock means a state in which an option is available, while Lock means a state in which an option is unavailable.

Options are classified into software and hardware type. You can view the contents of an option in the Setting Mode.

6.6.1 Option Types

SONOACE X8 options become available by entering an Option Password or installing hardware.

For option types and registration methods, refer to the following table.

Option	Registration Method (Unlock)
3D	Adding Motor Board + Motor Board Installation
3D XI	Entering Option Password
Cardiac Measurement	Entering Option Password
CW Function	CW Board Installation + Entering Option Password
Spatial Compound Image	Entering Option Password
DICOM	Entering Option Password
DICOM SR	Entering Option Password
ECG	ECG Installation + Select ECG Install in the Admin Mode.
Dynamic MR	Dongle Installation + Entering the Dongle Password

[Table 6-1] Option Types

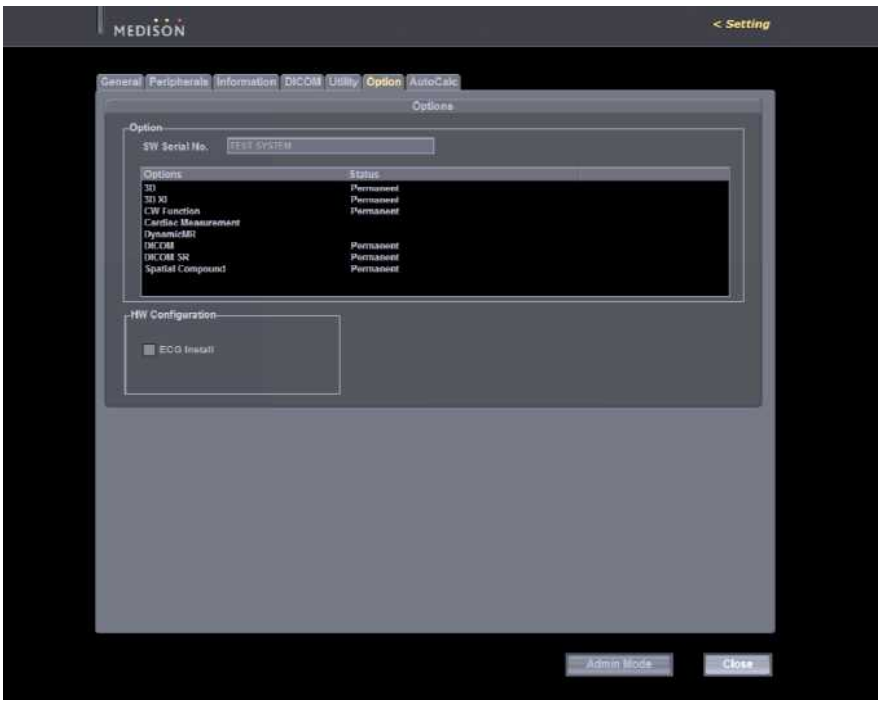
NOTE 3D XI will not work if there is no 3D Option (Motor Board).

6.6.2 Registering Options

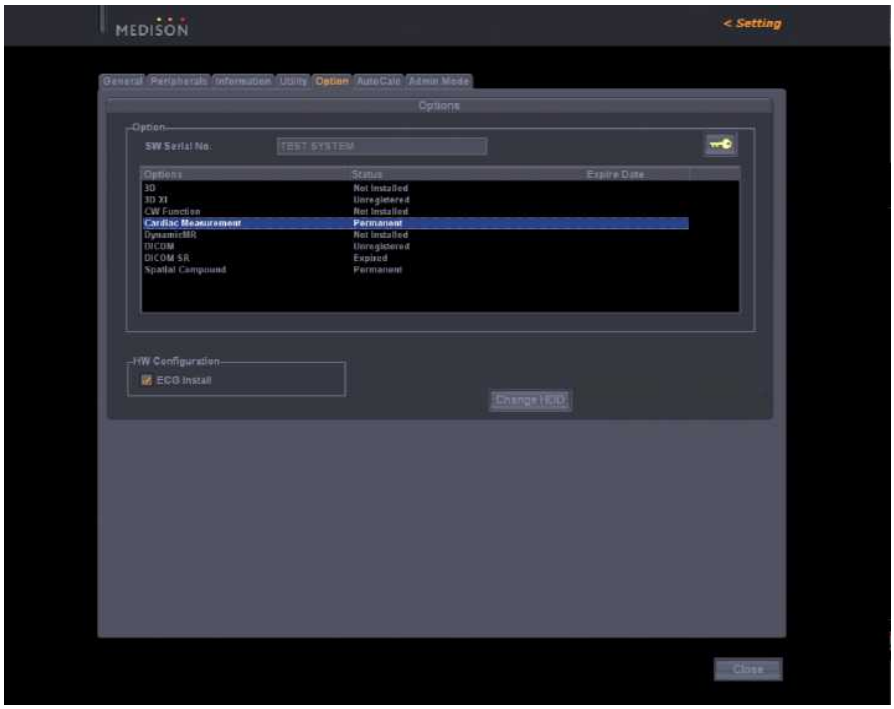
6.6.2.1 Entering Option Password

Procedures to register (Unlock) an option by entering a password will be described below.

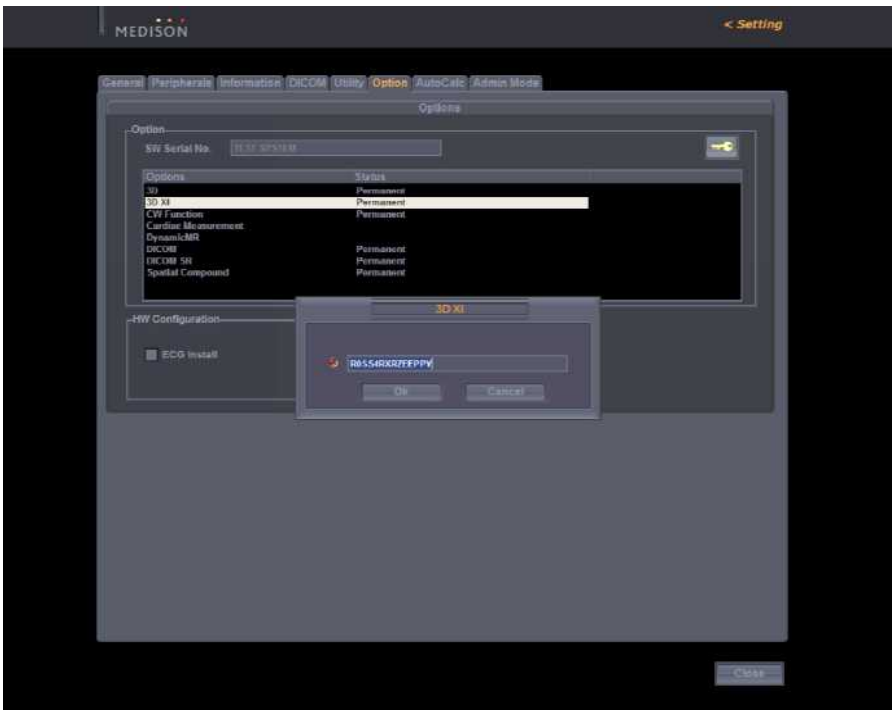
1) Switch to the Admin Mode referring to “6.5.1 Entering Admin Mode”
2) The key-shaped button at the top right of the Option tab is activated. When this button is activated, you can enter an Option Password.
3) Select an option to be added, click the key-shaped button and enter the password.
4) If the entered password is correct, press the [OK] button and restart the system



[Figure 6-8] Deactivated Option Tab



[Figure 6-9] Activated Option Tab



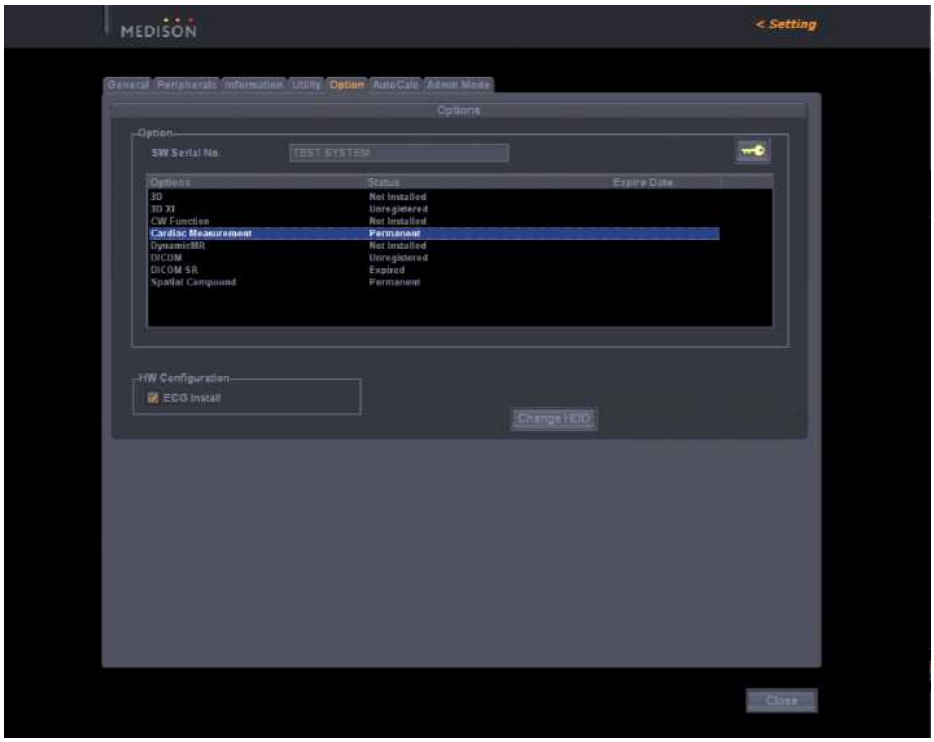
[Figure 6-10] Entering Option Password

6.6.2.2 Registering Option Password after Replacing the HDD

SONOACE X8 is designed so that the Option Password is maintained even after replacing the HDD.

Procedures to enter the Option Password after replacing the HDD are described below.

1) Switch to the Admin Mode referring to “6.5.1 Entering Admin Mode”
2) The [Change HDD] button appears in the center of the Option tab.
3) Click the [Change HDD] button. Then the Option Password of the product is entered (Unlock).
4) Confirm the Option Unlock and restart the system.



[Figure 6-11] Change HDD

6.6.2.3 Registering 3D Option

If a Motor Board is added and Option password for 3D Option is entered, the 3D Option is registered (Unlock).

6.6.2.4 Registering ECG Option

If you add the ECG Module and select [ECG Install] in the activated Option tab, the ECG Option is registered (Unlock).

6.6.2.5 Registering Dynamic MR Option

Dynamic MR is registered when the dongle is installed and the Option Password for Dynamic MR is entered.

1) When the system is on, install the dongle and then turn the power on.
2) In the activated Option tab, enter the Password provided by the Dynamic MR. Then the Dynamic MR Option is registered (Unlock).

6.6.3 Deleting Options

Procedures to delete options are described below.

1) Switch to the Admin Mode referring to “6.5.1 Entering Admin Mode”
2) The key-shaped button at the top right of the Option tab is activated. When this button is activated, you can delete an Option Password.
3) Select an option to be deleted, click the key-shaped button and then delete the password.
4) If you have deleted a password, click the [OK] button and then restart the system.

6.6.4 Option Status

Option registration statuses are listed below.

1) Not Installed: Option is not available because there is no installed hardware device.
2) Unregistered: Option is not available because the Option Password is not entered
3) Installed: Although the hardware device has been installed, Option is not available because the Option Password is not entered.
4) Permanent: The Option Password is entered and the option is available.
5) Restricted: Although the Option Password has been entered, the term for using the option is limited.

7 Troubleshooting

7.1 Overview

Chapter 7 describes basic troubleshooting procedures.

NOTE Procedures for troubleshooting expected problems are described. Unexpected situations may occur.

Procedures for troubleshooting normal problems are described.

Contents Troubleshooting

7.2 Power

7.2.1 Power Failure

This may occur if the power cord is not properly connected or the Power Supply is not working.

1) Check if the power cord is properly connected and if the cut-off switch of the ADM is turned on.
2) Check the fuse status.
3) Connect another device to the wall outlet and check if it works.
   If the device works, there is a Power Supply problem.
   If the device does not work, the problem is down to the wall outlet.
4) Check if the system fan works.
   If the fan works, the problem is not a power supply problem.
   If the fan does not work, a PC Power problem is likely.
5) Check if the NOR Alarm LED of ADM is on.
   If the NOR LED is on, DDM is normal.
   If the OVP, OLP or OTP LED is on, there is a problem with the DDM.
6) Disconnect the power cord and connect it again after 1 or 2 minutes.
   When you turn the Power Switch on and off several times, the Power Supply works for 1 or 2 minutes without supplying power.
7) Check the output voltage of the ADM.
   The input voltage for the PC Power Supply is 110V/220V.
   The input voltage for the DDM is around 24V.
   If the voltage is not within the normal range, an ADM problem is likely.
8) Check the PC Power Supply and DDM.

7.2.2 Power cannot be turned off

A software error or PC Motherboard, PCI Board, DVI Board or LCD IF Board problem is likely.

1) The power is automatically turned off when the Power Switch is pressed for more than 3 seconds.If software such as printer software is running or an operating system error occurs, the power is not turned off.
2) If you cannot turn the power off after completing the procedures in 1), a PC Motherboard, PCI Board, DVI Board or LCDIF Board problem is likely.

7.2.3 Power is automatically turned off

Power cord, PC Mother Board, PCI Board, or LCDIF Board trouble is expected.

1) Check if the power cord is properly connected and if the cut-off switch of ADM is turned on.
2) Check the fuse status.
3) Connect another device to the wall outlet and check if it works.
   If the device works, it is due to Power Supply problem.
   If the device does not work, it is due to wall outlet problem.
4) If the power is automatically turned off after completing the procedures of "1), 2), and 3)", PC Mother Board, PCI Board, DVI Board or LCD IF Board trouble is expected.

7.3 Monitor

7.3.1 Blank Screen

DVI Cable or VGA Cable is improperly connected or monitor or PC Part trouble is expected.

1) Try to print to check the product status.
   If printing is normal, monitor or PC Part trouble is expected.

2) Check the cable is properly connected with the monitor.
   Check the DVI Cable connection of the PC Part and LCD IF Board.
   Check the DVI Cable connection of the LCD IF Board and monitor.
   Check the DVI Cable and VGA Cable.

3) If no problem has been found in the above "1) and 2)", monitor and PC Part trouble is expected. Check the DVI Board and VGA Card of the PC Part.

7.3.2 Screen Color is Abnormal

DVI Cable of the monitor or PC Part is improperly connected or monitor or PC Part trouble is expected.

1) Check the monitor connection cable status.
   Check the DVI Cable connection of the PC Part and LCDIF Board.
   Check the DVI Cable connection of the LCDIF Board and monitor.
   Check the DVI Cable and VGA Cable.

2) If no problem has been found in the above "1)", monitor and PC Part trouble is expected. Check the DVI Board and VGA Card of the PC Part.

7.4 Error Messages

7.4.1 System hangs after an error during booting

Temporary software error or product trouble is expected.

1) Turn the power off by force and then turn it on again in 1 to 2 minutes.
2) If the symptom continues after completing "1)", check when the error message appears.
   If the error message appears while Windows XP is running, operating system or PC Part trouble is expected.
   If the error message appears after SONOACE X8 logo appears, system software or Ultrasound System Part trouble is expected.

7.4.2 System works even if an error occurred

Temporary software error or product trouble is expected.

1) Turn the power off by force and then turn it on again in 1 to 2 minutes.
2) If the symptom continues after completing "1)", check when the error message appears.
   If the error message appears while Windows XP is running, operating system or PC Part trouble is expected.
   If the error message appears after SONOACE X8 logo appears, system software or Ultrasound System Part trouble is expected.

7.5 Image

7.5.1 No BW Mode Image Echo

Probe and the system connection, BF Board or DDM trouble is expected.

1) Check the connection between the probe and the system.
2) Check if probe oscillation sound is heard.
   If oscillation sound is heard, the problem may be DDM trouble.
3) Check if the NOR Alarm LED of ADM is on.
   If NOR LED is on, DDM is normal.
   If OVP, OLP or OTP LED is on, the problem is DDM trouble.
4) If no problem has been found in the above "1), 2), and 3)", BF Board trouble is expected.

7.5.2 No BW Mode Image Format

Probe and the system connection, Ultrasound System Part or PC Part trouble is expected.

1) Check the connection between the probe and the system.
2) Check if probe oscillation sound is heard.
   If oscillation sound is heard, the problem may be DDM trouble.
3) Check if the NOR Alarm LED of ADM is on.
   If NOR LED is on, DDM is normal.
   If OVP, OLP or OTP LED is on, the problem is DDM trouble.
4) If no problem has been found in the above "1), 2), and 3)", Ultrasound System Part or PC Part trouble is expected.

7.5.3 Noise Like Rain over the BW Mode Image (Noise)

Power noise or BF Board trouble is expected.

1) Check if the system shares the wall outlet with another device.
   If the system shares the wall outlet with a device that uses electric motor or consumes high power, noise may be generated.
2) If the symptom continues when you connect the system to the wall outlet of another room, the problem is power noise.
3) If no problem has been found in the above "1) and 2)", BF Board trouble is expected.

7.5.4 PW Doppler Mode Trouble

Ultrasound System trouble is expected.

1) If BW Mode is normal, BE Board trouble is expected.

2) If BW Mode has a problem, BF Board trouble is expected.

7.5.5 CW Doppler Mode Trouble

Ultrasound System trouble is expected.

1) If PW Doppler Mode is normal, CW Board trouble is expected.

2) If PW Doppler Mode has a problem, BE Board trouble is expected.

7.5.6 Color Doppler Mode Trouble

Ultrasound System trouble is expected.

1) If BW Mode is normal, BE Board trouble is expected.

2) If BW Mode has a problem, BF Board trouble is expected.

7.5.7 Motion Mode Trouble

Ultrasound System trouble is expected.

1) If BW Mode is normal, BE Board trouble is expected.

2) If BW Mode has a problem, BF Board trouble is expected.

7.5.8 3D and Li ve 3D Trouble

Ultrasound System, PC Part, or 3D Probe trouble is expected.

1) If BW Mode is normal, BE Board trouble is expected.

2) If BW Mode has a problem, BF Board trouble is expected.

8 Disassembly and Reassembly

8.1 Overview

Chapter 8 describes how to disassemble SONOACE X8.

Refer to this chapter when you upgrade or repair the hardware.

WARNING

The system contains dangerous high voltage. Never disassemble the system. There is a risk of electric shock and injury.

The repair of the system and the replacement of parts must be carried out by an authorized engineer or the customer care department of MEDISON Co., Ltd.

The company is shall not be held liable for any injury and damage caused by not following this warning.

WARNING

When working with the system on, do not wear a static electricity protective wristband. There is a risk of electric shock and injury.

NOTE

When disassembling or reassembling the system, wear static electricity protective gloves and a wristband.
These will prevent any accidents due to carelessness, and damage to the system due to static electricity.

[Figure 8-1] Static Electricity Protective Gloves and Wristband

Contents Disassembly and Reassembly

8.2 Disassembly and Reassembly of the External Case

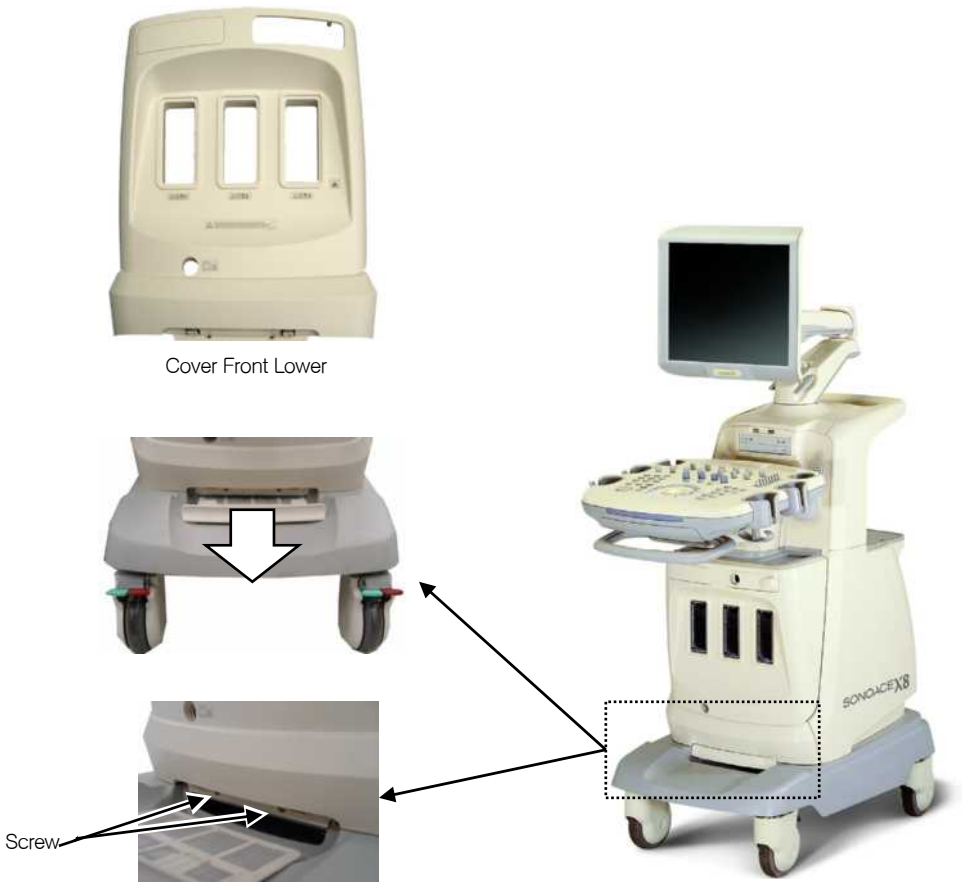
8.2.1 Preparations

Prepare a (+) screwdriver and static electricity protective gloves.

Shut down the system referring to “3.7 System Shutdown (Power Shut Down)”.

8.2.2 Cover Front Lower

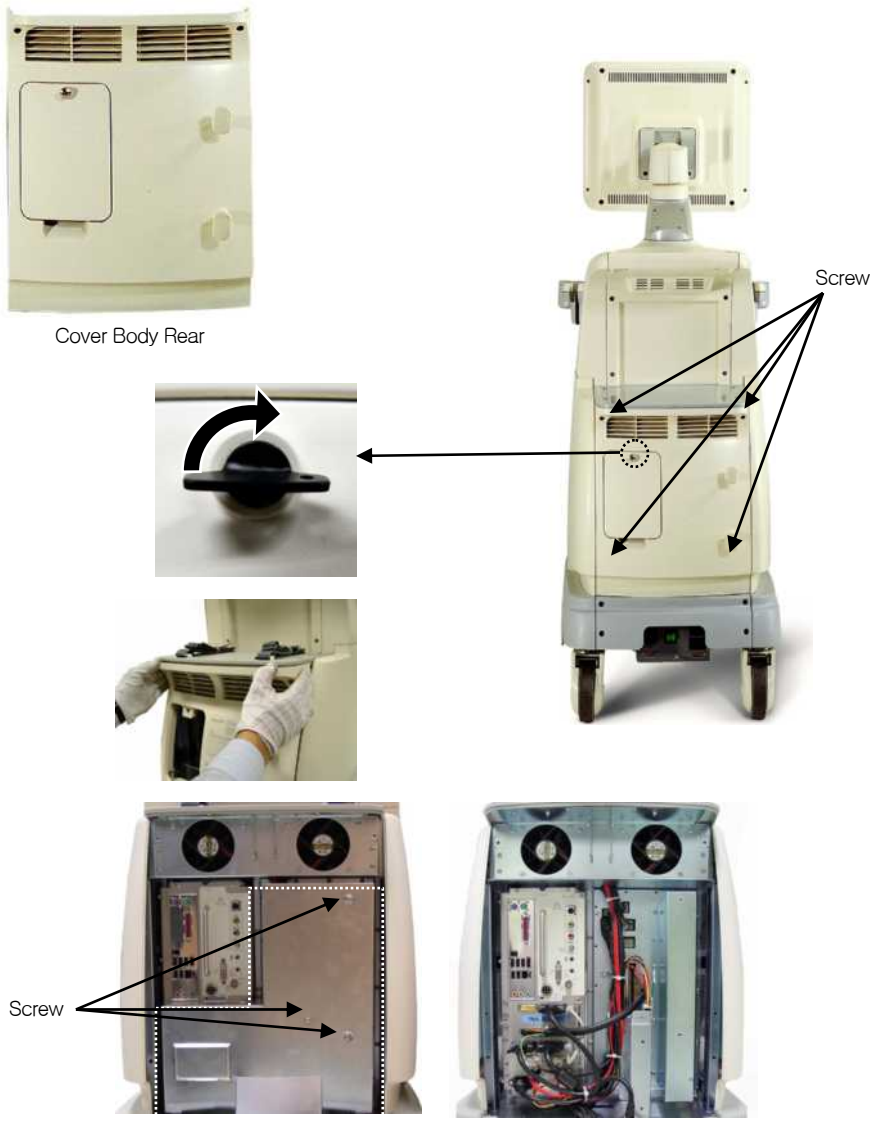
1) Hold and pull the Air Filter in order to separate it.
2) Remove the 2 screws at the bottom of the Cover Front Lower using the (+) screwdriver.
3) Hold and pull the lower part of the Cover Front Lower to separate it.



[Figure 8-2] Cover Front Lower

8.2.3 Cover Body Rear

1) Hold the handle of the Cover Body Rear Door, pull it while turning it through 90 degrees to separate it.
2) Remove the 4 screws at the upper part of the Cover Body Rear using the (+) screwdriver.
3) Hold and pull the upper part of the Cover Body Rear to separate it.
4) Remove the screws at the EMI Cover using the (+) screwdriver.
5) Hold and pull the of the EMI Cover.

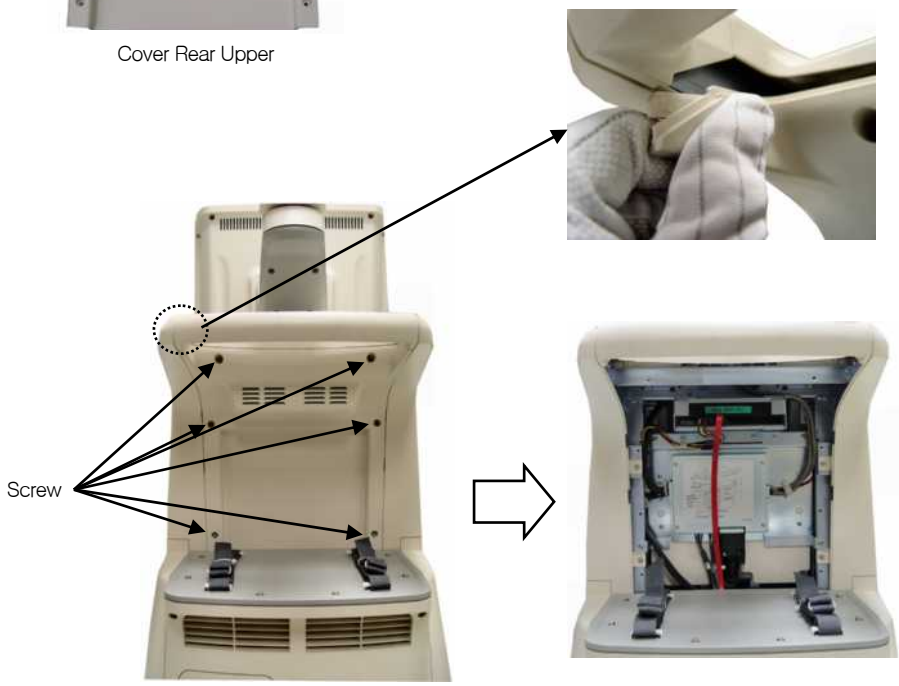


[Figure 8-3] Cover Body Rear

8.2.4 Cover Rear Upper

1) Remove the 6 screws of the Cover Rear Upper using the (+) screwdriver.
2) Hold and pull the upper part of the Cover Rear Upper to separate it.

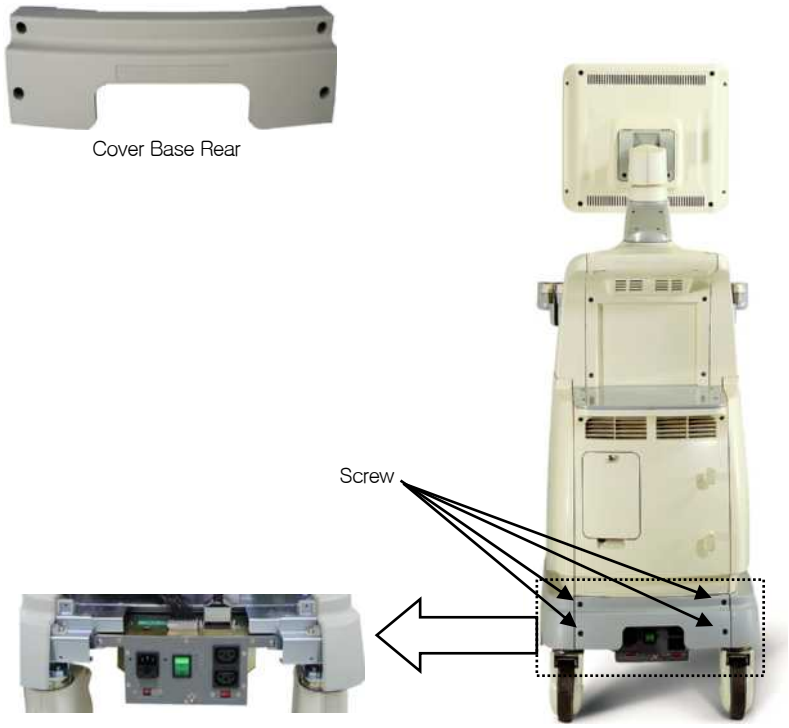
Cover Rear Upper



[Figure 8-4] Cover Rear Upper

8.2.5 Cover Base Rear

1) Remove the 4 screws of the Cover Base Rear using the (+) screwdriver.
2) Hold and pull the Cover Base Rear to separate it.



[Figure 8-5] Cover Base Rear

8.3 Disassembly and Reassembly of the LCD Monitor

8.3.1 Preparations

Prepare a (+) screwdriver and static electricity protective gloves.

Prepare an LCD Monitor Panel protective cover.

Shut down the system referring to “3.7 System Shutdown (Power Shut Down)”

8.3.2 LCD Monitor

1) Lift the LCD Monitor up. Ensure there is sufficient space for disassembly.
2) Remove the 2 screws from the Cover Rear Back LCD using the (+) screwdriver and separate it.
3) Remove the 8 screws from the Cover Rear LCD using the (+) screwdriver and separate it.
4) Put the LCD Monitor down and secure it so that the LCD Panel is safe.
5) Hold the LCD Panel and remove the 4 fixing screws of the LCD Panel using the (+) screwdriver.

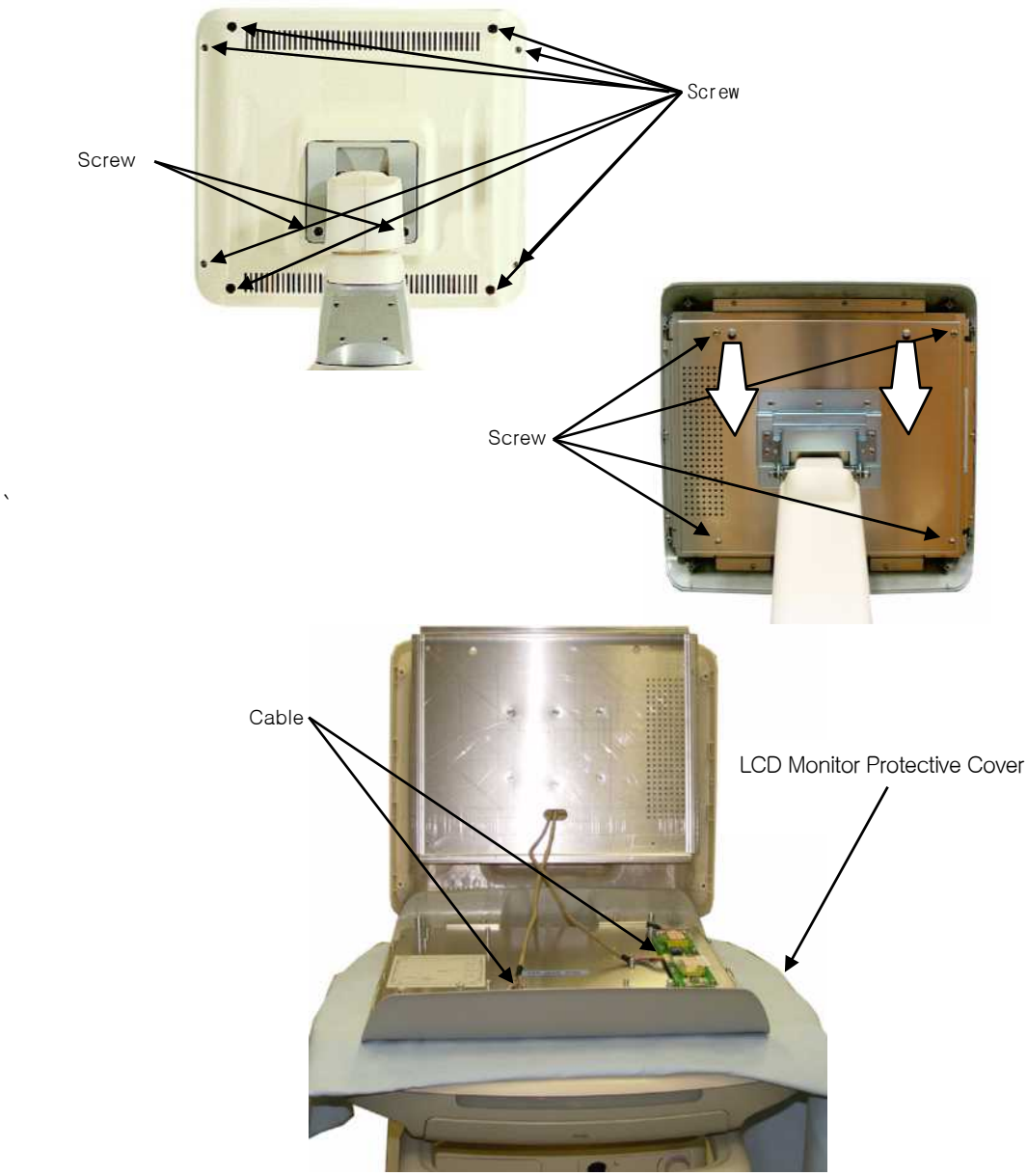
WARNING

Although there is a catch to secure the LCD Panel, it may come off and fall, which will damage it.

When disassembling or assembling the LCD Monitor, it is recommended to do it with another person.

6) Hold the LCD Panel with both hands and disassemble it. Then place it over the LCD Monitor protective cover. Since the LCD Cable may be damaged, work slowly.
7) Remove the fixed screws using the (+) screwdriver and separate the LCD Cable.

[Figure 8-6] LCD Monitor (1)



[Figure 8-6] LCD Monitor (2)

8.4 Disassembly and Reassembly of the Ultrasound System PCB Part

8.4.1 Preparations

Prepare a (+) screwdriver and static electricity protective gloves.

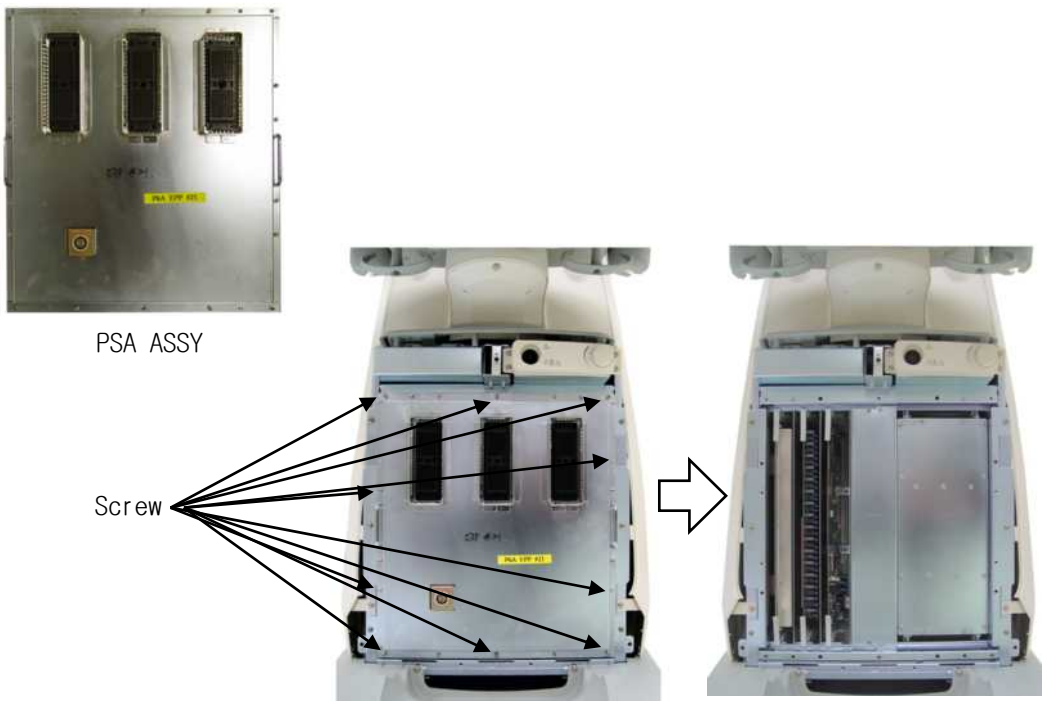
Shut down the system referring to “3.7 System Shutdown (Power Shut Down)

8.4.2 PSA ASSY

1) Disassemble the Cover Front Lower referring to “8.2.2 Cover Front Lower”.
2) Remove the 10 screws from the PSA ASSY using the (+) screwdriver.
3) Hold the PSA ASSY with both hands and pull it to disassemble it.

WARNING

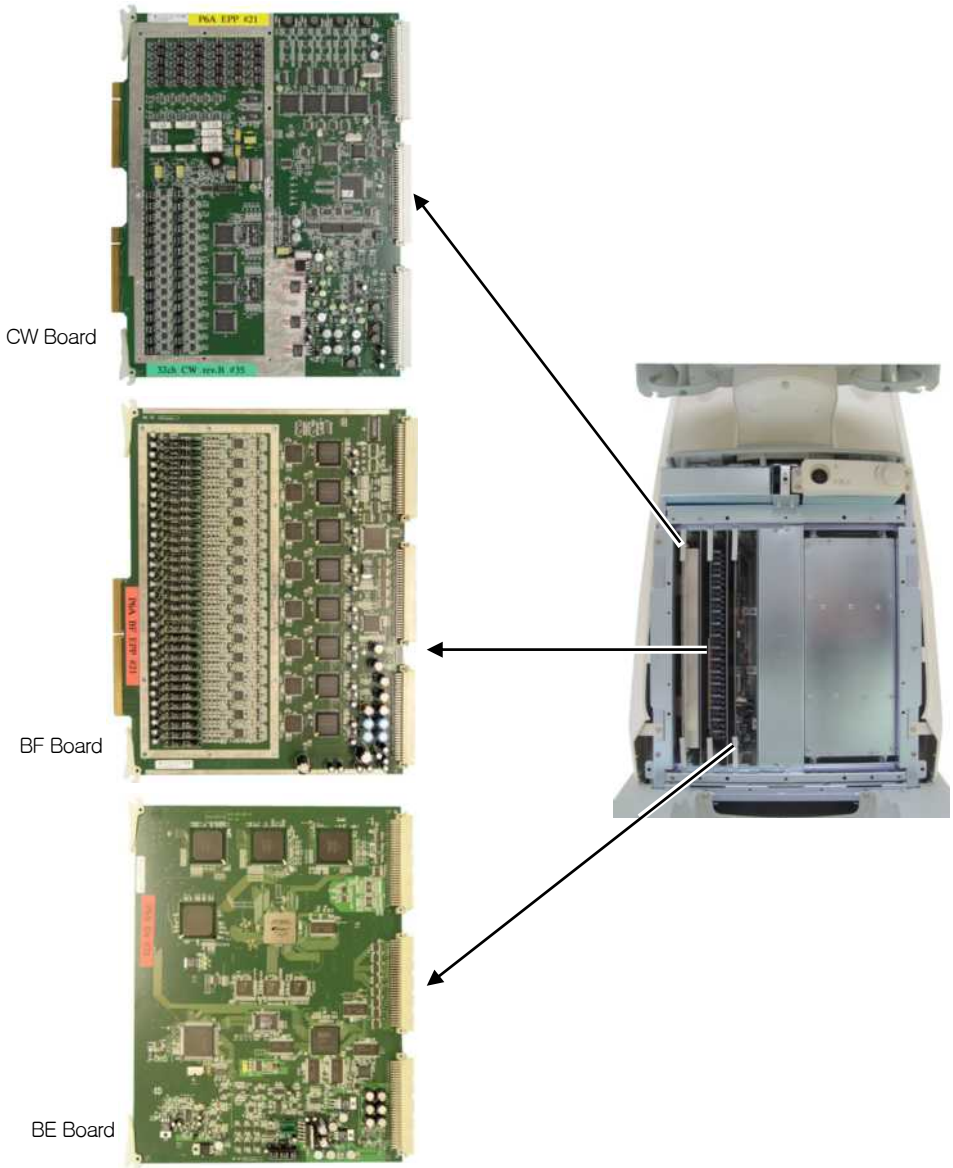
Since the edge of the PSA ASSY is sharp, disassemble it with care.



[Figure 8-7] PSA ASSY

8.4.3 CW Board, BF Board , BE Board

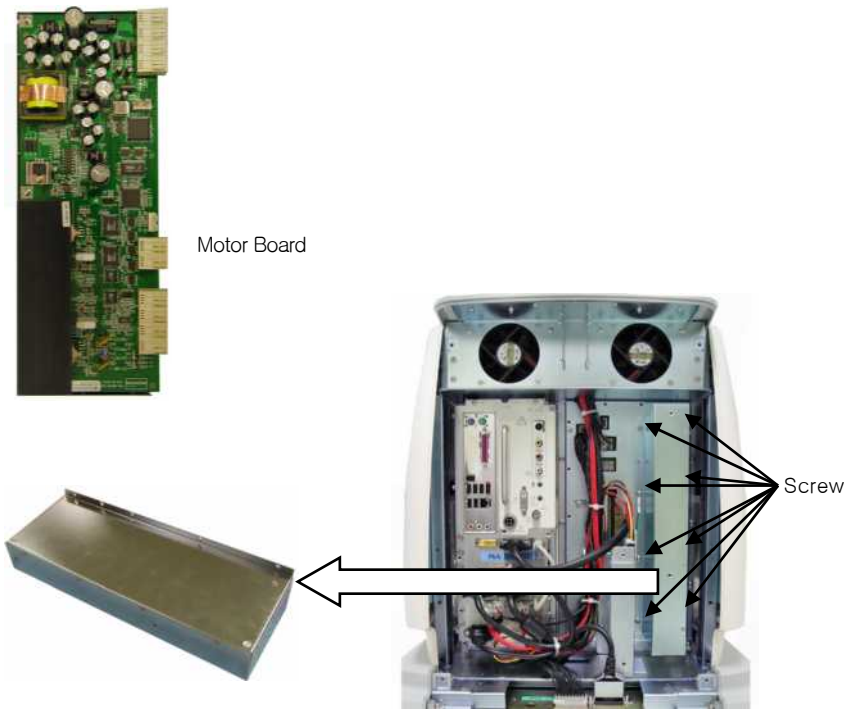
1) Disassemble the Cover Front Lower referring to “8.2.2 Cover Front Lower”.
2) Disassemble the PSA ASSY referring to “8.4.2 PSA ASSY”.
3) Hold the handle of the CW Board with both hands and pull it to separate it.
4) Hold the handle of the BF Board with both hands and pull it to separate it.
5) Hold the handle of the BE Board with both hands and pull it to separate it.



[Figure 8-8] CW Board, BF Board , BE Board

8.4.4 Motor Board

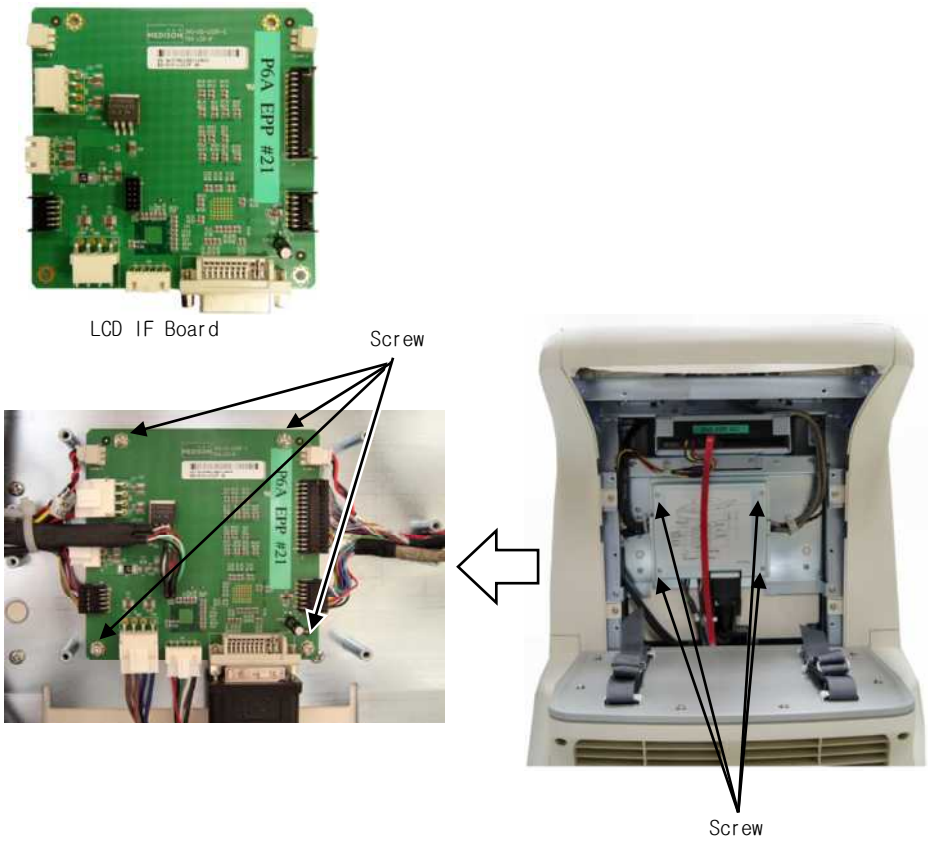
1) Disassemble the Cover Body Rear referring to “8.2.3 Cover Body Rear”.
2) Remove the 8 screws of the EMI Cover Motor Board using the (+) screwdriver.
3) Hold the Motor Board and pull it straight out to separate it.
4) Separate the Motor Board from the EMI Cover.



[Figure 8-9] Motor Board

8.4.5 LCD IF Board

1) Disassemble the Cover Rear Upper referring to “8.2.4 Cover Rear Upper”.
2) Separate the ODD S-ATA Cable and make sufficient space for the disassembly.
3) Remove the 4 screws of the EMI Cover LCD IF Board using the (+) screwdriver and separate it.
4) Separate the cable from the LCD IF Board.
5) Remove the 4 screws of the LCD IF Board using the (+) screwdriver and separate it.



[Figure 8-10] LCD IF Board

8.5 Disassembly and Reassembly of the HDD

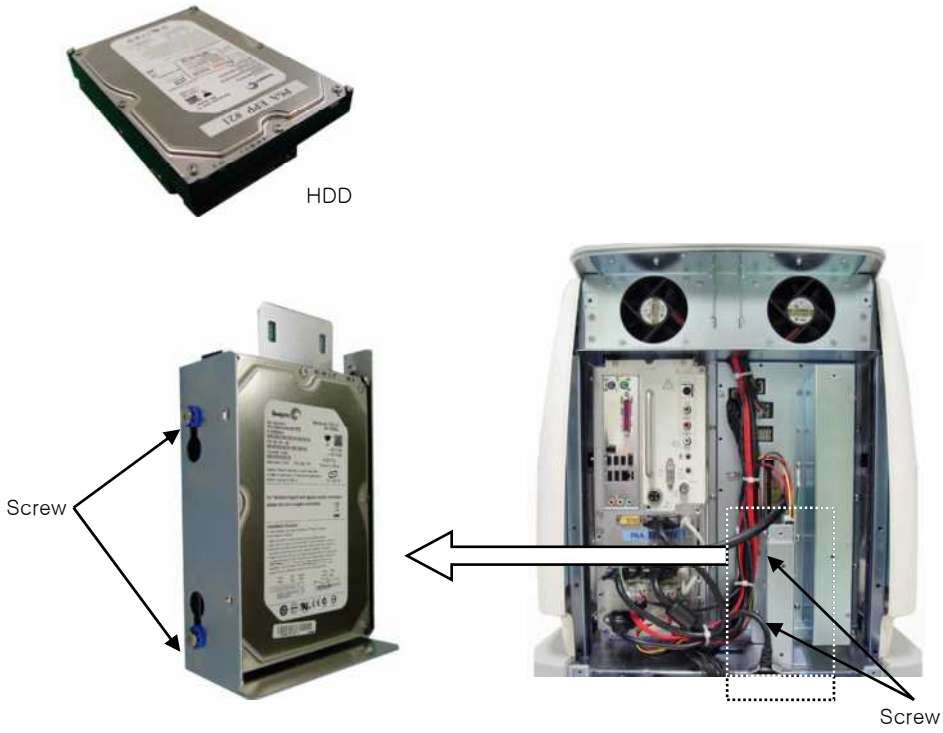
8.5.1 Preparations

Prepare a (+) screwdriver and static electricity protective gloves.

Shut down the system referring to “4.7 System Shutdown (Power Shut Down)”

8.5.2 HDD

1) Disassemble the Cover Body Rear referring to “8.2.3 Cover Body Rear”.
2) Separate the HDD S-ATA Cable and Power Cable.
3) Remove the 4 screws of the EMI Cover HDD using the (+) screwdriver and separate it.
4) Separate the HDD from the EMI Cover.



[Figure 8-11] HDD

8.6 Disassembly and Reassembly of the PC Part

8.6.1 Preparations

Prepare a (+) screwdriver and static electricity protective gloves.

Shut down the system referring to “3.7 System Shutdown (Power Shut Down)”.

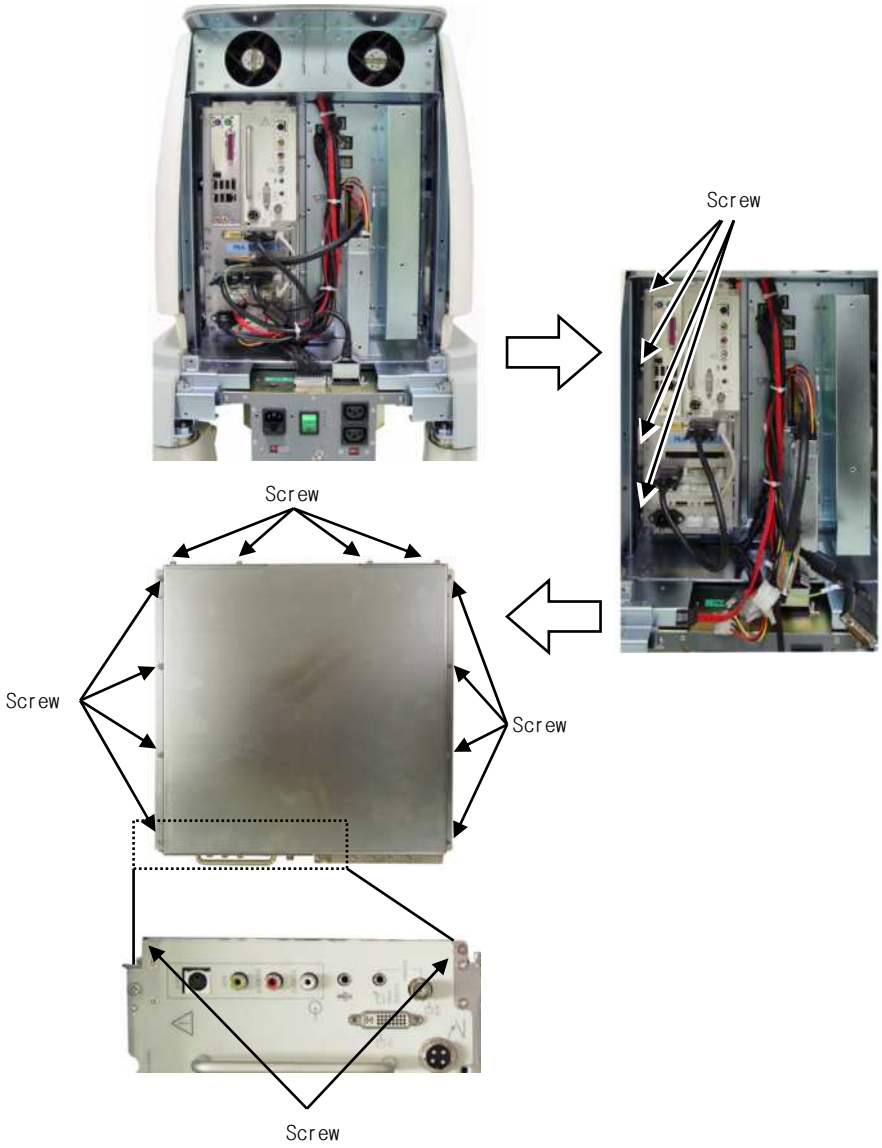
8.6.2 PC Part

1) Disassemble the Cover Body Rear referring to “8.2.3 Cover Body Rear”.
2) Disassemble the Cover Base Rear referring to “8.2.5 Cover Base Rear”.
3) Separate all the cables connected to the PC Part.
4) Remove the 4 screws of the PC Part using the (+) screwdriver.
5) Hold the handle of the PC Part and pull it to separate it.
6) Remove the 8 screws of the Cover PC Part using the (+) screwdriver.

WARNING

Since the edge of PC Part is sharp, disassemble it with care.

[Figure 8-12] PC Part (1)



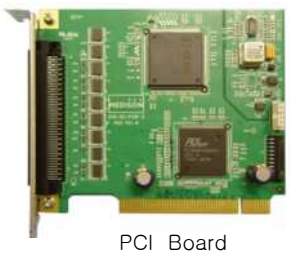
[Figure 8-12] PC Part (2)

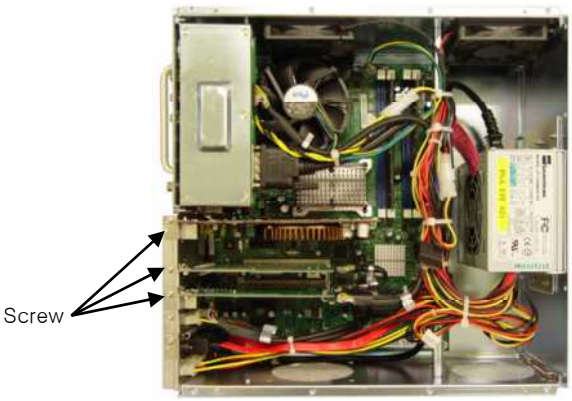
8.6.3 DVI Board, PCI Board, VGA Card

1) Disassemble the PC Part referring to “8.6.2 PC Part”.
2) Remove the fixing screw for the DVI Board using the (+) screwdriver.
3) Separate all the cables connected to the DVI Board.
4) Hold the DVI Board and separate it from the PCI Slot.
5) Disassemble the PCI Board in the same way as you disassembled the DVI Board.
6) Unlock the Card and disassemble the VGA Card in the same way as you disassembled the DVI Board.


VGA Card


DVI Board

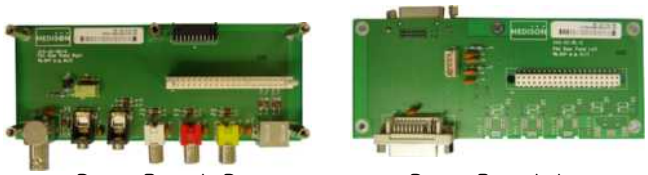

PCI Board

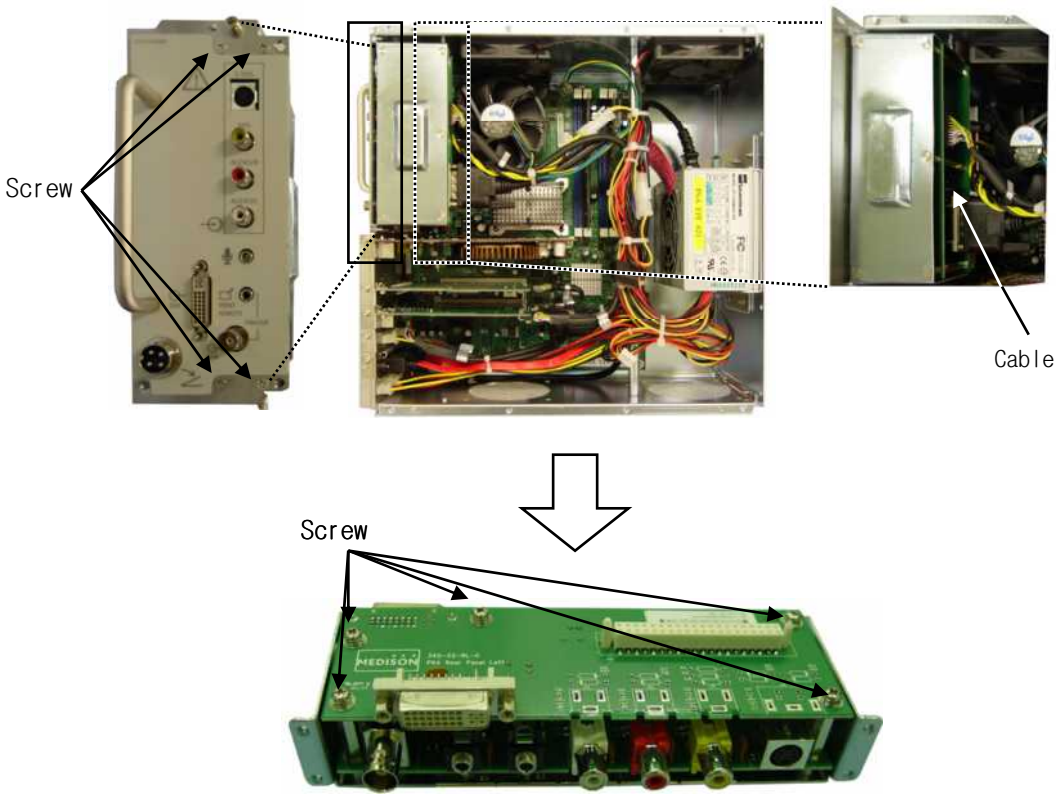


[Figure 8-13] DVI Board, PCI Board, VGA Card

8.6.4 Rear Board

1) Disassemble the PC Part referring to “8.6.2 PC Part”.
2) Separate all the cables connected to the Rear Board.
3) Remove the 4 screws of the Rear Board using the (+) screwdriver.
4) Disassemble the Rear Board, which is connected by screws.





[Figure 8-14] Rear Board

8.6.5 PC Mother Board

1) Disassemble the PC Part referring to “8.6.2 PC Part”.
2) Disassemble the DVI Board, PCI Board, and VGA Card referring to “8.6.3 DVI Board, PCI Board and VGA Card”.
3) Disassemble the Rear Board referring to “8.6.4 Rear Board”.
4) Remove the 11 screws of the PC Motherboard using the (+) screwdriver and separate it.

[Figure 8-15] PC Mother Board

8.7 Disassembly and Reassembly of the Power Supply

8.7.1 Preparations

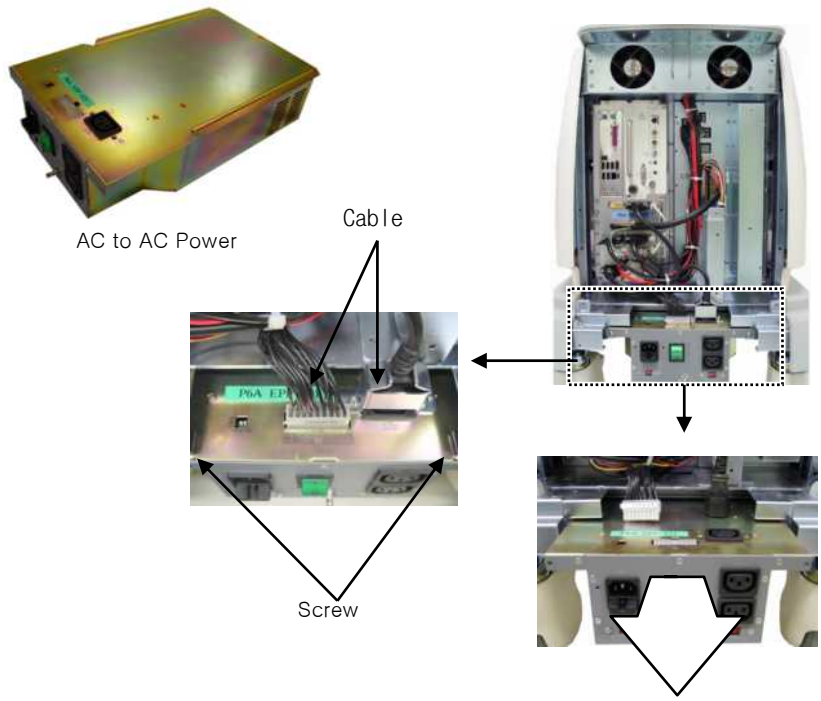
Prepare a (+) screwdriver and static electricity protective gloves.

Shut down the system referring to “6.7 System Shutdown (Power Shut Down)”.

8.7.2 AC to DC Power Module

1) Disassemble the Cover Body Rear referring to “8.2.3 Cover Body Rear”.
2) Disassemble the Cover Base Rear referring to “8.2.5 Cover Base Rear”.
3) Remove the cable connected to the AC to DC Power Module.
4) Remove the 2 screws of the AC to DC Power Module using the (+) screwdriver.
5) Hold the AC to DC Power Module and pull it to separate it.

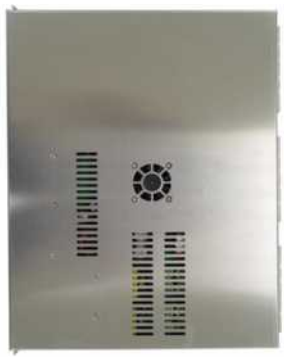
WARNING Since the ADM is heavy, take care when disassembling it. If the ADM falls suddenly, it may cause an injury.



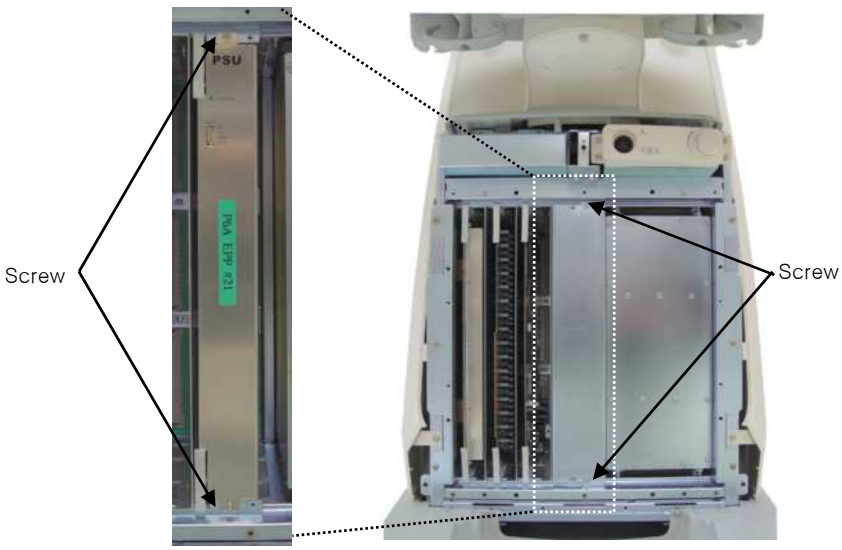
[Figure 8-16] AC to DC Power Module

8.7.3 DC to DC Power Module

1) Disassemble the Cover Front Lower referring to “8.2.2 Cover Front Lower”.
2) Remove the 2 screws of the DC to DC Power Module using the (+) screwdriver.
3) Hold the handle of the DC to DC Power Module with both hands and pull it to separate it.



DC to DC Power Module

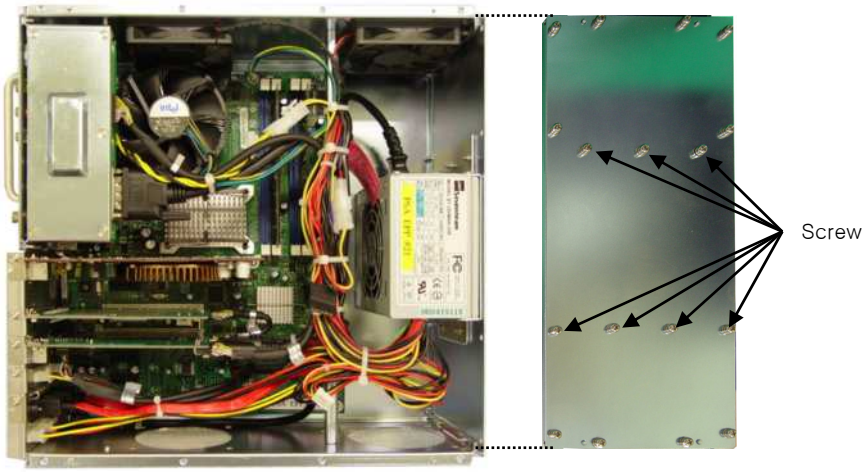


[Figure 8-17] DC to DC Power Module

8.7.4 PC Power Supply

1) Disassemble the PC Part referring to “8.6.2 PC Part”.
2) Separate the cable connected to the PC Power Supply.
3) Remove the 7 screws of the PC Power Supply using the (+) screwdriver.

PC Power Supply



[Figure 8-18] PC Power Supply

8.8 Disassembly and Reassembly of the Control Panel

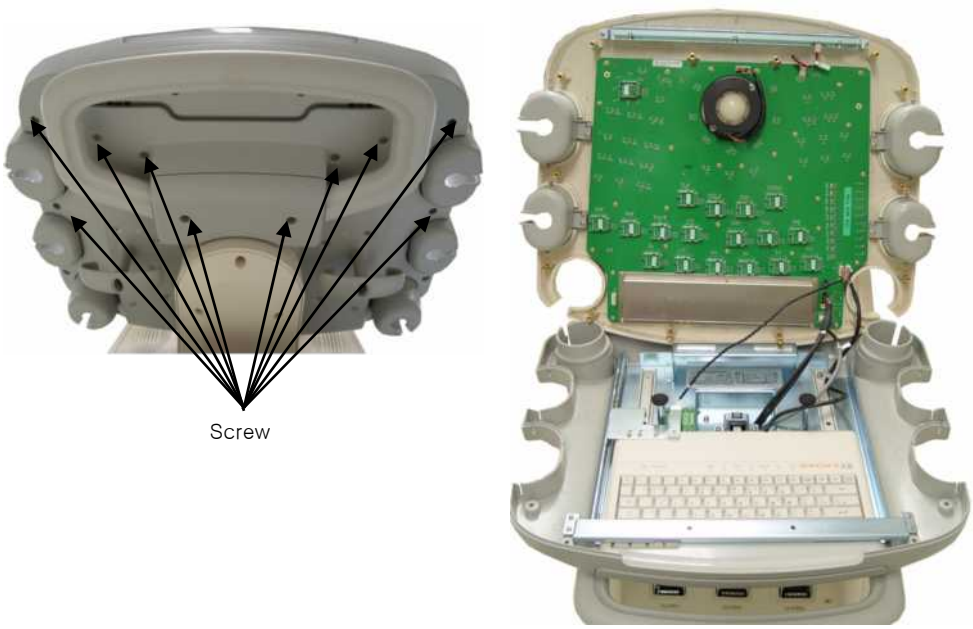
8.8.1 Preparations

Prepare a (+) screwdriver and static electricity protective gloves.

Shut down the system referring to “3.7 System Shutdown (Power Shut Down)”

8.8.2 Control Panel

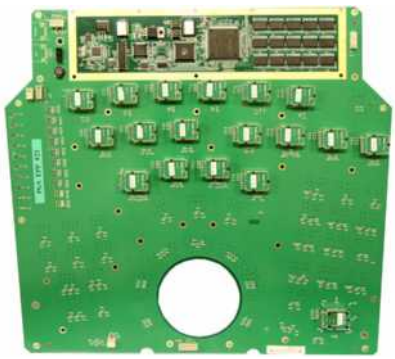
1) Disassemble it while the Alphanumeric Keyboard is open.
2) Remove the 14 screws of the Control Panel using the (+) screwdriver.
3) Separate the cable connected to the Key Matrix Board.
4) Separate the upper board of the Control Panel.

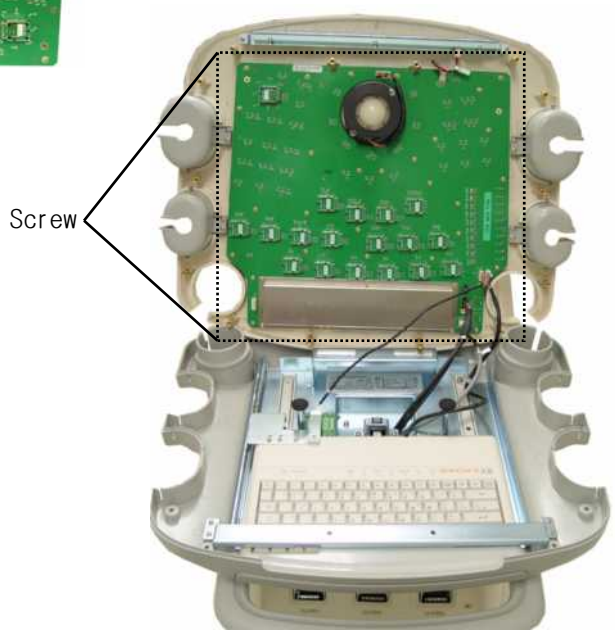


[Figure 8-19] Control Panel

8.8.3 Key Matrix Board

1) Disassemble the upper board of the Control Panel referring to “8.8.2 Control Panel”.
2) Take the Switch Cap off the Control Panel.
3) Remove the 32 screws of the Key Matrix Board using the (+) screwdriver and separate it.

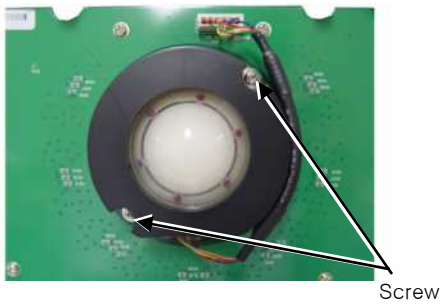

Key Matrix Board



[Figure 8-20] Key Matrix Board

8.8.4 Track Ball

1) Disassemble the upper board of the Control Panel referring to “8.8.2 Control Panel”.
2) Separate the cable connected to the Key Matrix Board.
3) Remove the 2 screws for the Trackball using the (+) screwdriver and separate it.

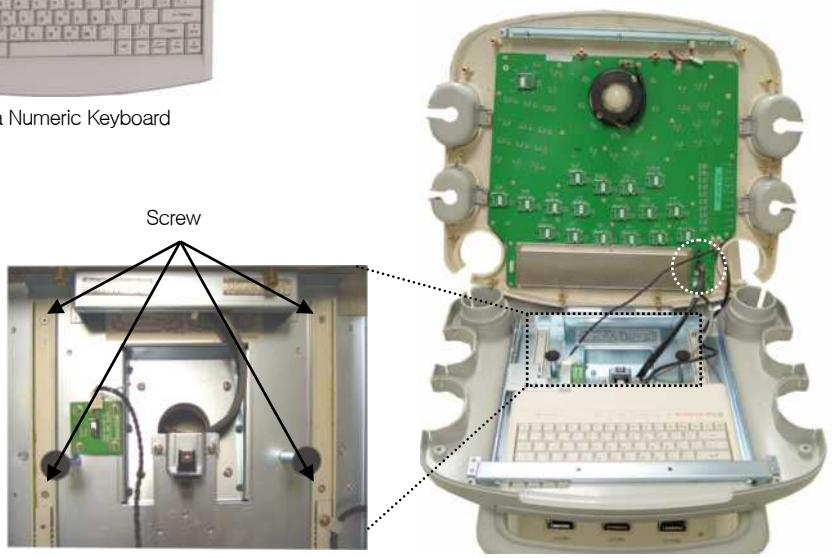


[Figure 8-21] Track Ball

8.8.5 Alpha Numeric Keyboard

1) Disassemble the upper board of the Control Panel referring to “8.8.2 Control Panel”.
2) Separate the cable connected to the Key Matrix Board.
3) Open the Alphanumeric Keyboard.
4) Remove the 4 screws of the Alphanumeric Keyboard using the (+) screwdriver and disassemble it.

Alpha Numeric Keyboard



[Figure 8-22] Alpha Numeric Keyboard

8.9 Disassembly and Reassembly of the DVD

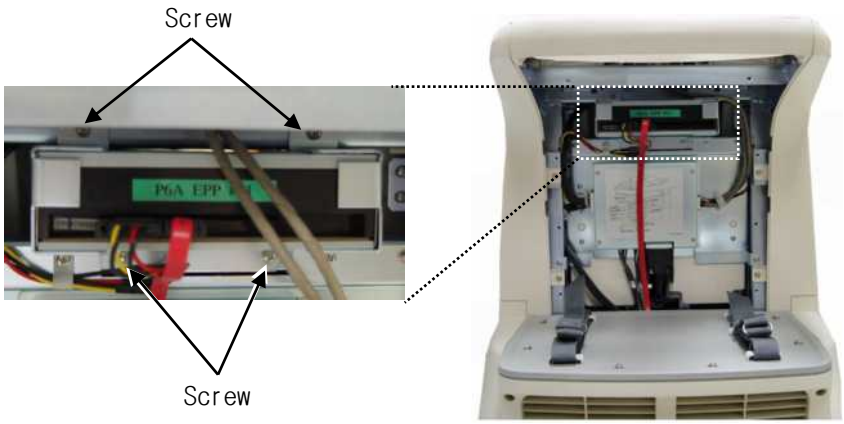
8.9.1 Preparations

Prepare a (+) screwdriver and static electricity protective gloves.

Shut down the system referring to “3.7 System Shutdown (Power Shut Down)”.

8.9.2 DVD

1) Disassemble the Cover Rear Upper referring to “8.2.4 Cover Rear Upper”.
2) Separate the cable connected to the ODD.
3) Remove the 4 screws fixing the ODD using the (+) screwdriver.
4) 4) Hold the ODD and pull it to separate it.



[Figure 8-23] DVD

8.10 Disassembly and Reassembly of the ECG Module

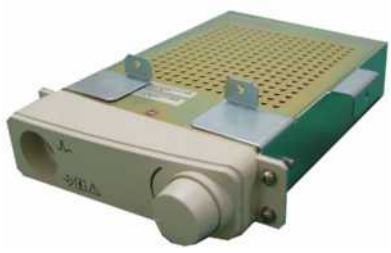
8.10.1 Preparations

Prepare a (+) screwdriver and static electricity protective gloves.

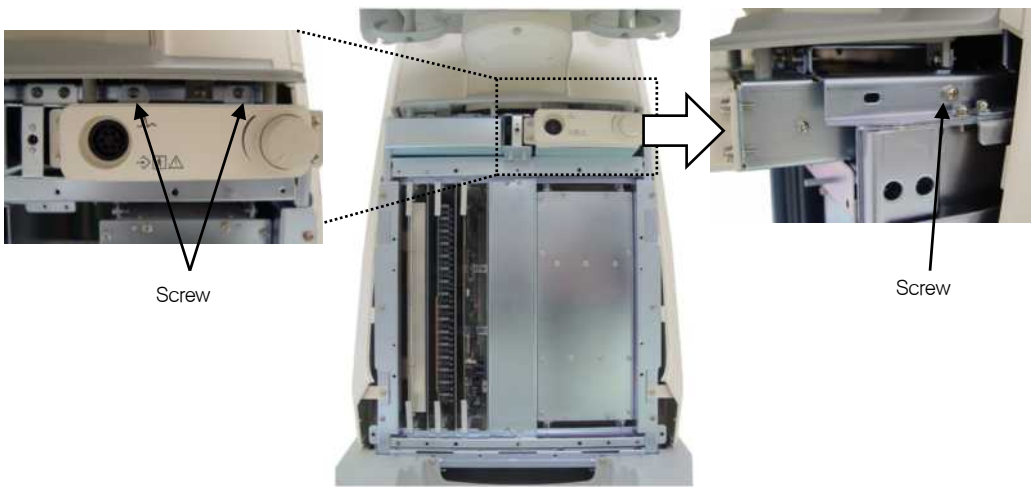
Shut down the system referring to “3.7 System Shutdown (Power Shut Down)”.

8.10.2 ECG Module

1) Disassemble the Cover Front Lower referring to “8.2.2 Cover Front Lower”.
2) Remove the 3 screws fixing the ECG Module using the (+) screwdriver.
3) Hold the ECG Module and pull it to separate the connected cable.



ECG Module



[Figure 8-24] ECG Module

9 Probe

9.1 Overview

The probe is a device that sends and receives ultrasound for acquiring image data. It is also called a Transducer or Scanhead.

The system limits patient contact temperature to 43 degrees Celsius, and acoustic output 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.

Contents Probe

9.2 Probe List

The ultrasound image scanner uses probes to obtain graphic data of the human body and then displays it on the screen. Always use application-specific probes in order to obtain the best quality images. It is also important to configure the probe with the best settings for the particular organ being scanned.

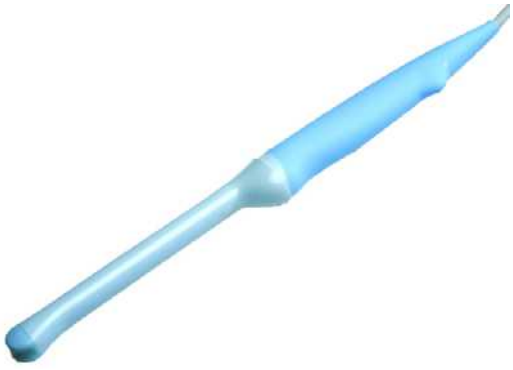
Probe	Application	Preset
C2-5EL	Abdomen	Aorta, Appendix, General, Renal
	Gynecology	Adnexa, Endometrium, General, Uterus
	OB	Early, Fetal Heart, General
C3-7EP	Abdomen	Aorta, Appendix, General, Renal
	Gynecology	Adnexa, Endometrium, General, Uterus
	OB	Early, Fetal Heart, General
HL5-12ED	Muskuloskeletal	Elbow/Wrist, General, Hand/Foot, Shoulder/Knee
	Pediatric	Abdomen, General,
	Small Parts	Breast, General, Superficial, Testicle, Thyroid
	Vascular	Arterial, Carotid, General, Venous
L5-12EC	Muskuloskeletal	Elbow/Wrist, General, Hand/Foot, Shoulder/Knee
	Pediatric	Abdomen, General,
	Small Parts	Breast, General, Superficial, Testicle, Thyroid
	Vascular	Arterial, Carotid, General, Venous
L5-12/50EP	Muskuloskeletal	Elbow/Wrist, General, Hand/Foot, Shoulder/Knee
	Abdomen	Abdomen, General,
	Small Parts	Breast, General, Superficial, Testicle, Thyroid
	Vascular	Arterial, Carotid, General, Venous
P2-4AH	Abdomen	Aorta, General, Renal
	Cardiac	Aortic arch, General
	Pediatric Cardiology	Aortic arch, General
	TCD	General
P3-5AC	Abdomen	Aorta, General, Renal
	Cardiac	Aortic arch, General
	Pediatric Cardiology	Aortic arch, General
	TCD	General

Probe	Application	Preset
NER4-9ES	Gynecology	Adnexa, Endometrium, General, Uterus
	OB	Cervix, Fetal Heart, General
	Urology	Bladder, General, Prostate
NEV4-9ES	Gynecology	Adnexa, Endometrium, General, Uterus
	OB	Cervix, Fetal Heart, General
	Urology	Bladder, General, Prostate
3D2-6ET	Abdomen	Aorta, Appendix, General, Renal
	Gynecology	Adnexa, Endometrium, General, Uterus
	OB	Early, Fetal Heart, General
3D4-8EK	Abdomen	Aorta, Appendix, General, Renal
	Gynecology	Adnexa, Endometrium, General, Uterus
	OB	Fetal Heart, Cervix, General
3D4-8ET	Abdomen	Aorta, Appendix, General, Renal
	Gynecology	Adnexa, Endometrium, General, Uterus
	OB	Fetal Heart, Cervix, General
3D5-9EK	Gynecology	Adnexa, Endometrium, General, Uterus
	OB	Early, Fetal Heart, General
	Urology	Bladder, General, Prostate
CW2.0	Cardiac	General
CW4.0	Cardiac	General
	Pediatric Cardiology	General

3D4-8ET & 3D2-6ET

L5-12/50EP

NEV4-9ES



NER4-9ES

[Figure 9-1] Medison New Probe

9.3 Thermal Index (TI) Tables

TI values displayed on the screen title bar can change depending on probes and applications. SONOACE X8 decides automatically which TI value will be displayed out of TIs, TIb, and TIc. The TI values are as follows,

Probe	Applications											
	General	Obstetrics	Gynecology	Abdomen	Pediatric Abdomen	Cardiac	PediatricCardiology	Urology	Vascular	Small Parts	Musculoskeletal	TCD
C2-5EL	TIs	TIb	TIs	TIs	TIb							
C3-7EP	TIs	TIb	TIs	TIs	TIb							
HL5-12D	TIs			TIs			TIs		TIs	TIs	TIs	
L5-12EC	TIs			TIs			TIs		TIs	TIs	TIs	
L5-12/50EP	TIs			TIs			TIs		TIs	TIs	TIs	
P2-4AH	TIs			TIs		TIs						TIc
P3-5AC	TIs			TIs		TIs						TIc
NER4-9ES	TIs	TIb	TIs					TIs				
NEV4-9ES	TIs	TIb	TIs					TIs				
3D2-6ET	TIs	TIb	TIs	TIs	TIb							
3D5-8EK	TIs	TIb	TIs	TIs	TIb							
3D4-8ET	TIs	TIb	TIs	TIs	TIb							
3D5-9EK	TIs	TIb	TIs	TIs	TIb							
CW2.0	TIs					TIs						
CW4.0	TIs					TIs						

9.4 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.

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
  - Lanolin
  - Any lotions or gels containing perfume

9.5 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.

9.5.1 Install the Sheaths

1) Put on sterile gloves. Unpack the sheath and fill it with acoustic coupling gel.
2) Insert the probe into the sheath and pull the latex tip to cover the probe completely. If possible, cover the probe cable as well.
3) Ensure that there is no air bubble within the ultrasound gel. If necessary, secure the sheath to the probe and the probe cable.
4) Dispose of the sheath after use.

WARNING

- Always keep sheaths in a sterile state.
- Sheaths are disposable. Do not reuse them.
- If sheaths are torn or soiled after use, clean 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.

9.6 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.

9.6.1 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 reused, as they are complex in design and expensive. Consequently, protective devices such as sheaths must be used, and the safety instructions must be followed 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

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..

9.6.2 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 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.

9.7 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.

9.7.1 Information of Detergent, Disinfectant, and Ultrasound Gel

Use an appropriate one with following tables. The information is also listed on the Medison web site. (http://www.medison.com)

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	C2-5EL	●	●	●	●	●	●	●	●	●	●
	C3-7EP		●	●	●	●					
LA	HL5-12ED		●	●	●	●		●	x	●	
	L5-12EC	●	●	●		●					
	L5-12/50EP										
PA	P2-4AH	●		●	●	●				●	
	P3-5AC	●	●	●	★	●	●	●		●	●
EC	NER4-9ES		●	●							
	NEV4-9ES		●	●							
3D	3D2-6ET	●	●	x	●	●	●			●	
	3D4-8EK	x	x	x	●	x	x			x	x
	3D4-8ET	●	●	x	●	●	●			●	
	3D5-9EK	x	x	x	●	x	x			x	x
CW	CW2.0	●									
	CW4.0										

Names		Disinfectants					Cleaner				Gel
		Milton	Vircon	Sporox II	Gigasept AF [3]	Gigasept FF	Enzol	Klenzyme	Isopropyl alcohol(70%)	Metrizyme	Aquasonics 100 [3]
Type		Liquid						NA	Liquid		Gel
Active Ingredient		Sodium Hypochlorite	NA	Hydrogen Peroxide	Succindialdehyde, Formaldehyde	Bersteinsaure	Dodeylphenoleth oxylate, Sodium Xylene Sulfonate	Proteolytic Enzymes	Alcohol	Propylene Glycol	
CA	C2-5EL	●	●	●	●	●	●	●	●	●	●
	C3-7EP			x			●	●		●	●
LA	HL5-12ED			x			●	●	x	●	●
	L5-12EC										
	L5-12/50EP										
PA	P2-4AH			●			●	●		●	
	P3-5AC	★	x	x	x	★	●	●	x	●	●
EC	NER4-9ES										
	NEV4-9ES										
3D	3D2-6ET			x		●		●		●	●
	3D4-8EK	x	x	x	x	x					●
	3D4-8ET			x		●		●		●	●
	3D5-9EK	x	x	x	x	x					●
CW	CW2.0	●	●	x	x	●	●	●	x	●	●
	CW4.0										

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)
Glgasept 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)

9.7.2 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.

9.7.3 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.

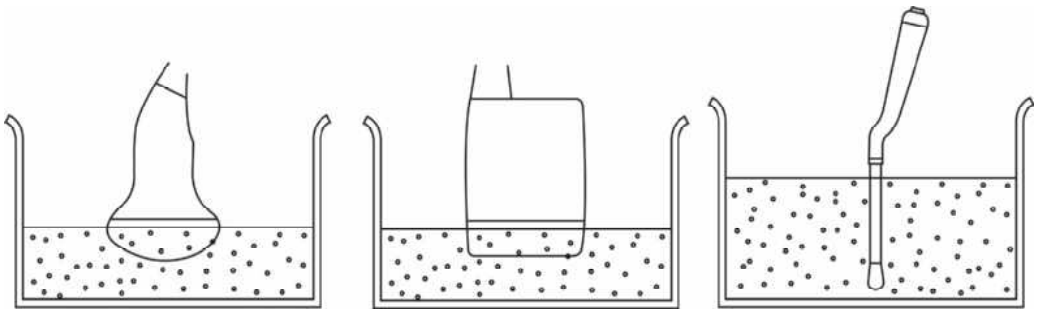
WARNING

- 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 9-2] Disinfection

10 User Maintenance

10.1 Overview

Chapter 10 describes how to extend the life of SONOACE X8.

It includes are how to maintain the product and how to backup information.

Make sure to read this chapter for proper maintenance of the product.

Contents User Maintenance

10.2 System Maintenance

10.2.1 Installation Requirements

When installing:

1) Avoid humidity.
2) Avoid direct sunlight.
3) Avoid places with extreme temperature variations.
4) Optimal conditions for the system are temperatures of 10° ~ 35° C and humidity of 30% ~ 75%.
5) Avoid heat sources.
6) Avoid dusty and unventilated areas.
7) Avoid places where the system is likely to be exposed to vibration or impacts.
8) Avoid places where the system is likely to be exposed to chemical substances or gases.

NOTE The user must ensure that the safety inspections are performed every two years according to the requirements of safety standard EN 60601-1. Only trained persons are allowed to perform the safety inspections mentioned above.

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.

10.2.2 Cleaning and disinfections

WARNING

Always use protective eyewear and gloves when cleaning and disinfecting the equipment.

10.2.2.1 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.

10.2.2.2 Disinfections

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

[Table 10-1] Solutions

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.

10.2.3 Cleaning the Air Filter

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 10-1] 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.

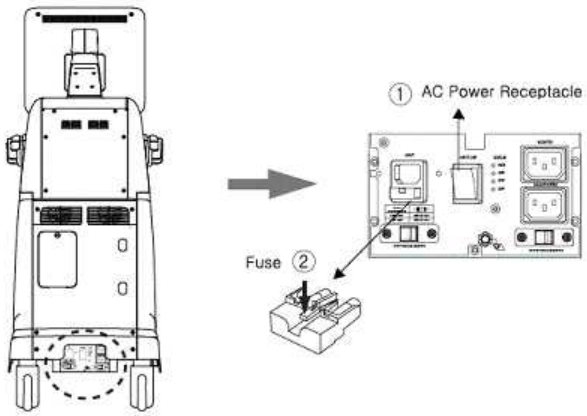
NOTE Allow the wet filter to dry thoroughly before installing. The wet filter can cause the malfunction.

10.2.4 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 10-2] Fuse replacement

1) Turn off the system and disconnect the system power cord from the wa outlet. (See ①)
2) Press the fuse holder in the direction of the arrow and pull it out. (See ②)
3) Remove the old fuse and replace it with a new one.
4) After installing the new fuse, connect the plug to the system.

Input Ratings	Fuse Ratings	Maker	Order No.
100-120VAC	10AH/250V	Orisel	55T210000
200-240VAC	10A/H250V	Orisel	55T210000

[Table 10-2] Fuse Ratings

10.3 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.

10.3.1 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. Please 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 of User Manual'.

10.3.2 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 Management of User Manual'.

10.3.3 Software

The product software may be updated to enhance performance. The user cannot make any changes to the software. Please contact the MEDISON customer support 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 (Windows XP™), and should you desire to upgrade the operating system, please follow the instructions of the operating system manufacturer.

11 Service Part List

11.1 Overview

This chapter 11 contains information on the SONOAE X8 Service Part

Please refer to the SONOACE X8 Compatibility Matrix to Check the replacement parts and their software versions for each system configuration.

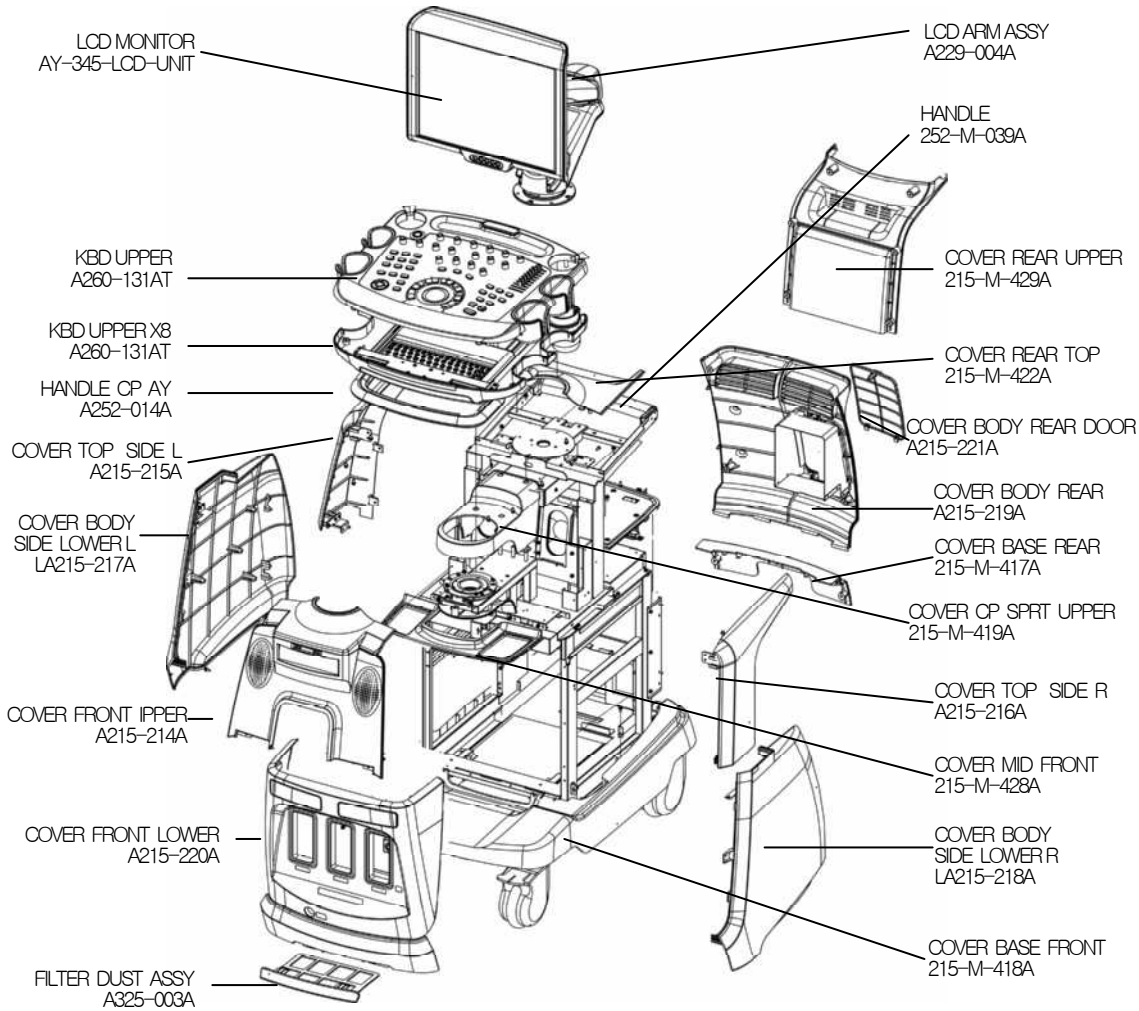
For installing and verifying system parts, please refer to figures and part table in this chapter.

Part numbers are indicated in the corresponding table.

Prior to ordering parts, please verify whether the existing parts can be replaced according to the current service policy

Contents Service Part List

11.2 Cover

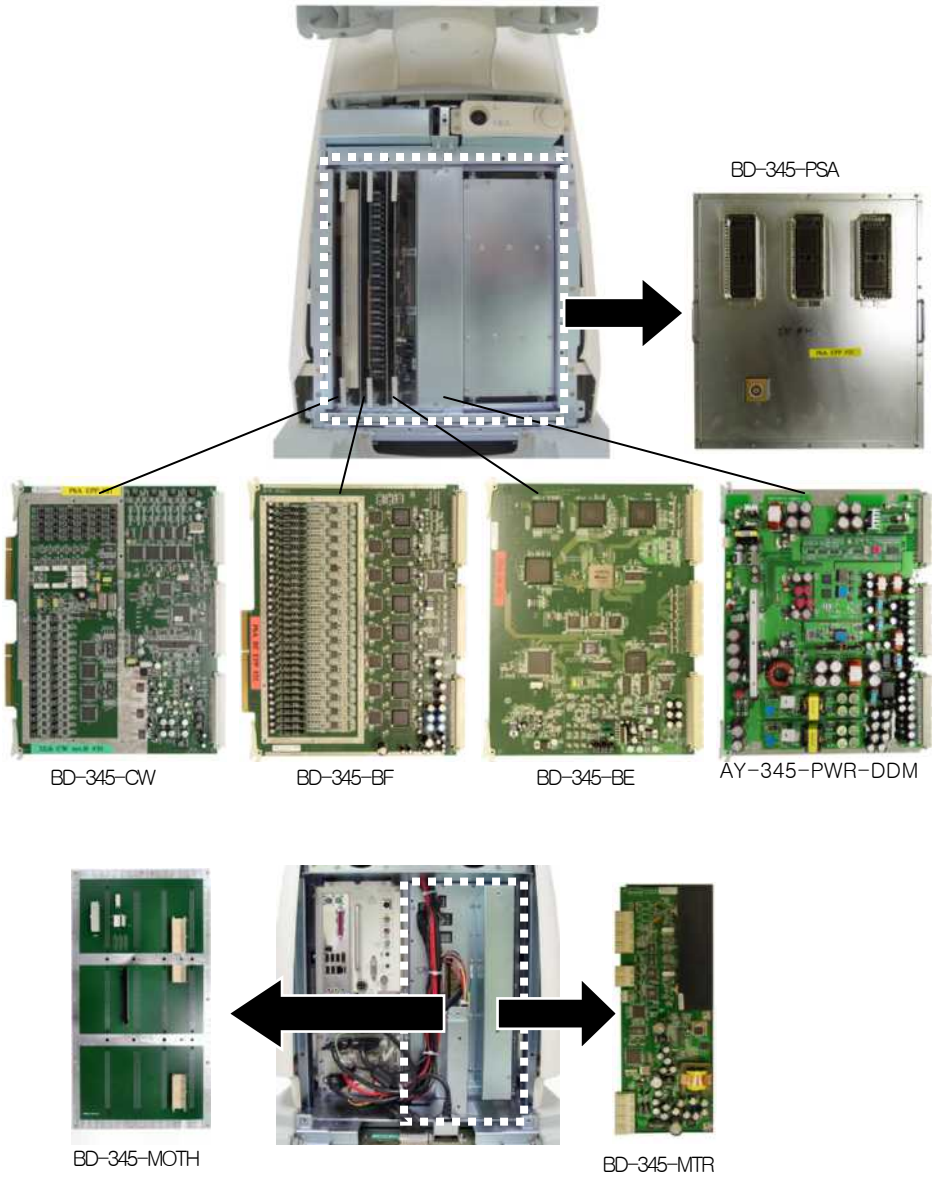


[Figure 10-1] SONOACE X8 Cover

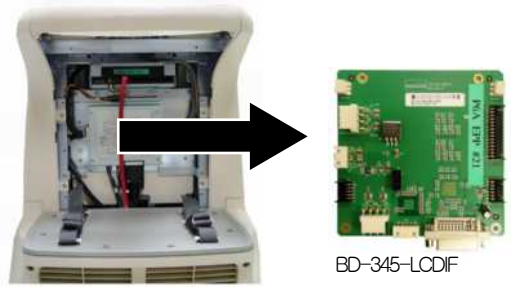
PART NAME	PART NUMBER	DESCRIPTION
COVER BASE FRONT	215-M-418A	COVER BASE FRONT X8
COVER BASE REAR	215-M-417A	COVER BASE REAR X8
COVER BODY REAR	A215-219A	COVER BODY REAR X8
COVER BODY REAR DOOR	A215-221A	COVER BODY REAR DOOR X8
COVER BODY SIDE LOWER L	A215-217A	COVER BODY SIDE LOWER L X8
COVER BODY SIDE LOWER R	A215-218A	COVER BODY SIDE LOWER R X8
COVER CP SPRT UPPER	215-M-419A	COVER CP SPRT UPPER X8
COVER FRONT LOWER	A215-220A	COVER FRONT LOWER X8
COVER FRONT UPPER ASSY	A215-214A	COVER FRONT UPPER ASSY X8
COVER MID FRONT	215-M-428A	COVER MID FRONT X8
COVER MID REAR	215-M-436A	COVER MID REAR X8
COVER REAR TOP	215-M-422A	COVER REAR TOP X8
COVER REAR UPPER	215-M-429A	COVER REAR UPPER X8
COVER TOP SIDE LEFT	A215-215A	COVER TOP SIDE LEFT X8
COVER TOP SIDE RIGHT	A215-216A	COVER TOP SIDE RIGHT X8
FILTER DUST ASSY	A325-003A	FILTER DUST ASSY X8
HANDLE	252-M-039A	HANDLE X8
HANDLE CP AY	A252-014A	HANDLE CP AY X8
KBD BOTTOM	A260-132A	KBD BOTTOM X8
KBD UPPER	A260-131A	KBD UPPER X8

[Table 10-1] SONOACE X8 Cover

11.3 Ultrasound System Part



[Figure 10-2] Ultrasound System Part

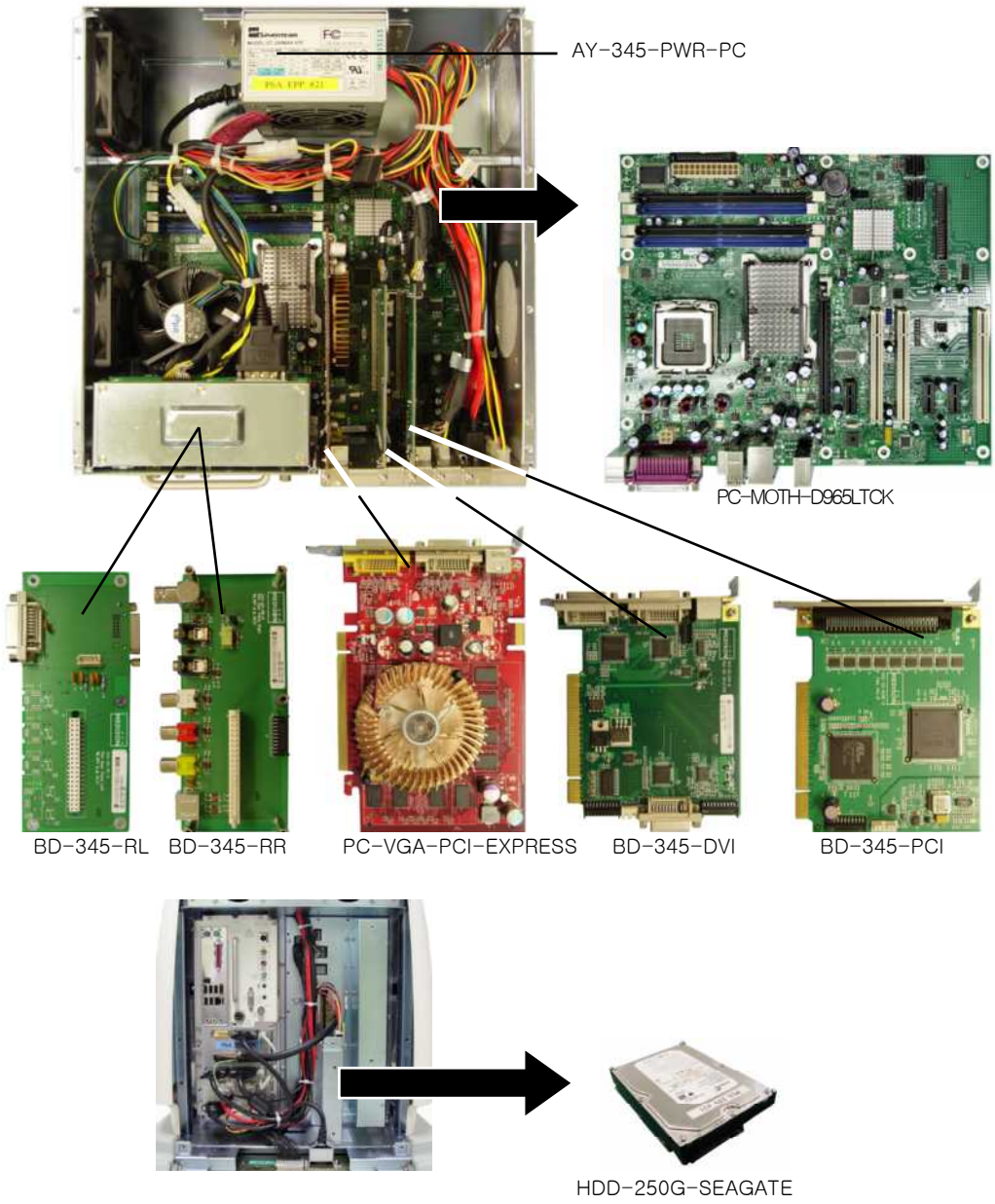


[Figure 10-2] Ultrasound System Part

PART NAME	PART NUMBER	DESCRIPTION
BE BOARD	BD-345-BE	BACK END BD X8
BF BOARD	BD-345-BF	BF BD X8
C-CW BOARD	BD-345C-CW	NON CW BD X8
CW BOARD	BD-345-CW	CW BD X8
C-PSA BOARD	BD-345C-PSA	PSA BD (NON CW) X8
PSA BOARD	BD-345-PSA	PSA BD X8
MOTH BOARD	BD-345-MOTH	MOTHER BD X8
MOTOR BOARD	BD-345-MTR	MOTOR BD X8
LCDIF BOARD	BD-345-LCDIF	LCD INTERFACE BD X8
DDM POWER	AY-345-PWR-DDM	POWER AY DC-DC MODULE X8

[Table 10-2] Ultrasound System Part

11.4 PC Part

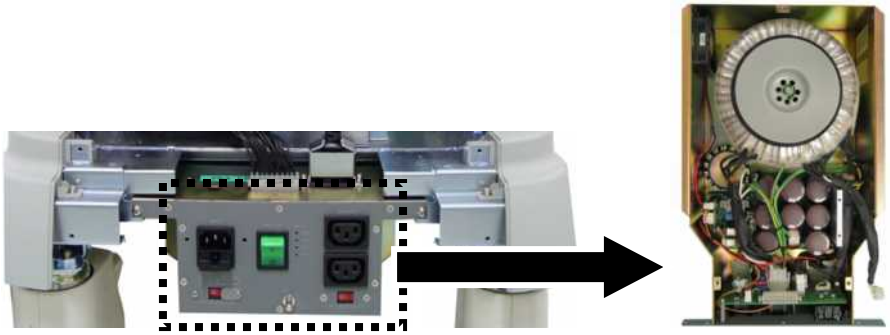


[Figure 10-3] PC Part

PART NAME	PART NUMBER	DESCRIPTION
DVI BOARD	BD-345-DVI	DIGITAL VIDEO INTERACTIVE BD X8
PCI BOARD	BD-345-PCI	PC INTERFACE BD X8
RR BOARD	BD-345-RR	REAR PANEL RIGHT BD X8
RL BOARD	BD-345-RL	REAR PANEL LEFT BD X8
PC MOTHER BD AY	AY-PCMOTH-345	INTEL ATX SAX8 MOTHER BD X8
PC MOTHER BD	PC-MOTH-D965LTCK	PC MOTHER INTEL ATX D965LTCK X8
PC VGA CARD	PC-VGA-PCI-EXPRESS	256M MEMORY, MSI NX7600GS X8
PC CPU FAN	FAN-CF80TM	CF80TM CPU FAN (APACK) X8
PC FAN	AY-FAN-345-PC1	PC FAN 1 ASSY X8
PC FAN	AY-FAN-345-PC2	PC FAN 2 ASSY X8
PC POWER	AY-345-PWR-PC	PC POWER ST-250MAK X8

[Table 10-3] PC Part

11.5 Power Part



AY-345-PWR-ADM

AY-345-PWR-PC

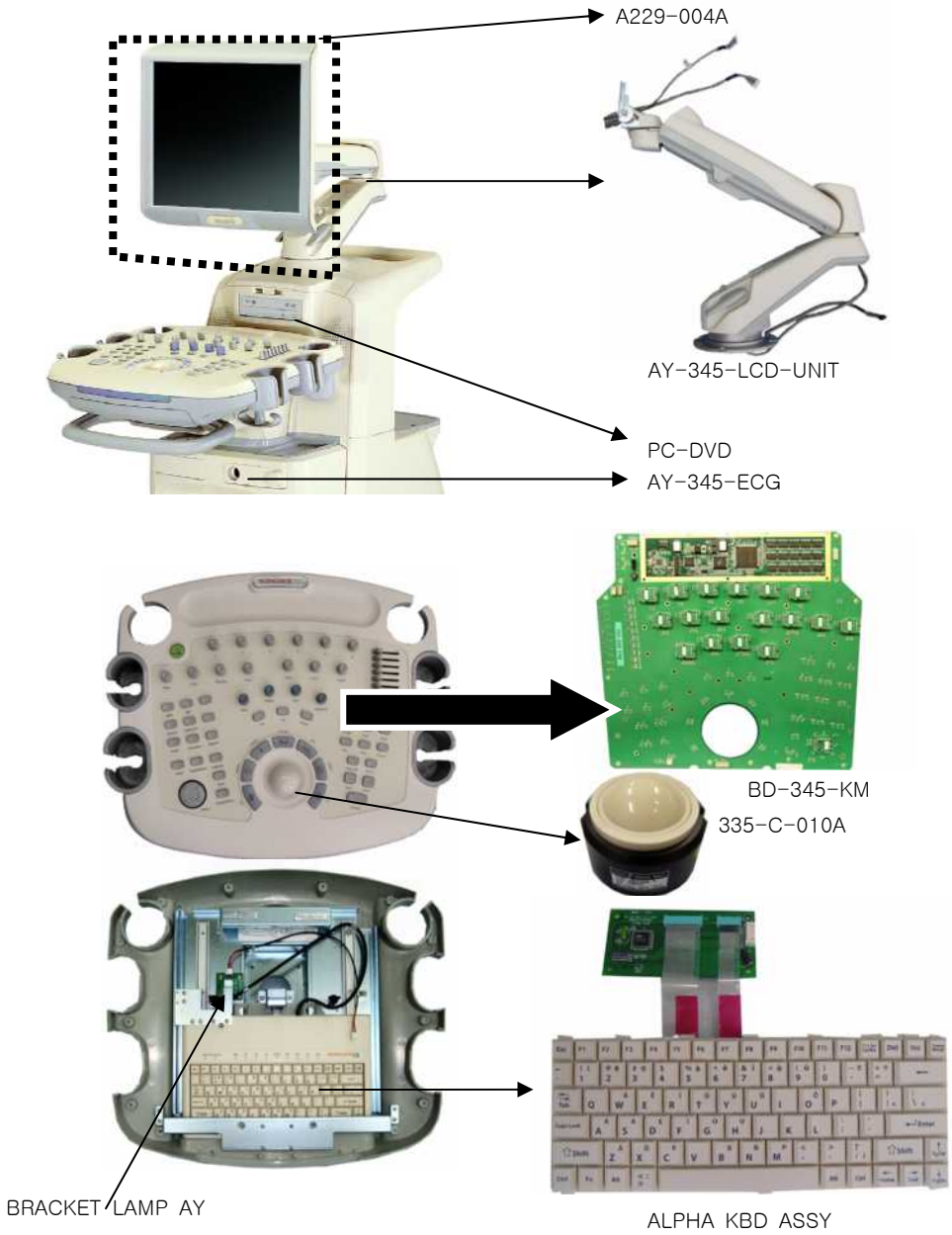
AY-345-PWR-DDM

[Figure 10-4] Power Part

PART NAME	PART NUMBER	DESCRIPTION
ADM POWER	AY-345-PWR-ADM	POWER AY AC-DC MODULE X8
DDM POWER	AY-345-PWR-DDM	POWER AY DC-DC MODULE X8
PC POWER	AY-345-PWR-PC	PC POWER ST-250MAK X8

[Table 10-4] Power Part

11.6 User Interface Part

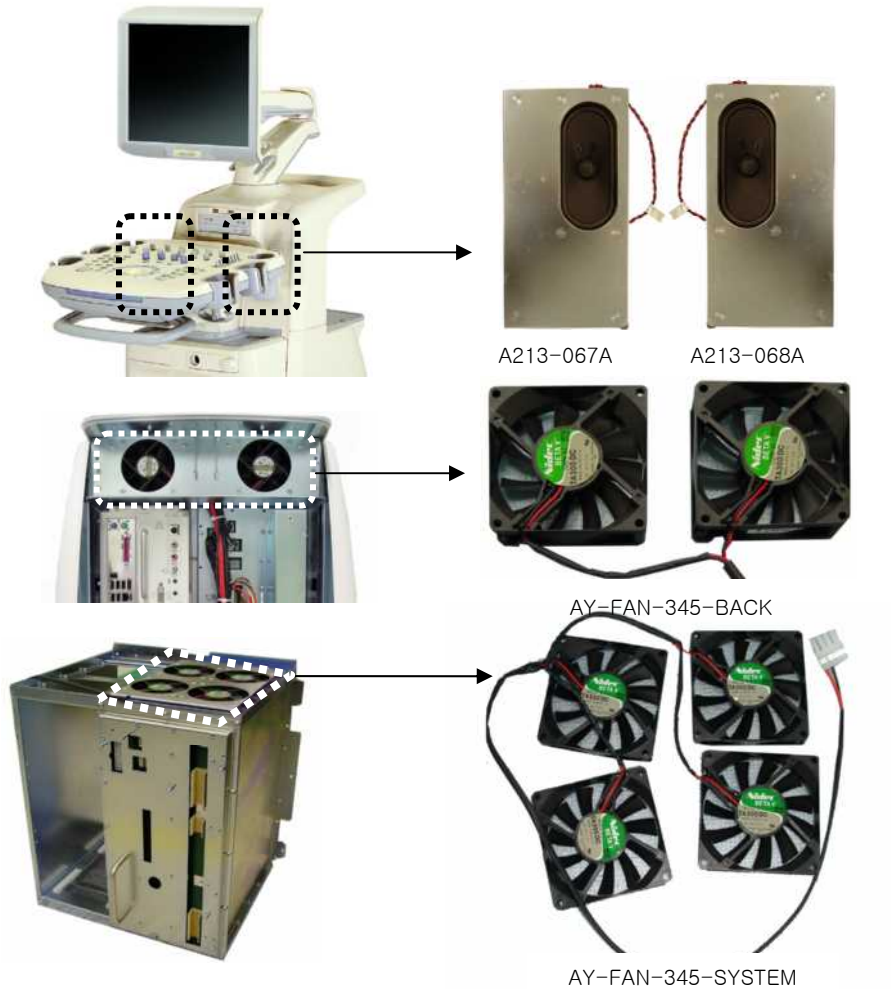


[Figure 10-5] User Interface Part

PART NAME	PART NUMBER	DESCRIPTION
AHLPA KEY AY	A260-133A	ALPHA KBD ASSY X8
DVD	PC-DVD	DVD X8
ECG	AY-345-ECG	ECG MODULE X8
KM BOARD	BD-345-KM	KEY MATRIX BD
LAMP BD CHASSIS	A235-057A	BRACKET LAMP AY X8
LAMP BOARD	BD-345-LAMP	LAMP BD X8
LIMIT BOARD	BD-345-LIMIT	LIMIT BD X8
TRACKBALL	335-C-010A	TRACKBALL YEL UNIT 58MM TAMAGAWA
LCD ARM AY	A229-004A	LCD ARM ASSY X8
LCD AY	AY-345-LCD-UNIT	LCD MONITOR X8

[Table 10-5] User Interface Part

11.7 Electric Part



[Figure 10-6] Electric Part

PART NAME	PART NUMBER	DESCRIPTION
SPEAKER	A213-067A	CASE LEFT SPEAKER ASSY X8
SPEAKER	A213-068A	CASE RIGHT SPEAKER ASSY X8
SYSTEM FAN	AY-FAN-345-SYSTEM	SYSTEM FAN ASSY X8
SYSTEM FAN	AY-FAN-345-BACK	BACK FAN ASSY X8

[Table 10-6] Electric Part

11.8 Cable Part

PART NAME	PART NUMBER	DESCRIPTION
CABLE	CABLE-345-STD	CABLE ASSY X8
CABLE	WH-345-SIG-01	DVI-PCI DATA CABLE X8
CABLE	WH-345-SIG-02	DVI-REAR DATA CABLE X8
CABLE	WH-345-SIG-03	FOOT S/W DATA CABLE X8
CABLE	WH-345-SIG-04	PC POWER CABLE X8
CABLE	WH-345-SIG-05	PC USB DATA CABLE X8
CABLE	WH-345-SIG-06	KM DATA CABLE X8
CABLE	WH-345-SIG-07	SPEAKER DATA CABLE X8
CABLE	WH-345-SIG-08	ECG CABLE X8
CABLE	WH-345-SIG-09	FRONT USB DATA CABLE X8
CABLE	WH-345-SIG-10	ALPHAKEY DATA CABLE X8
CABLE	WH-345-SIG-11	HDD GROUND X8
CABLE	WH-345-PWR-01	ATX POWER EXTENSION CABLE X8
CABLE	WH-345-PWR-02	PC POWER EXT CABLE X8
CABLE	WH-345-PWR-03	PC AC POWER CABLE X8
CABLE	WH-345-PWR-04	SYSTEM POWER CABLE X8
CABLE	WH-345-PWR-05	HDD POWER CABLE X8
CABLE	WH-345-PWR-06	LCDIF POWER CABLE X8
CABLE	WH-345-PWR-07	KM POWER CABLE X8
CABLE	WH-345-PWR-08	ODD POWER CABLE X8
CABLE	WH-345-PWR-09	LAMP POWER CABLE X8
CABLE	WH-345-PWR-10	LIMIT SWITCH CABLE X8

[Table 10-7] Cable

11.9 Option

PART NAME	PART NUMBER	DESCRIPTION
OPTION	OPT-345-DMR	DYNAMIC MR X8
OPTION	OPT-345-SCI	SPATIAL COMPOUND IMAGING X8
OPTION	OPT-345-4D	LIVE 3D X8
OPTION	OPT-345-3DXI	3DXI X8
OPTION	OPT-345-CARDIAC	CARDIAC MEASUREMENT X8
OPTION	OPT-345-CW	CE FUNCTION X8
OPTION	OPT-345-ECG	ECG MODULE X8
OPTION	OPT-345-DICOM	DICOM, DICOM MR X8

[Table 10-8] Option

11.10 Probe

PART NAME	PART NUMBER	DESCRIPTION
PROBE	PB-C2-5EL	C2-5EL
PROBE	PB-C3-7EP	C3-7EP
PROBE	PB-HL5-12ED	HL5-12ED
PROBE	PB-L5-12EC	L5-12EC
PROBE	PB-L5-12/50EP	L5-12/50EP
PROBE	PB-P2-4AH	P2-4AH
PROBE	PB-P3-5AC	P3-5AC
PROBE	PB-NER4-9ES	NER4-9ES
PROBE	PB-NEV4-9ES	NEV4-9ES
PROBE	PB-3D2-6ET	3D2-6ET
PROBE	PB-3D4-8EK	3D4-8EK
PROBE	PB-3D4-8ET	3D4-8ET
PROBE	PB-3D5-9EK	3D5-9EK
PROBE	PCW-20-FGG/3B	CW2.0
PROBE	PCW-40-FGG/3B	CW4.0

[Table 10-9] Probe

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