• MySonoU5 • SERVICE MANUAL

ENGLISH

MYSONO U5 Service Manual

ENGLISH
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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 medical electrical systems.
- IEC/EN 60601-1-2 Electromagnetic compatibility -Requirements and tests.
- IEC/EN 60601-2-37 Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment.
- IEC 61157 Declaration of acoustic output parameters.
- ISO 10993-1 Biological evaluation of medical devices.
- UL 60601-1 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).

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 service department of MEDISON Co., Ltd.

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

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

For safe use of this product, 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.

If You Need Assistance

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

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General Information

Overview 1.1

Chapter 1 contains the information necessary to plan the Troubleshooting of MySono U5 The MySono U5 is a high-resolution color ultrasonographic image scanner with deep penetration which provides a variety of measurement functions.

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1.2 Features and Advantages of MySono U5

- Digital Beamforming: The MySono U5 incorporates Digital Beam Forming, the advanced proprietary technology provided by MEDISON.
- A variety of applications: The MySono U5 is designed for use in a variety of ultrasound applications including obstetrics, gynecology, abdominal, vascular, extremities, cardiac, urology and breast applications.
- Various diagnostic Modes: 2D Mode, M Mode, Color Doppler Mode, Power Doppler Mode, PW Spectral Doppler Mode.
- 3D imaging: More detailed 3D and 4D image can be acquired.
- Measurement and Reporting In addition to basic measurements such as distance, area, circumference and volume, the MySono U5 provides a variety of applicationspecific measurement functions. The resulting measurement data can be collated through its reporting function.
- Review of Scanned Images: The MySono U5 displays Cine images of 2621 frames and loop images of 4086 lines.
- SonoViewTM: An integrated ultrasound image management system, which allows you to archive, view and exchange image data.
- Digital Imaging and Communication in Medicine (DICOM): A communication protocol, which allows you to archive, transfer and print images via a network...
- Easy Connection of Peripheral Devices A variety of peripheral devices can be easily connected to the MySono U5.

1.3 Product Configuration

This Product consists of the cart(option), the console and the probes.

1.3.1 Console

Whilst the inside of the console consists of devices enabling the implementation of ultrasound images, the outside of the console consists of various connection ports and handles.



[Figure 1-1] Console of MySono U5



[Figure 1-2] Rear and side of MySono U5



1.3.2 **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'.

1.3.3 MySono U5 Cart(Optional)

The MySono U5 System can be placed on a cart during use or for transport. For more information on installing and using the MySono U5 Cart, please refer to the installation guide that comes with it.

Specifications 1.4

| Physical Dimensions | Height: 70mm Width: 360mm Depth: 291mm Weight: more than 5.4kg (without battery) |
|-----------------------|--|
| Battery Pack | Hight: 23mm Width: 214.6mm Depth: 59mm Weight: less than 400g |
| Monitor | 15 inch LCD monitor |
| Probe connections | One probe port |
| Probes | Curved Linear Array: C3-7 Linear Array: L5-12 Phased Array: P2-4 Endocavity Curved Linear Array: EV4-9 Volume Probe: 3D2-6 |
| Electrical Parameters | Input:100~240VAC, 0.7~1.63A, 47~63Hz Output:19VDC, 7.9A, 150W Max |
| 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°C ~ 35°C Storage & Shipping: -25°C ~ 60°C |



| Input / Output Connections | Video (DVI-I) port Network port USB port Microphone port Audio port |
|-------------------------------|--|
| Auxiliary | Video (DVI-I) port Network port USB port Microphone port Audio port |
| Application | Abdomen, Obstetrics, Gynecology, Musculoskeletal, Small Parts, Vascular, Cardiac, Pediatric Cardiology, TCD, Urology |
| 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 Tissue Doppler Imaging (TDI) mode Tissue Doppler Wave mode 3D imaging mode 4D imaging mode Dual modes Combined modes Simultaneous mode Zoom |
| Focusing | Transmit focusing, maximum of eight points (four points simultaneously selectable) Digital dynamic receive focusing (continuous) |

| Gray Scale | 256 (8 bits) |
|--|---|
| Measurement Packages | Obstetrics, Gynecology, Cardiac, Carotid, Urology, Fetal Echo, LE Artery, UE Artery, LE Vein, UE Vein, Radiology, TCD, Thyroid, Breast, Testicle, Superficial, Pediatric Hips, MSK * Refer the Chapter 5 for additional information |
| Measurement | Obstetrics, Gynecology, Cardiology, Carotid, Fetal Echo, UE Artery, LE Artery, UE Vein, LE Vein, Radiology, TCD, Thyroid, Breast, Testicle, Superficial, Pediatric Hips, MSK * Refer the Chapter 5 for additional information |
| Image Storage | Maximum 2,621 frames for CINE memory Maximum 4,086 Lines for LOOP memory Image filing system |
| 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) | Frame average Edge Enhancement / Blurring Gamma-scale windowing Image orientation (left/right and up/down, rotation) White on black/black on white Zoom |

2 Safety

2.1 Overview

Chapter 2 contains the information necessary to Safety

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

MySono U5 is intended for use by or by the order of, and under the supervision of a licensed physician who is directly qualified to use the medical device.

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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 classifies a connection or warn of potential hazards. The classifications and symbols are shown below.

| Symbols | Description |
|---------------------------|--|
| === | DC (direct current) voltage source |
| 木 | Isolated patient connection (Type BF applied part). |
| \bigcirc | Power switch (Supplies/cuts the power for product) |
| A | Indicates a caution for risk of electric shock. |
| 4 | Indicates dangerous voltages over 1000V AC or over 1500V DC. |
| <u></u> | Isolated patient connection (Type BF applied part). |
| (<u>+</u> | Power switch (Supplies/cuts the power for product) |
| | Electrostatic discharge |
| \Rightarrow | Data Output port |
| \Rightarrow | Data Input port |
| $\overline{\diamondsuit}$ | Data Input/Output port |
| \bigcirc | Left and right Audio / Video input |

| Symbols | Description |
|-------------|--|
| \bigcirc | Left and right Audio / Video output |
| | Print remote output |
| > | Foot switch connector |
| | ECG connector |
| ● ✓• | USB connector |
| • | Microphone connector |
| \cap | Audio port |
| IPX7 | Protection against the effects of immersion. |
| IPX1 | Protection against dripping water. |
| | Probe port |
| | Network port |



2.2.2 Labels

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



[Figure 2-1] Marked on the bottom of the product

2.3 **Electrical Safety**

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

CAUTION



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

2.3.1 **Prevention of Electric Shock**

WARNING



- There is a risk of electric shock if the externally mounted recording and monitoring devices are not properly grounded.
- Never open the product housing cover. There is high voltage power within the product. All internal adjustments and replacements must be made by the MEDISON Customer Service.
- Always check the product housing, cables, cords, plugs, etc. before use. Do not use the product if the surface is cracked, chipped, or split, the housing is damaged, or the cable is abraded.
- Always disconnect the system from the wall outlet prior to cleaning the system.
- All patient contact devices, such as probes, must be removed from the patient prior to application of a high voltage defibrillation pulse.
- Never use the product in proximity to any flammable anesthetic gases(N_2O) or oxidizing gases. There is a risk of explosion.
- Be sure only to use an AC adaptor that is recommended by MEDISON.

CAUTION



- 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.
- Do not touch SIP/SOP and the patient simultaneously. There is a risk of electric shock from leakage current.



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.

2.3.2 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.

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.
- Always perform the pre-ESD preventive procedures before using connectors marked with the ESD warning label.
 - Apply anti-static spray on carpets or linoleum.
 - Use anti-static mats.
 - Ground the product to the patient table or bed.
- It is highly recommended that the user be given training on ESDrelated warning symbols and preventive procedures.

2.3.3 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.

2.3.4 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).

2.3.4.1 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 | |
| RF Emission (Radiation) CISPR 11 | Group 1 Class B | cause any interference in nearby electronic equipment. The Ultrasound System is suitable for use in all | |
| Harmonic Emission IEC 61000-3-2 | Class A | establishments, including domestic establishments and those directly connected to | |
| Flicker Emission IEC 61000-3-3 | Complies | the public low-voltage power supply network that supplies building used for domestic purpose. | |



2.3.4.2 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 | Туре | Length |
|----------------|--------------|--------|
| DVI | Shielded | Normal |
| USB | Shielded | Normal |
| LAN(RJ45) | Twisted pair | Any |
| MIC | Unshielded | Any |
| Printer Remote | Unshielded | Any |
| Audio R.L | Shielded | Normal |

2) Probe

The transducers listed in Chapter 9. 'Probes' when used with this product, have been tested to comply with Group 1 Class B emission as required by International Standard CISPR

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.

WARNING



Use of unapproved cables, probes or accessories may increase the electromagnetic emission or decrease the durability of the ultrasound product..

| 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 | ±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% <i>U</i> τ (>95% dip in <i>U</i> τ) for 0.5cycle 40% <i>U</i> τ (60% dip in <i>U</i> τ) for 5 cycle 70% <i>U</i> τ (30% dip in <i>U</i> τ) for 25 cycle <5% <i>U</i> τ (<95% dip in <i>U</i> τ) for 5 s | <5% UT (>95% dip in UT) for 0.5cycle 40% UT (60% dip in UT) for 5 cycle 70% UT (30% dip in UT) for 25 cycle <5% UT (<95% dip in UT) 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 | 3 Vrms | 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. |
|---------------------------|--|-------|---|
| IEC 61000-4-6 | 150 kHz to 80MHz | | Recommended separation distance $d = [\frac{3,5}{V_1}]\sqrt{P}$ $d = [\frac{3,5}{V_1}]\sqrt{P}$ 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 and 800MHz, the higher free | 3 V/m | Where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> 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. 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 $[V_1]\ V/m$.

2.3.4.3 Recommended separation distances between portable and mobile RF communications equipment and the ACCUVIX V20

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.

| | Separation distance according to frequency of transmitter [m] | | | |
|---|---|--|---|--|
| Rated maximum output power of transmitter [W] | 150kHz to 80MHz $d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$ | 80MHz to 800MHz $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ | 800MHz to 2.5GHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ | |
| | 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.

2.3.4.4 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.

2.3.4.5 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 does 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 Safety Note

- Do not apply excessive force to the product.
- Be sure to install the console on a stable surface. MEDISON recommends MySono U5 CART (optional).
- Do not rest the console on your lap while using it as it could cause a burn.
- 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 foreign bodies, such as bits of metal, do not get into the system.

CAUTION



- Do not block the ventilation slots.
- Do not keep this equipment in the closed space, such as a bag or a case, with turing it on.
- Do not unplug the power cable by pulling the cable. The cable may be damaged, resulting in short circuit or disconnection. Always unplug it by holding the plug body.
- Excessive bending or twisting of cables on patient-applied parts may cause failure or intermittent operation of the system.
- Incorrect cleaning or sterilization of a patient-applied part may cause permanent damage.

2.4.2 Moving the Equipment

Use the handle on the rear of the product, and move the product slowly. You can also move the product by using the MySono U5 CART (optional).

CAUTION

Always turn the power off and disconnect the cables before moving the product.

NOTE

When using the MySono U5 CART, try to avoid parking it on a slope. If this is necessary for a while, please lock the wheel brakes.



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 (Tlb) 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 (Tlc) 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, occurs 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 evertures inherent accustic output modeling errors, and measurement variability.

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:

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

where: In Situ = In Situ Intensity Value

Water = Water Value Intensity

e = 2.7183

a = Attenuation Factor

Tissue a(dB/cm-MHz)

Brain .53 Heart .66

Kidney.79

Liver .43 Muscle .55

I = skin line to measurement depth (cm)

f = Center frequency of the transducer/system/mode combination(MHz)

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

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

Since this value is not the true *In Situ* intensity, the term "derated" is used.

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

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



- For disposing of the system or accessories that have come to the end of their lifespan, contact the vendor or follow appropriate disposal procedures.
- You are responsible for complying with the relevant regulations for disposing of wastes.
- The lithium ion battery used in the product must be replaced by a MEDISON service engineer or an authorized dealer.



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.

2.7 Battery Pack

Before using the battery, you should read and understand the following warnings and cautions

WARNING



- Maintain the battery pack at the proper temperature when charging, discharging, and storing. For more detailed information about temperature ranges, please refer to Chapter 8, "Maintenance and Storage."
- When connecting the battery pack, please pay attention to the direction of positive and negative terminals. If connected in the wrong direction, a short circuit can occur.
- Be careful not to allow any metal to touch the terminals of the battery pack.
- Do not disassemble or modify the battery pack.
- Do not heat or burn the battery pack.
- Do not store or use the battery pack in hot locations such as near heaters or fire. Especially, make sure that it is not exposed to a high temperature of 60 degrees Celsius or higher.
- Do not place the battery pack in direct sunlight.
- Do not handle the battery pack with sharp objects.
- Do not impact or step on the battery pack.
- Do not use damaged battery pack.
- Do not solder or repair the battery pack.
- Do not directly connect the battery pack to an electric outlet.
- If you do not use MySono U5 for more than a month

CAUTION



Explosion, ignition, or burning of the battery pack can damage the product. For more information regarding this, please note the following precautions:

- Do not soak the battery pack in water or get it wet.
- Do not put the battery pack in an electronic oven or a pressure vessel.
- When liquids leak from the battery pack, or it smells or radiates heat, do not store it or use it in a place near combustible materials.
- Do not use the battery pack when unusual conditions are detected such as odor, heat, deformations, or discoloring.

Installing the Product

3.1 **Overview**

Chapter 3 contains the information necessary to plan the installation of MySono U5 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.

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3.2 **Transportation**

MySono U5 is a sensitive piece of electronic medical equipment. Take care when moving it.

3.2.1 **Precautions for Transportation**

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.

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.

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

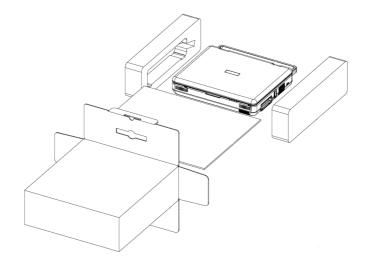
[Table 3-1] Temperature and Humidity Requirements



Unpacking 3.3

3.3.1 Unpacking the Box.

- 1) Remove the box.
- 2) Take the product and accessory boxes out and put them in a safe place.



[Figure 3-1] Unpacking the Box

3.3.2 **Package Contents**

This product comes with a box containing a variety of accessories

3.3.3 MySono U5 Cart (Option)

The MySono U5 System can be placed on a cart during use or for transport. For more information on installing and using the MySono U5 Cart, please refer to the installation guide that comes with



[Figure 3-2] MySono U5 Cart

Precautions for Installation 3.4

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.



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.

CAUTION

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



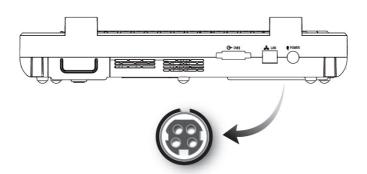
Sudden temperature change causes dew and may generate problems in the product.

| 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 AC Adapter**

Connect the AC adapter to the power port found at the back of the console. If power is supplied via the AC adapter, the battery is automatically re-charged.



[[Figure 3-3] Power Port

CAUTION

When connecting the AC adapter, be careful which way round you connect it. If it is connected the wrong way round, the pins may be bent or broken.

NOTE

- You do not need to connect the AC adapter if you intend to operate the system on the battery only.
- For detailed information on replacing and managing the battery pack, please refer to Chapter 8, "Maintenance."
- (In North America) For 120 Volt applications, use only UL Listed detachable power cord with NEMA configuration 5-15P type (parallel blades) plug cap. For 240 Volt applications use only UL Listed Detachable power supply cord with NEMA configuration 6-15P type (tandem blades) plug cap.

3.5.3 **Connecting the Probe**

MySono U5 provides 4 probe connections on its front panel.

The probe connections are numbered 1, 2, 3 and 4 from the left. MySono U5 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.





Unlocked State Locked State [Figure 3-4] Probe Connections

CAUTION

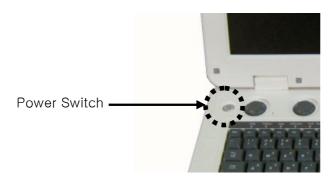


Although you can connect a probe when the power is on, do not connect or disconnect a probe during the booting sequence of the product.



3.6 **Starting the Product**

Press the On/Off button when the power is off. Booting begins, and the product logo appears on the screen. When booting is completed, the 2D mode screen appears in End Exam status.



[Figure 3-5] Power Switch

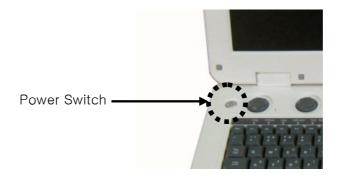
- 1 The booting sequence is displayed on the LCD monitor. As the Windows XP logo disappears, the MySono U5 logo and loading bar appear.
- ② The loading bar fills with color. This represents data being copied to the Front End and Back End of system by the PC software.
- ③ When software data copying is completed, the ultrasound picture appears and the system becomes ready.

3.7 **Shutting down the Product**

Press the On/Off button while using the system

3.7.1 **Power Switch**

1) Turning the system off: Press the On/Off switch at the right side of the control panel (keyboard). Press and hold down the button for 2 seconds to turn the product On



[Figure 3-6] Power Switch

NOTE

Pressing the On/Off button for longer than four seconds forces the system to power off, which can damage the hard disk in the console.

CAUTION



- Make sure that none of keyboard buttons are pressed unintentionally or accidentally, as this can cause system malfu-nction.
- If the system is powered on again after a forced power-off, it may shut down briefly and then turn on again. This occurs due to the unique characteristics of the Intel® PC Main Board built into the system, and does not indicate a defect.



3.8 **Connecting the Peripherals**

MySono U5 provides various connectors so that various external devices can be connected. Based on needs, various peripheral devices can be connected via the corresponding ports located on the left, right or rear side of the console

CAUTION



Be sure to power off the console before connecting or removing peripheral devices to/from via USB ports. Otherwise, the system and the peripheral devices connected may malfunction.

NOTE

For information on using a peripheral device, please refer to the corresponding user manual.

The following products are recommended.

- ① DVD-multi: DVD+R, DVD-R, DVD+RW, DVD-RW, CD-R, CD-RW
- 2 USB Video Printer
 - Color: Mitsubishi CP30DW, SONY UP-D23MD
 - Black and Whiite: Mitsubishi P93DW, SONY UP-D897
- ③ USB Magnetic Optical (MO) Disk Drive: 1.4G External USB Optical Drive
- 4 A USB-to-Serial converter (RS-232C) with FTDI Chipset (FTDI FT232BMcompatible).
- 5 Miscellaneous: USB Flash Memory media

NOTE

- A USB 1.1 flash memory module may not be properly recognized by the system. If this is the case, remove the memory module and then mount it again.
- Use Utility > Storage Manager to mount or remove a USB storage device.
- For flash memory modules that support functionality other than regular data storage, test to see if data can be properly saved with your desktop PC before using them.

3.9 **Battery Pack**

The product's battery is a lithium ion pack. When the AC adapter is not connected or the power supply through the AC adapter is not stable, MySono U5 uses the power of battery pack.

WARNING



- During use, when you see a message saying that the battery is running out of power, save your diagnosis content immediately and connect the AC adapter to the product. If you continue to use the product without connecting the adapter, a warning message will appear and the system will be exited automatically.
- Use the battery pack when the AC power supply is not stable or the external earth line is weak.
- The battery pack and the AC adapter are intended only for use with the MySono U5. You must always use the battery pack recommended by Madison.

When using MySono U5, the battery power can vary depending on the diagnosis mode being used and the connected peripherals.

If you have used most of the battery power while using the product, connect the AC adapter to the battery pack and charge it. If you want to change to a spare battery pack, stop the system and change it.

NOTE

- 3D/4D mode can only be used when the AD adapter is connected.
- Before using the battery pack, you must fully understand the battery safety issues described in Chapter 1, "Safety."
- For detailed information on replacing and managing the battery pack, please refer to Chapter 8, "Maintenance and Storage."



3.9.1 Battery Icon

The battery icons displaying the status of the battery appear in the user information area of the screen. Check the remaining power level from the battery icon when the power is being supplied from the battery pack.

The meanings of battery icons are described below.

| Icon | Status | Notes |
|------|--|------------------------------------|
| | The AC adapter is connected. | The battery pack is being charged. |
| | Remaining battery power: 100~75% | |
| | Remaining battery power: 75~50% | The AC adapter is not |
| | Remaining battery power: 50~25% | connected. |
| | Remaining battery power: below 25% | |
| 8 | The AC adapter and the battery pack are not connected, or the battery has a problem. | |

[[Table 3-3] Icon

3.10 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) In the Utility menu, select Setup.
- 2) The Setting screen will appear. Select a tab that has items to specify.
- 3) Specify settings for each item.
- 4) Save and finish the setting. Press the Close button on the monitor screen or the Exit button on the touch screen or the control panel to switch to scan mode. Press Return button on the touch screen to go back to the Utility menu.

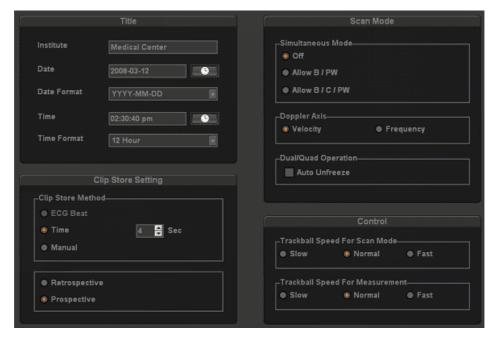
※ Tips! – Selecting a tab

You can select a tab in either of two ways as desired.

- 1) Use the Trackball and the Set button to select a tab.
- 2 Press a button on the touch screen.

3.10.1 General System Setup

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



[Figure 3-7] Setup-General



3.10.1.1 Title

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

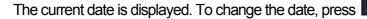
1) Institution

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

NOTE

You cannot input following characters; # [";:? | ₩

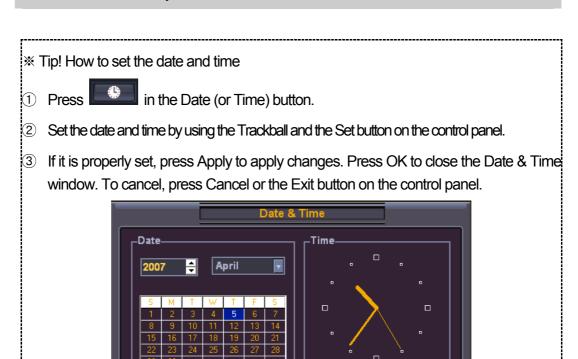
2) Date





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
- You can select the year from 2006 to 2027.



[Figure 3-8 Date & Time]

10:36:26 A

Cancel

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.

3.10.1.2 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.

- ① ECG Beat: Specify the heart beat as 1-8 beats.
- ② Time: Specify it as 1 − 8 seconds.
- ③Manual: 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.

3.10.1.3 Scan mode

1) Simultaneous Mode

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

- ①Off: Select this if you do not wish to use simultaneous mode.
- ②Allow 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.
- 3Allow B/C/PW: Select this if you wish to use simultaneous mode for both 2D/PW and for 2D/C/PW.



2) Doppler Axis

Select the axis scale unit in Spectral Doppler Mode.

- 1) Velocity: Specify the Doppler axis scale unit in cm/s (mm/s).
- ② Frequency: Specify the Doppler axis scale unit in kHz.

3) Dual / Quad Operation

Specify whether the selected area is activated in Dual or Quad mode. If 'Auto Unfreeze' is selected, the selected area will be activated in Dual or Quad mode all the time.

3.10.1.4 Control

You can specify display-related options

1) Track Ball Speed for Scan Mode

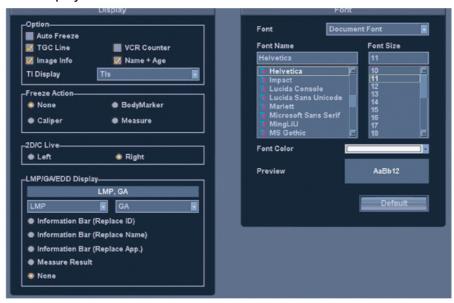
Specify the Trackball speed as Slow, Normal or Fast.

2) Track Ball Speed for Management

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

3.10.2 **Display Setup**

Select the Display



[Figure 3-9] Setup-Display

3.10.2.1 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.

① Auto Freeze: If the product is unused for 5 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.

- 2 Post Map: This sets whether to display the Post Map in the feedback area on the screen.
- 3 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) Freeze Action

Select a function to execute when the Freeze button on the control panel is pressed. Available options are Bodymark, Caliper, Measure and None.

3) 2D/C Live

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.
- Disable Horizontal Format: Turn off the Horizontal Dual function in 2D/C Live mode.

4) LMP / GA Display

Select the LMP and GA display of the patient information.

Information Bar (Replace ID): LMP and GA are displayed at the ID position of the title area.

Information Bar (Replace Name): LMP and GA are displayed at the Name position of the title area.



- Measure Result: During measurement, LMP and GA are displayed along with measurements.
- None: Neither LMP or GA is displayed on the screen.

3.10.2.2 Font

1) Font: Select the font to use in.

2) Font Name: Select the font type to use.

3) Font Size: Select the font size to use.

4) Font Color: Select the font color to use.

5) Preview: Preview window displays the font you selected.

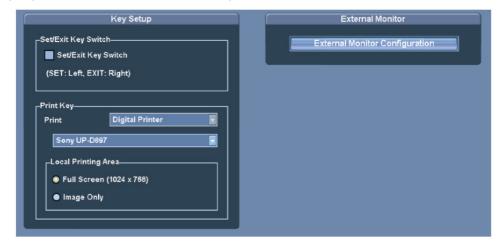
6) Default: Go back to the default setting like below.

| | Document Font | Measure Result Font |
|------------|---------------|---------------------|
| Font Name | Helvetica | Verdana |
| Font Size | 11 | 11 |
| Font Color | White | Yellow |

NOTE Certain fonts may not appear correctly on the screen.

3.10.3 **Peripherals Setup**

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



[Figure 3-10] Setup-Peripherals

3.10.3.1 Key Setup

1) Set / Exit Key Switch

Set the location of the Exit and Set buttons on the control panel. Select the checkbox to make the SET / EXIT button on the left work as Set and the button on the right work as Exit

2) Print Key

Set the functionality of the Print 1 and Print 2 buttons on the control panel. Select from Analog Printer, Digital Printer or Record. Also set a printer or VCR to use when each button is pressed.

3) Printing Area

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

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

3.10.3.2 External Monitor

Specify the external monitor connected to the system.

NOTE

Specify settings for this item and reboot the system to use the external monitor.

3.10.4 **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 3-11] Setup-Information

NOTE

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

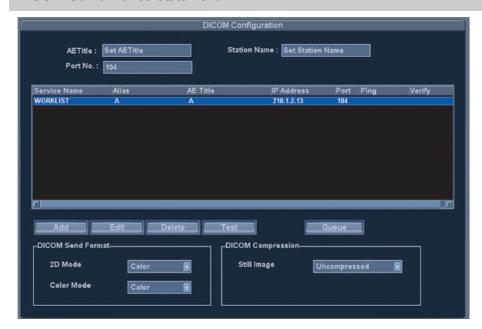


3.10.5 **DICOM Setup (Option)**

Select the **DICOM**. 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 3-12] Setup-DICOM

3.10.5.1 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. V201, V202, etc.)

3) Port No.

Enter the port number of the server being used.

3.10.5.2 Adding DICOM Service

Specify the format in which images are sent to DICOM.

1) 2D Mode

Specify the format in which 2D images are sent.

2) Color Mode

Specify the format in which color images in C or PD Mode are sent.

3.10.5.3 Adding DICOM Service

Specify whether still images will be compressed when they are sent via DICOM.

If **Uncompressed** is selected, still images are sent without any compression. If **JPEG Baseline** is selected, still images are compressed before they are sent.

3.10.5.4 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:

- ① Batch: Send all saved images when you click the **End Exam** button.
- ② 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

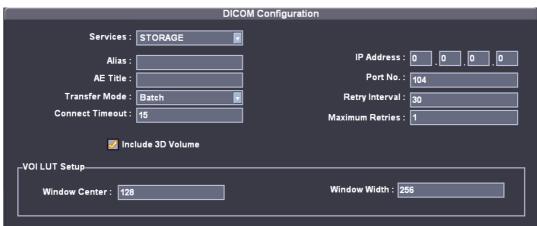
Specify how long the system will wait before it retries when transmission fails. You can specify it in seconds.

9) Maximum Retries

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

3.10.5.4.1 Storage Server Information

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



[Figure 3-13] 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.

① 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.

2 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

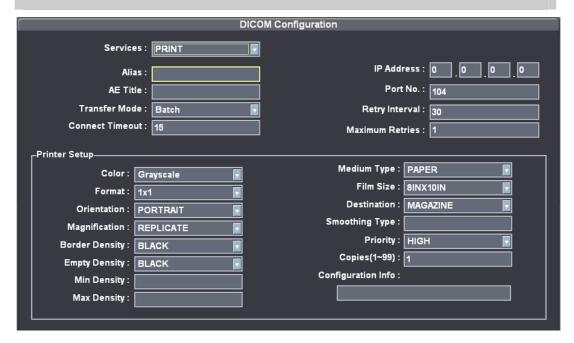
When selected, the 3D volume data is transferred when a 3D image is saved. You should select this option only when the Storage service supports MEDISON 3D volume data.

3.10.5.4.2 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 3-14] DICOM Configuration-Print

1) Color

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

2) Format

Specify the paper layout. Select from 1×1 , 1×2 , 2×2 , 2×3 , 3×3 , 3×4 , 3×5 , 4×4 ,



4×5 and 4×6 .

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 \times 10 inch, 5 inch \times 11 inch, 10 inch \times 12 inch, 10 inch \times 14 inch, 11 inch \times 14 inch, 11 inch \times 17 inch, 14 inch \times 14 inch, 14 inch \times 17 inch, 24cm × 24cm, 24cm × 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

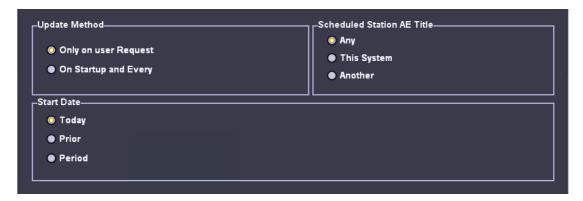
Enter the number of copies between 1 and 99.

15) Configuration Info

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

3.10.5.4.3 Worklist Server Information

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



[Figure 3-15] 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**.

② 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.

- ① Any: Retrieve the patient list stored in all AE Titles in the server.
- ② This System: Retrieve the patient list specified under the DICOM tab.
- 3 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

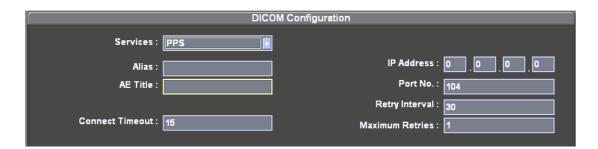
Specify the range of dates to search.

- Today: Retrieves the patient list for the current date.
- ② Range: Retrieves the patient lists for the period between n days befor and after the current date.
- 3 Past Week: Retrieves the patient lists for 7 days before the current
- 4 Past Month: Retrieves the patient lists for a month before the current date.
- 5 Custom Date: Retrieves the patient list for the specified date.

3.10.5.4.4 PPS Server Information

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

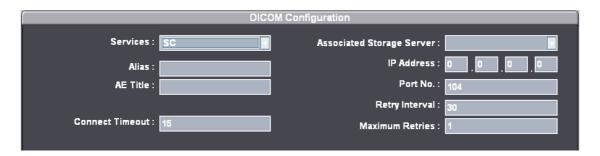
It can be configured in the same way as for the Storage server.



[Figure 3-16] DICOM Configuration-PPS

3.10.5.4.5 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.

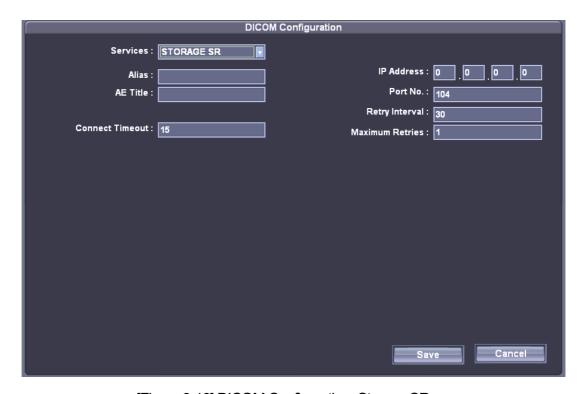


[Figure 3-17] DICOM Configuration—Storage

1) Associated Storage Server Select an image storage server to connect.

3.10.5.4.6 Storage SR Server Information

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



[Figure 3-18] DICOM Configuration—Storage SR

3.10.5.3 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.

3.10.5.5 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

3.10.5.6 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.

3.10.5.7 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.

3.10.5.7.1Job 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 3-19] 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.

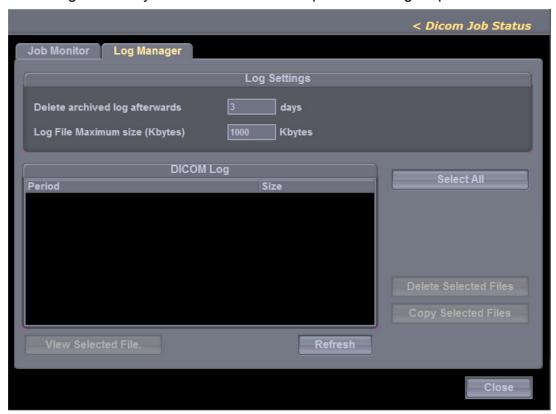
3) Restart Service

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.

3.10.576.2 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 3-20] 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.
- 2 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.

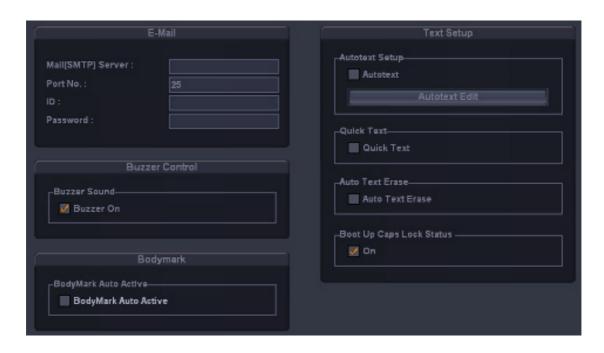
2) Manage Log File

DICOM Log shows information on log files.

- Select All: Select all log files.
- (2) Delete Selected Files: Delete the selected log file.
- 3 Copy Selected Files: Copy the selected log file to an external storage media.
- **(4**) View Selected File: Display the details of the selected log file on the screen.
- **(5)** Refresh: Update the information of a log file.

3.10.6 Utilities Setup

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



[Figure 3-21] Utility

3.10.6.1 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.

3.10.6.2 Buzzer Control

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

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.

3.10.6.3 BodyMaker

BodyMarker Auto Active: 'If 'BodyMarker Auto Active' is selected, the system automatically enters the BodyMarker input mode when the Freeze button is pressed.

3.10.6.4 Text Setup

1) Quick Text

Check this checkbox to enable Quick Text. If Quick Text is enabled, pressing any key on the keyboard switches to Annotation Mode.

The **Quick Text** checkbox is checked by default.

NOTE

 Text can be still entered if Quick Text is not enabled. To switch to Text Mode, press the **Text** key on the keyboard.

2) Auto Text Erase

Check this checkbox if you want to delete the entered text automatically after entering text and returning to the scan mode by pressing the Freeze button.

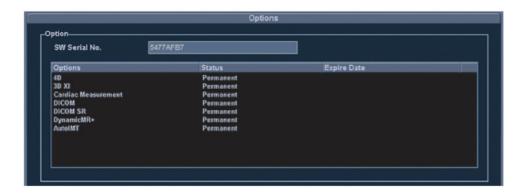
3) Boot up Caps Lock Status

Check this checkbox to turn Boot up Caps Lock Status On. Text will be entered in capital letters by default.



3.10.7 **Option Setup**

Select the Option. You can enable or disable optional software and hardware.



[Figure 3-22] Set-up Options

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 MySono U5:

4D **DICOM SR**

3D XI Dynamic MR+

Cardiac Measurement Auto IMT

DICOM

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.

3.10.8 **Auto Calc**

In the **Setup** screen, select the **AutoCalc** tab. Auto Calc. is a function that is available in Spectral Doppler Mode. It uses measurement data to perform certain calculations automatically

NOTE

The specified items appear in Spectral Doppler Mode only when **Auto Calc** in the soft menu is clicked.



[Figure 3-23] Set-up Options

3.10.8.1 AutoCalc Setting

Check this checkbox to select or deselect item(s) for automatic calculation. You can select up to 6 items.

Peak Systolic Velocity Time Averaged Mean Velocity

End Diastolic Velocity Diastole / Systole Ratio Time Averaged Peak Velocity Max Pressure Gradient Mean Pressure Gradient Resistive Index **Pulsatility Index** Velocity Time Integral

Systole / Diastole Ratio PeakA

The Peak Systolic Velocity and End Diastolic Velocity for the selected item(s) will not be displayed at all if they are 0 (zero). The Timed Averaged Mean Velocity will be displayed only when **Mean Trace** is **On**.

Checking the Product

4.1 **Overview**

Chapter 4 describes how to check MySono U5 and how to check if its major functions and the power supply are working properly.

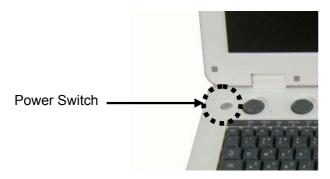
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4.2 **Starting the Product**

Press the On/Off button when the power is off. Booting begins, and the product logo appears on the screen. When booting is completed, the 2D mode screen appears in End Exam status.



[Figure 3-5] Power Switch

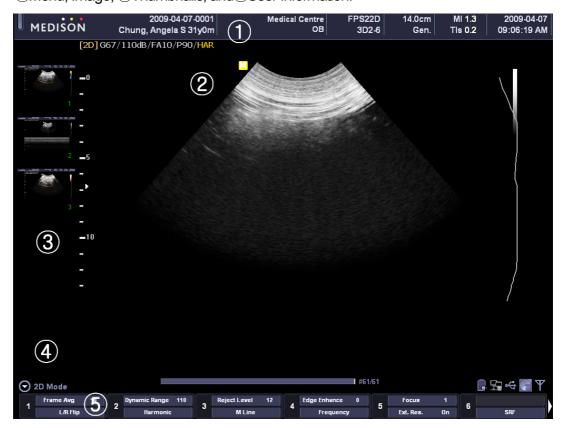
- 1 The booting sequence is displayed on the LCD monitor. As the Windows XP logo disappears, the MySono U5 logo and loading bar appear.
- 2 The loading bar fills with color. This represents data being copied to the Front End and Back End of system by the PC software.
- ③ When software data copying is completed, the ultrasound picture appears and the system becomes ready.

4.3 Monitor

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

4.3.1 Monitor Display

The monitor displays ultrasound images, operation menus and a variety of other information. The screen is divided into six sections: ①Title, ②Measurement ③Menu, Image, ④Thumbnails, and⑤User Information.



[Figure 4-3] Monitor Display

1 Title Area

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

2 Measurement Menu

The measurement menu appears in this area during measurement. Use Menu dialbutton to select an item from the menu.

③ Image Area

The ultrasound image, image information, annotation, and measurement are



displayed in the image area.

(4) Thumbnails Area

Saved images, by pressing the Save button on the control panel, are displayed in the thumbnails area.

Click a thumbnail with a pointer to enlarge. When there are more than 9 images, the arrow button on the screen can be used for navigation.

(5) User Information Area

User information area provides a variety of information necessary for system use e.g. current system status, bodymarkers, and so on.

......

*** Tips! Identifying the current system state**



: Shows the battery state. Please refer to 'Battery Pack' part in this chapter for more information.



: Shows the network status.



: Indicates whether a removable disk is connected. If you doubleclick this icon, the **Storage Manager** screen will be displayed.



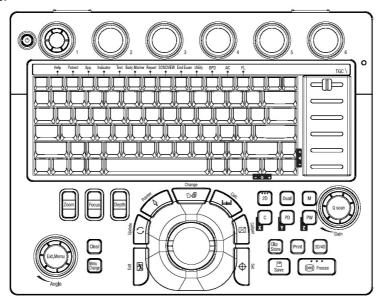
: Shows the amount of the total & available disk space in the system.



: Indicates whether Wireless LAN is connected.

4.4 **Control Panel**

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



[Figure 4-4] Control Panel

4.4.1 **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.

| On/Off | Turn the system on/off. |
|------------------------------------|--|
| Soft Menu dial-buttons (1-6) | Use the Soft Menu that appears on the screen. Available menu items may vary depending on the current system state. Press or rotate a dial-button to adjust the desired setting. |

***Tips! Using Soft Menu dial-buttons**

The Soft Menu is divided into top and bottom sections as below:

- Top Menu (1): Rotate a dial-button to select an item.
- Sub Menu (②): Press a dial-button to select an item.





| TGC | Six slides are used to adjust Time Gain Compensation (TGC) values by depth. |
|----------------------|--|
| Zoom | Zoom in or out the image. The zoom navigation box will be displayed in the User Information area. To exit the zoom mode, press the Exit button. |
| Focus | Use this switch to adjust the focus position. The focus position changes on the ruler as you adjust its position. |
| Depth | Use this switch to adjust the scanning depth for the selected image. The depth information changes in the Title area as you adjust the depth. |
| | Ext. Menu : Press the dial-button to turn the Soft Menu page. Ext. Menu is an abbreviation for 'Extension Menu'. |
| Ext. Menu / Angle | Angle: Rotate the dial-button to adjust the angle. In Spectral Doppler Mode, the angle of the sample volume can be adjusted by 1°. In 2D Mode and View Area is not 100%, rotate the 2D image left or right side. Use this button to adjust the probe cursor or the indicator angle in BodyMarker or Indicator Mode respectively. |
| Clear | Use this button to erase the text, indicator, BodyMarker, and measurement data from the displayed image. |
| Menu Change | Use this button to toggle the menu or Soft Menu on the screen. |
| Trackball | Use the trackball to move the cursor on the screen. It can also be used to search through Cine or Loop images when Freeze is enabled. |
| Set / Exit | There is one button on each side of the trackball. The function of each button can be specified according to your preference at Utility > Setup > Peripherals > Key Setup - Set: Use this option to select an item or value. - Exit: Use this option to exit the current mode and return to the previous setting. |
| Update | Use this button to display the selected image in panning mode. If it is pressed in PW Spectral Doppler Mode, the system will switch to D Only Mode. |

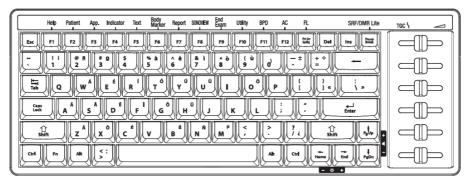
| Pointer | Press this button to show an arrow-shaped pointer in scan mode. Press it again to hide it. |
|------------------|--|
| Change | Use this button to change the function of the trackball. |
| Calc. | Use this button to take measurements for the selected application. |
| Caliper | Use this button to take basic measurements such as distance, volume, circumference and area. Press it again to exit the basic measurement mode. |
| 2D / Single | - 2D: Use this button to enable 2D Mode. Pressing this button in 2D mode does not disable the mode. Pressing it in Combined Mode switches to 2D Mode. - Single: In Dual Mode, press this button to switch to 2D Mode. |
| Dual | In 3D View, it can be used to adjust Reference Slice. Use this button to enable Dual Mode. |
| М | Use this button to enable/disable M Mode. |
| C/x | Use this button to enable/disable Color Doppler Mode. In 3D View Mode, it can be used to rotate the selected image along the X-axis. |
| PD/y | Use this button to enable/disable Power Doppler Mode. In 3D View, it can be used to rotate the selected image along the Y-axis. |
| PW/z | Use this button to enable/disable PW Spectral Doppler Mode. In 3D View Mode, it can be used to rotate the selected image along the Z-axis. |
| Q Scan / Gain | Q Scan: Press this dial-button to enable Quick Scan. If Quick Scan is enabled, 'Q Scan' is shown in the right hand side of the screen. Gain: Rotate this dial-button to adjust Gain in each mode. In 3D View, it can be used to move the reference image. |
| Clip Store | Use this button to save Cine images. The saved images can be played in SONOVIEW or scan mode. |



| Print | Use this button to print the image on the screen via a printer. |
|---------|--|
| 3D / 4D | Use this button to enable/disable 3D/4D Mode. |
| Save | Use this button to save the selected image or report in a database. |
| Freeze | Use this button to freeze the image that is being scanned. Press it again to return to scan mode. |

4.4.2 Alphanumeric keyboard

The alphanumeric keyboard is under the control panel. This is used to type in text or performs some functions.



[Figure 4-6] Alphanumeric keyboard

| Help | Displays help text on the screen. |
|-----------|---|
| Patient | Opens the <i>Patient Information</i> screen allowing you to select a patient ID or enter new patient data. |
| Арр. | Opens the <i>Applications</i> screen allowing you to select or change an application. |
| Indicator | Places an arrow-shaped indicator onto the selected image. |
| Text | Allows you to enter text on the selected image manually. However, if the Quick Text checkbox is checked at Utility > Setup > Utility > Text Setup, you can enter text without pressing this button. |

| BodyMarker | Shows the list of BodyMarkers. Allows you to place a BodyMarker onto the selected image. Each time it is pressed, the list of BodyMarkers toggles. |
|-------------------|--|
| SRF / DMR Lite | Enables or disables SRF or DynamicMR Lite. If it is enabled, 'SRF' or 'DMR' will appear in the right hand side of the Image area. |
| Report | Displays the <i>Ultrasound Report</i> screen showing the measurement results for the current application. |
| SONOVIEW | Launches an image filing program, SONOVIEW $^{\text{TM}}$. |
| End Exam. | Ends the examination for the current patient and resets the related data. |
| Utility | Shows the Utility menu. |
| Space bar | Each time it is pressed, on-screen information disappears in the order of Image Data → Post Map → TGC. After they have disappeared, all three sets of data are displayed again if it is pressed. |
| ←, → | Allows you to adjust the monitor brightness. |
| ↑,↓ | Allows you to adjust volume in Spectral Doppler Mode. |

****Tips! Adjusting the brightness of the keyboard**

While holding down the Fn key, press the 1 key to increase the brightness of the back light. To decrease the brightness, press the 2 key with the same way.



Checking the Performance 4.5

4.5.1 **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 the signal when you shake the cable.

2) Control Panel and LED Status

Press on control panel key and check if the corresponding character is displayed on the

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.

4.5.2 **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.
- The 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.
- ① Check if the image changes according to Depth change when the focus is changed.
- ① 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.
- Check if the image changes according to Depth change when the focus is changed.
- ① 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.



- Check if there is an image brightness change when the GAIN is adjusted. (3)
- 4 Check if the image select menus (EE, DR, View Area, Tissue, Frame Rate, Sane angle, Power) work properly.
- Check if image changes according to Depth change.
- Check if image changes according to Depth change when focus is changed.
- Check if the speed change and information is correct according to the SPEED conversion step.
- Check if an image is reversed when Negative operates.
- Oheck if the Top Down Format and Side by Side Format Image Image are correct when Loop Format is selected.
- 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.
- 6 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.
- ① 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.
- ① Check if the Color Bar is reserved when the Invert key is pressed.
- 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.
- 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.
- Operate the filter and check if small signals in the spectrum are removed.
- Operate the Invert and check if the Doppler waveform is reversed.
- 8 Operate the Angle.
- Move the SV or Size and check if it works properly.
- ① Change the Spectrum Type and check if the spectrum video changes.
- 11) Check if Sound Volume works properly.
- ② Check if the line when appears when Auto Calc runs is continuous and if the subsequent calculations are automatically done correctly.
- Check if the Top Down Format and Side by Side Format Image are correct when LOOP FORMAT is selected.
- (4) 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

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

Product Structure

5.1 **Overview**

Chapter 5 describes the internal structure and operation mechanism of MySono U5.

This chapter must be read for the product maintenance and upgrade.

MySono U5 is Software DSC-applied ultrasound system.

It not only adopted 15 inch LCD monitor and provides high resolution ultrasound Image, 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.

MySono U5 can use up to 128 Element probes and adopted Digital Beamforming of TX 32 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 1024 X 768 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.

MySono U5 consists of the following major components.

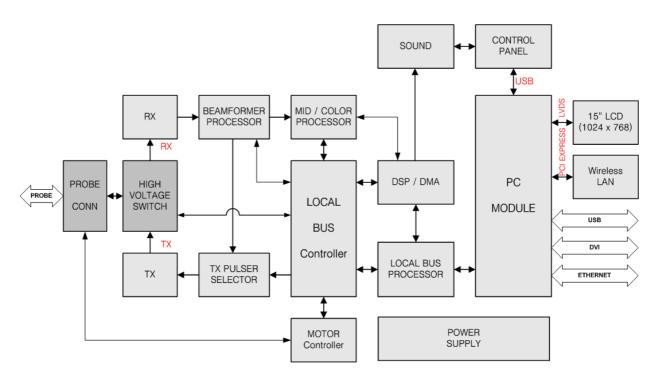
- Ultrasound System Part : PSA, Main Board, PC Mother Board, DC to DC Power Module
- User Interface Part : LCD Monitor, Control Panel, Alphanumeric Keyboard, Track Ball
- ERC. Part: HDD Board, Battery Sub Board



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System Block Diagram 5.2



[Figure 5-1] System Block Diagram



5.3 Basic Structure of MySono U5

5.3.1 Overview

MySono U5 consists of Ultrasound System Part, User Interface 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 MySono U5.

Front End Part refers to the PSA (Probe Select Assembly), and BF (Beamformer). 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) and PC Module. The RF signal generated in the BF(Beamformer) is processed to diagnosis image such as BW, Color Doppler, PW Doppler, and Power Doppler and displayed on the monitor so that users can see it. In addition, new technologies such as Q-SCAN and DMR are applied to provide various diagnosis.

User Interface Part refers to the LCD monitor and control panel

5.3.2 Ultrasound System Part

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 Module 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.

PC Module 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 Module 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, MySono U5 used software DSC and displayed ultrasound image on the LCD monitor.

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

Ultrasound System Part consists of the components.

- PSA(Probe Select Assembly)
- Main Board(BF, BE)
- PC Module
- DDM (DC to DC Power Module)



[Figure 5-2] Ultrasound System Part

5.3.3 **User Interface Part**

User Interface Part enables users to view ultrasound image on the LCD monitor and control MySono U5 through the control panel and touch panel.

The image output from the PC Part is transferred to the LCD monitor and external device. Image output interface includes VGA and DVI. The control panel enables users to easily operate the system through various interfaces.

The User Interface Part consists of the following components.

- LCD Monitor (LCD Inverter Board)
- Control Panel Board
- Track Ball
- Alphanumeric Keyboard

5.3.4 ETC. Part

HDD Board, Battery Sub Board, Power adapter



5.4 **PSA**

5.4.1 **Major Function**

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

It includes Probe Connector function and High voltage switch function.

It has 1 260-Pin Array Probe Connector. The pins of Probe Connector are defined for Probe ID and HV-MUX control functions. High Voltage Switching is applied so that the BF (Beamformer)'s 32 Channel Signal and Probe's 128 Element are switched.



Front view

Back view

[Figure 5-3] PSA Diagram

5.4.2 **Specification**

- 32 Channel BF Board Support
- 260 Pin Array Probe Connector 1 ea
- Static CW Probe Connector 1 ea
- High Voltage Switching (32 Channel: 128 Element) 8ea
- Probe ID Reader
- 3D Probe Data Path

5.4.3 **High Voltage Switching Process**

MySono U5 supports 32 Channels and 128 Elements Probes.

Since the Beamformer Part's Pulser and Receiver circuit consists of 32 Channels only, additional Element Selection is necessary. Element Selection uses 8 High Voltage Switches and switches based on the Control Signal output from the Main Board's Control Logic(CPLD).

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



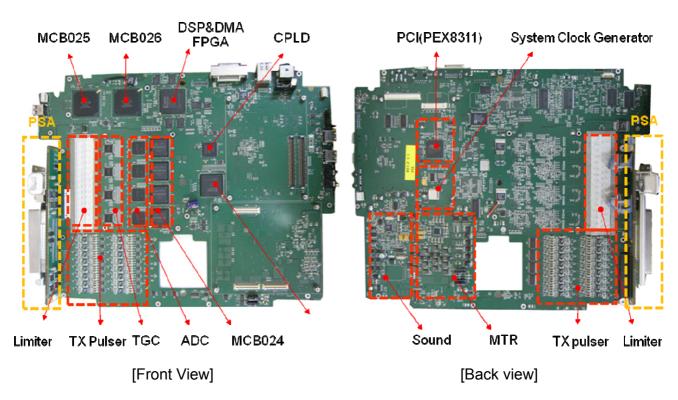
5.5 **Main Board**

5.5.1 **Major Function**

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).

Main Board consists of BF(Beamformer) Part, DSP(Digital Signal Processing) & DMA Part, PCI Part, MTR(Motor Control) Part and Analog Sound Part, Non-CW Part.

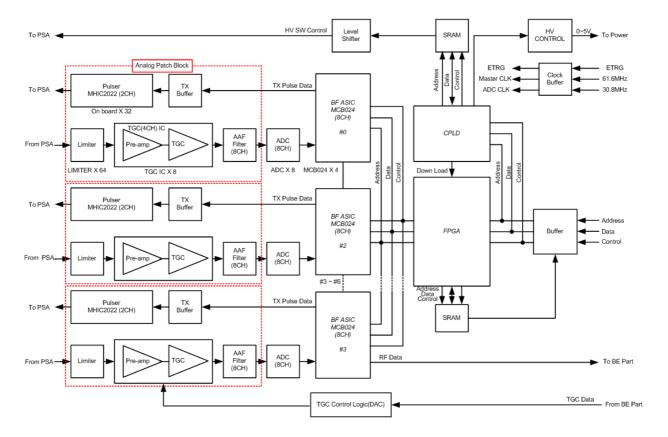


[Figure 5-4] Main Board

5.5.2 **Beamformer Part**

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 32 Channel and supports up to 128 Element Probe. It consists of TX Pulser circuit, Receiving circuit and 8 Beamformer ASIC(MCB024) to construct the Active aperture 128 Channels and does the Dynamic Apodization, Multi Beam Receiving, and TGC functions to enhance ultrasound image.



[Figure 5-5] Beamformer Part Block Diagram

5.5.2.1 **Specification**

- TX Pulser 32ea (On Board)
- Limiter 32ea
- TGC amp 8ea (4 Channels)
- AD converter 4ea (8 Channels)
- BF ASIC 8ea (MCB024)
- RX Dynamic Aperture Function
- **RX** Apodization Function
- Trapezoidal Imaging Support
- Multi-Line Receiving Support
- TX Focal Point Support



5.5.2.2 Operation Mechanism

1) TX Pulser

The Exciting pulse data provided by BF ASIC(MCB024) is applied to TX Pulser via TX Pulse Buffer. TX Pulser 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.

Since Active aperture 32 Channels provide 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).

1) 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.

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.

Pre-Amp

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

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.

Low Pass Filter(Anti-aliasing)

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.

A/D Converter

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

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).

5.3.3 Non CW Part

Non-CW function provides System Clock Drive, Beamformer Sensing function, High Voltage Sensing function and PSA related signal.

5.5.3.1 **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
- 3D Probe Path Sine Drive/Return Cosine Drive Return Hall Signal



5.5.3.2 Operation Mechanism

1) Master Clock

It provides 61.6Mhz Master Clock of the Ultrasound System Part to the FE(Front End) Part and BE(Back End) Part so that the boards can be synchronized.

2) Beamformer Sensing

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

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.

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.

3) Beamformer TX Control

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

4) PSA Related

PSA related control functions also are executed in CPLD.

Probe ID Read

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

Probe Inset Check

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

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) 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 Board, System Mother Board, CW, PSA, and 3D Probe in order.

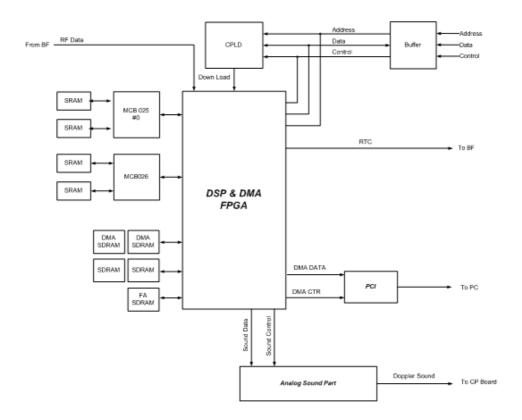
5.6 **Back End Part**

5.6.1 **Major Function**

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

DSP Part receives RF Data from the BF Part respectively, processes the data and outputs the data as image data such as BW Image, PW Doppler, Color Doppler, and Power Doppler. The image data pass through the Frame Average of the DSP & DMA 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 Part of MID processor(MCB025A), Color processor(MCB026A), FPGA and CPLD.



[Figure 5-6] Back End Part Block Diagram



5.6.2 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
- DMA Interface between Ultrasound System Part and PC Part Frame Average
- Real Time Controller (RTC)
- Analog Sound Part

5.6.3 DSP Part Operation Mechanism

1) BW Mode and M Mode Image Data Processing

RF data generated in the BF Part in Input to the 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).

The MID Processors (MCB025A) generate BW mode image data (hereafter, BW Data) and send the data to the FPGA.

The MID Processors (MCB025A) not only generate BW data but also do the functions of 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.

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

2) Doppler Image Data Processing

The RF data generated in the BF Part is input to the FPGA.

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

MID Processor (MCB025A) 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 FPGA again.

The FPGA that received the I/Q Data, sends the data to the Doppler DSP via filtering. I/Q Data passes through the Clutter Filter to remove the Wall (blood vessel wall) Noise

after the data are filtered by the FPGA. After that, the Doppler Sound is generated through the Hilbert transform that separates sound directions.

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.

3) Color Image Data Processing

RF Data generated in the BF Part are input to the FPGA.

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

MID Processor (MCB025A) 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 FPGA again.

The 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 FPGA again and passes through the Rejection, Smooth Filter, and Post Filter. Color Data are completed in the process.

4) 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 FPGA.

After that, the noise is removed and Doppler Sound is amplified and sent to the speaker.

5) DMA & RTC Operation Mechanism

DMA (Direct Memory Access) consists of FA(Frame Average) and DMA.

FA (Frame Average) processes the BW, Doppler, Color Data with the average of the current Frame's Scan line Data and the previous Frame's Scan line 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. Since DMA processes data using the DMA path with the PC Part, it plays key role to improve the product performance.

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), Line Type, and Scan Line signals necessary for the BF Part and BE Part's DSP Part. In addition, it internally controls the data flow in the DMA FPGA.



5.7 PCI Part

5.7.1 Major Function

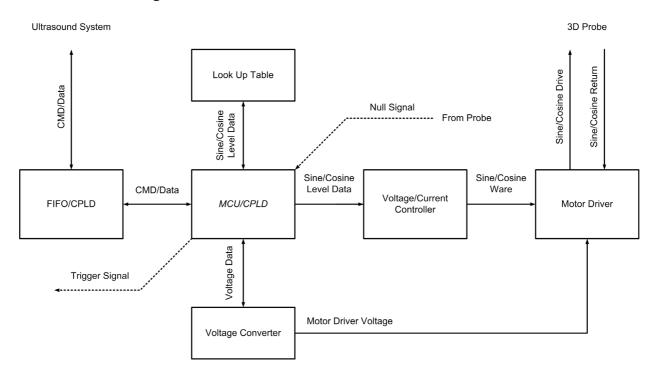
Peripheral Component Interconnect Part (PCI Part) interconnects the Ultrasound System Part and the PC Part. It is used as a DMA path to control and initilize the Ultrasound System Part and to handle the BW, Color, Doppler Data using the Software DSC(Software Digital Scanconversion).

5.8 **Motor Control Part**

5.8.1 **Major Function**

This Motor Control Part (MTR Part) is the Motor Driver to drive the 3D Probe.

5.8.2 **Block Diagram**



[Figure 5-7] Motor Board Block Diagram

5.7.3 **Specification**

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

5.7.4 **Operation Mechanism**

3D Probe implements 3D Mode by driving the Stepping Motor. The Motor Part does Feedback Control by using the SIN and COS waveform that has 90° 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 DMA.



5.9 PC Module

5.9.1 Major Function

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 Module is critical.

PC Mother Board has the following specifications.

CPU: Celeron 1.06GHz
 RAM: DDR2 2GB Memory

3) HDD: 160GB

4) OS : Windows XP Emb5) Display : 1024 X 768



[Figure 5-8] PC Module

I/O Port

| Video cassette recorder | VHS (DSUB Gender) | |
|--------------------------------------|-----------------------------------|--|
| video cassette recorder | S-VHS (DSUB Gender) | |
| External monitor | DVI | |
| External monitor | RGB (DSUB Gender) | |
| Thermal Printer | VCR Type | |
| mermai Pfintei | USB (Digital) Type - Recommended | |
| Extermal DVD multi recordable driver | -R/+R/-RW/+RW/CDR/CDRW | |
| USB | USB 2.0 (Port 3EA) | |
| USB | USB Flash Memory, USB MO, USB HDD | |



5.10 Software DSC

5.10.1 Major Function

MySono U5 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.

5.10.2 Operation Mechanism

The image data generated in the Main Board's are directly copied to the PC Memory in DMA mode

The data are saved in the Cine Memory through the UCAgency Buffer and processed by the Software DSC and the Image Save.

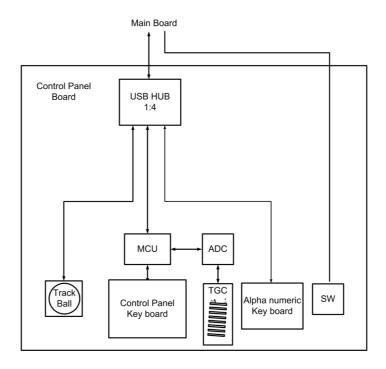
The Software DSC does all the functions can be done by the Hardware DSC. Processes the DSC by the Filter and Rendering and transfers data to the VGA. In addition, the delay problem when saving the image into the HDD has been resolved.

5.11 **Control Panel**

5.11.1 **Major function**

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

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



[Figure 5-9] Control Panel Block Diagram



5.12 Power Supply

5.12.1 Power adapter

1) Input Power

MySono U5 is designed so that it operates when the input voltage is either 100V~ 240V.

| Input Voltage | Input Frequency | Input Current |
|---------------|-----------------|---------------|
| 100 ~ 240 V | 47 ~ 63 Hz | 1.63 ~ 0.7A |

2) Output Power

| Output Voltage | Current min. | Current max. |
|----------------|--------------|--------------|
| 19 V | 0 A | 7.9 A |

5.12.2 DC to DC Power Module

| Output Voltage | Current min. | Current max. |
|----------------|--------------|--------------|
| +3.3Vdo | 1.2A | 12A |
| +5Vdo | 0.37A | 3.7A |
| +12Vdo | 0.35A | 3.5A |
| -5Vdo | 0.05A | 0.5A |
| -12Vdo | 0.02A | 0.2A |
| +5Vdo | 0.02A | 0.1A |
| 0 ~ +80Vdo | - | 0.02A |
| 0 ~ -80Vdo | - | 0.02A |
| 0 ~ +10Vdo | 0.1A | 1A |
| +97Vdo | | 0.02A |
| -97Vdo | - | 0.02A |

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.

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.

3) Over Temperature Protection (OTP)

If the temperature of the DDM Case is equal to or higher than $80\,^\circ\text{C}$, all powers of DDM are cut off.

Basic Maintenance

6.1 **Overview**

Chapter 6 describes basic MySono U5 maintenance procedures.

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

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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.



Upgrade 6.4

You can upgrade the software and hardware of MySono U5.

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 service department of MEDISON Co., Ltd.

6.4.1 **Software Upgrade**

Follow these instructions to software upgrade the system.

- 1) Prepare a software file provided by the customer service department of MEDISON
- 2) Turn on MySono U5.
- 3) When system booting is complete, enter windows mode referring to "6.3.1 Windows Mode"
- 4) Inert a Fresh Memory or USB CD/DVD ROM drive into the USB port.
- 5) Press the explorer in the Windows mode.
- 6) Press the upgrade file in the explorer

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 6-2].



[Figure 6-2] Admin Mode



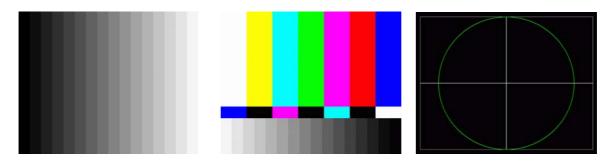
6.5.2 **Admin Mode Functions**

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.

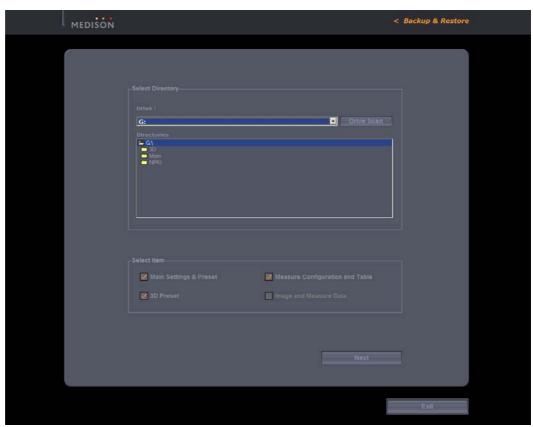


[Figure 6-3] Test Patterns

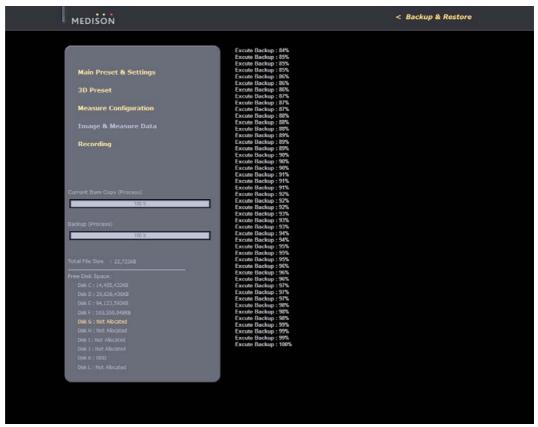
6.5.2.3 Restore

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 6-4] Restore Function



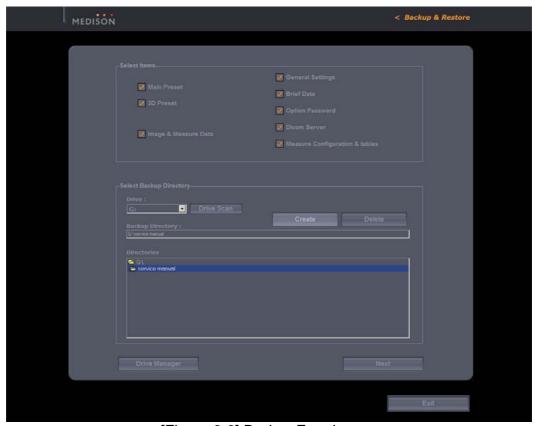
[Figure 6-5] Execution of Restore Function



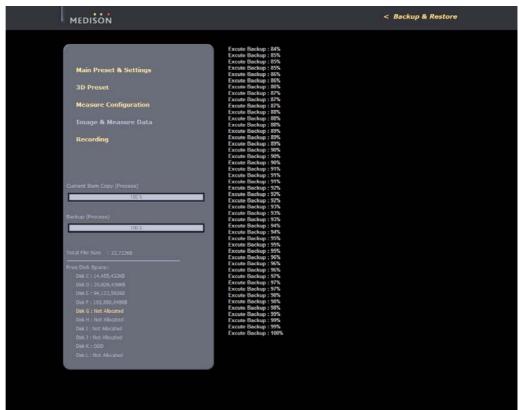
6.5.2.4 **Backup**

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 6-6] Backup Function



[Figure 6-7] Execution of Backup Function

6.5.2.5 VGA

Video Out Format

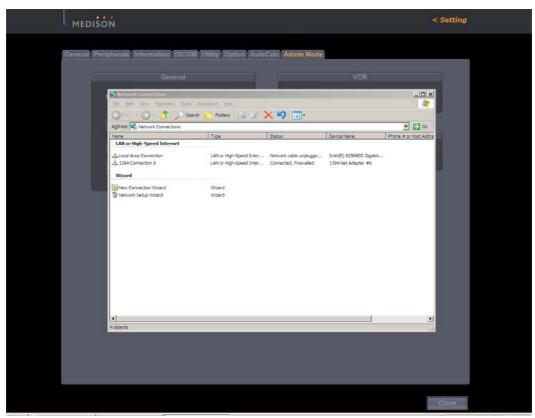
You can select the scan type for Video Out through filter. Supported scan types are NTSC and PAL.



Network Configuration 6.5.2.6

The Windows XP Network Configuration screen appears.

You can set up Network Settings such as DICOM, etc.



[Figure 6-8] Network Configuration

6.6 Adding and Deleting Options

This section describes how to add and delete options from MySono U5.

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

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 MySono U5:

4D DICOM SR

3D XI Dynamic MR+

Cardiac Measurement Auto IMT

DICOM

Status: Shows the current status of optional software.

- 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.



6.6.2 **Registering Options**

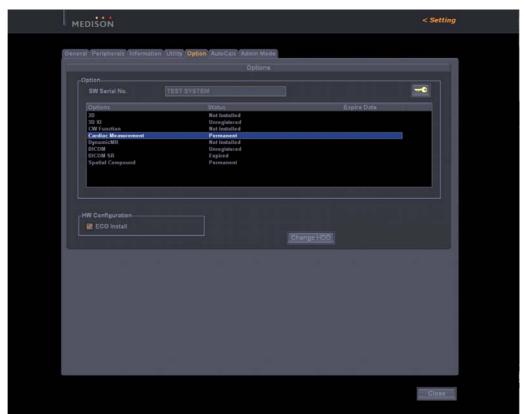
6.6.2.1 **Entering Option Password**

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

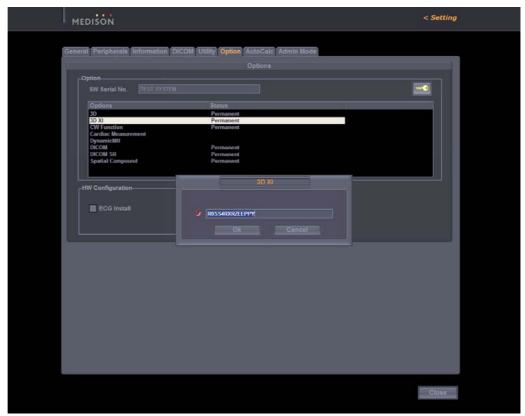
- 1) Switch to the Admin Mode referring to "6.5.1 Entering Admin Mode"
- The key-shaped button at the top right of the Option tab is activated. When this 2) button is activated, you can enter an Option Password.
- Select an option to be added, click the key-shaped button and enter the password.
- If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



[Figure 6-9] Deactivated Option Tab



[Figure 6-10] Activated Option Tab



[Figure 6-11] Entering Option Password

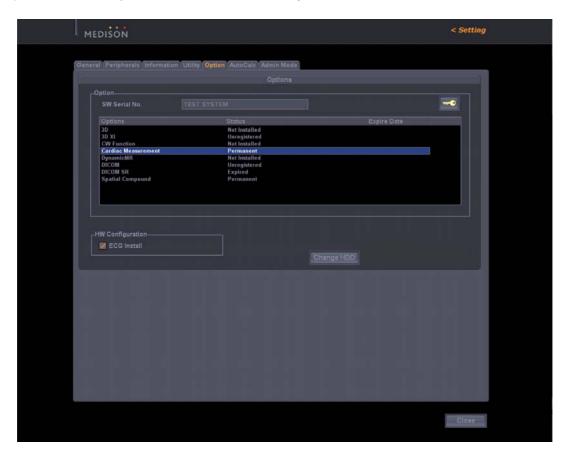


6.6.2.2 **Registering Option Password after Replacing the HDD**

MySono U5 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 6-12] Change HDD

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.

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.

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Power 7.2

7.2.1 **Power Failure**

This may occur if the AC power cord is not properly connected or the DDM(DC to DC Power Module) is not working.

- 1) Check the AC power cord status.
- 2) Connect another device to the wall outlet and check if it works. If the device works, there is a DDM(DC to DC Power Module) problem. If the device does not work, the problem is down to the wall outlet.
- 3) Check if the system fan works. If the fan works, the problem is not a DDM(DC to DC Power Module) problem. If the fan does not work, a DDM(DC to DC Power Module) problem is likely.
- 4) Check the DDM(DC to DC Power Module) and the AC Power cord.

7.2.2 Power cannot be turned off

A software error or PC Motherboard, Main Board problem is likely.

- 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, Main Board problem is likely.

7.2.3 Power is automatically turned off

Power cord, PC Mother Board, Main Board trouble is expected.

- 1) Check the AC power cord status.
- 2) Connect another device to the wall outlet and check if it works. If the device works, it is due to DDM(DC to DC Power Module) problem. If the device does not work, it is due to wall outlet problem.
- 3) If the power is automatically turned off after completing the procedures of "1), and 2)", PC Mother Board or Main Board trouble is expected.

7.3 **Monitor**

7.3.1 **Blank Screen**

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

7.3.2 **Screen Color is Abnormal**

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

- 1) Check the monitor connection cable status.
- 2) If no problem has been found in the above "1)", monitor and PC Part trouble is expected.



Error Messages 7.4

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 after 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 ACCUVIX V20 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 after 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 ACCUVIX V20 logo appears, system software or Ultrasound System Part trouble is expected.

7.5 Image

7.5.1 No BW Mode Image Echo and No BW Mode Image Format

Probe and the system connection, Main 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) If no problem has been found in the above "1), and 2)", Main Board trouble is expected.

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

Power noise or Main Board trouble is expected.

- 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)", Main Board trouble is expected.

7.5.3 PW Doppler Mode, Color Doppler Mode and M Mode Trouble

Main Board trouble is expected.

8 Disassembly and Reassembly

8.1 Overview

Chapter 8 describes how to disassemble MySono U5.

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 service department of MEDISON Co., Ltd.

The company is not responsible 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.



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



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8.2 Disassembly and Reassembly of a Basis

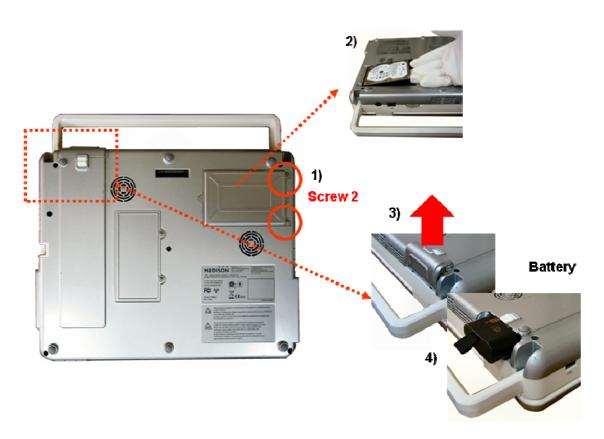
8.2.1 Preparations

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

Shut down the system referring to "3.7 Shutting down the Product".

8.2.2 HDD and Battery Pack

- 1) Remove the 2 screws of the HDD Cover using the (+) screwdriver and separate it.
- 2) Hold and pull the HDD to separate it.
- 3) Separate the Battery Cover.
- 4) Hold and pull the Battery Pack to separate it.

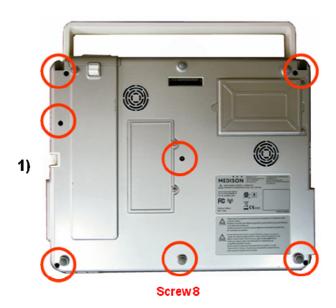


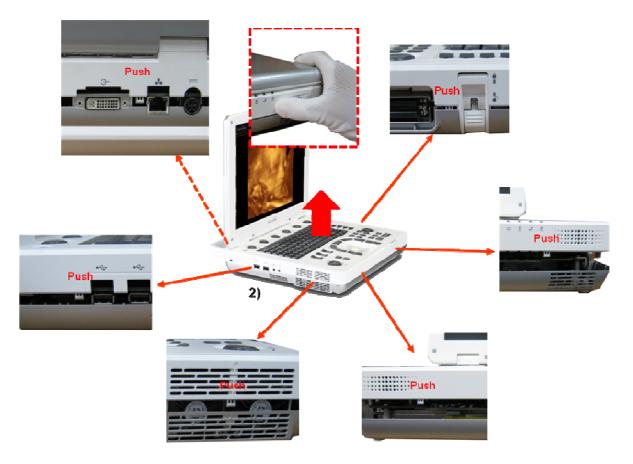
[Picture 8-2] HDD & Battery Pack



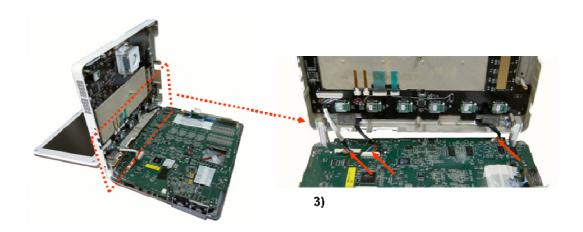
8.2.3 Middle of System

- 1) Remove the 8 screws of the Bottom(Cover C) using the (+) screwdriver.
- 2) Disassemble the System referring to "[Figure 8-3-a.b] Middle of System"





[Picture 8-3-a] Middle of System



[Picture 8-3-b] Middle of System



8.3 Disassembly and Reassembly of the Ultrasound System Part

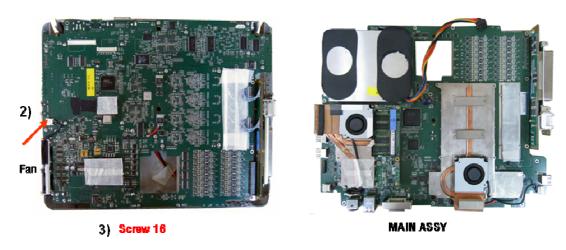
8.3.1 Preparations

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

Shut down the system referring to "3.7 Shutting down the Product".

8.3.2 MAIN ASSY

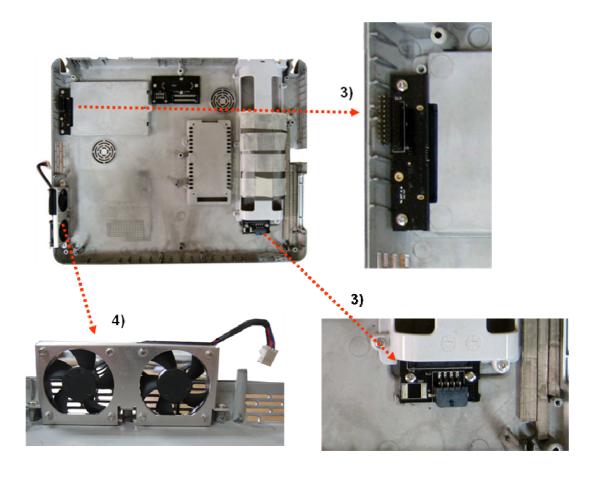
- 1) Disassemble the System referring to "8.2.3 Middle of System".
- 2) Separate the cables from the MAIN ASSY.
- 3) Remove the 16 screws of the MAIN ASSY using the (+) screwdriver and separate it.



[Picture 8-4] MAIN ASSY

8.3.3 Sub Board

- 1) Disassemble the System referring to "8.2.3 Middle of System".
- 2) Disassemble the MAIN ASSY referring to "8.3.2 MAIN ASSY".
- 3) Remove the 2 screws of the HDD Board using the (+) screwdriver and separate it.
- 4) Remove the 2 screws of the Battery Sub Board using the (+) screwdriver and separate it.
- 5) Remove the 2 screws of the FAN ASSY Cover using the (+) screwdriver and separate it.



[Picture 8-5] Sub Board



8.4 Disassembly and Reassembly of the Control Panel

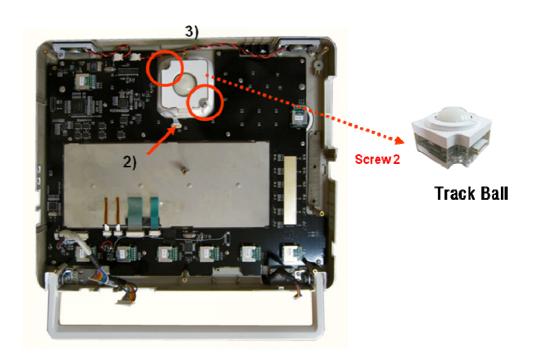
8.4.1 Preparations

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

Shut down the system referring to "3.7 Shutting down the Product".

8.4.2 Track Ball

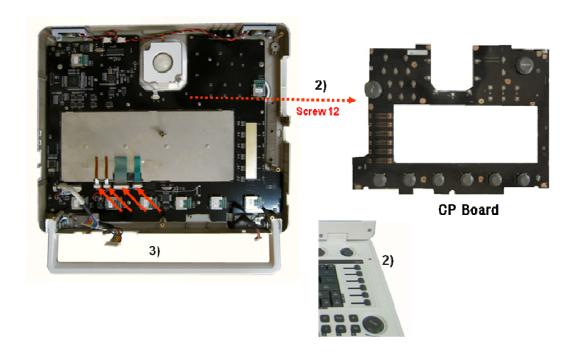
- 1) Disassemble the System referring to "8.2.3 Middle of System".
- 2) Separate the cables from the CP Board.
- 3) Remove the 2 screws of the Track Ball using the (+) screwdriver and separate it.



[Picture 8-6] Track Ball

8.4.3 **Control Panel Board**

- 1) Disassemble the System referring to "8.2.3 Middle of System".
- 2) Separate the TCG Cap
- 3) . Separate the cables from the CP Board.
- 4) Remove the 12 screws of the CP Board using the (+) screwdriver and separate it.

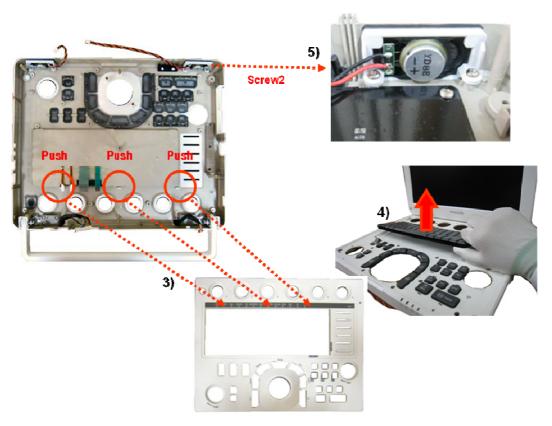


[Picture 8-7] Control Panel Board



8.4.4 Alpha numeric Keyboard and Speaker ASSY

- 1) Disassemble the System referring to "8.2.3 Middle of System".
- 2) Disassemble the CP Board referring to "8.3.4 Control Panel Board".
- 3) Separate the CP Board referring to "[Figure 8-9]".
- 4) Separate the Alpha numeric Keyboard.
- 5) Remove the 2 screws of the Speaker ASSY using the (+) screwdriver and separate it.



[Picture 8-8] Alpha numeric Keyboard & Speaker ASSY

8.5 Disassembly and Reassembly of the LCD Part

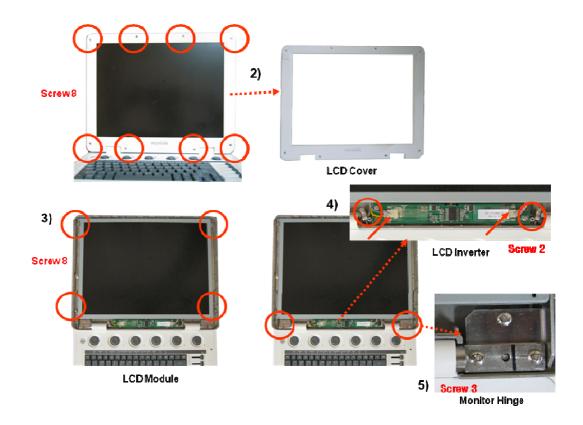
8.5.1 Preparations

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

Shut down the system referring to "3.7 Shutting down the Product".

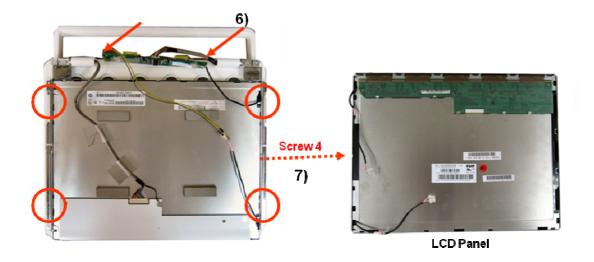
8.5.2 LCD Module

- 1) Disassemble the System referring to "8.2.3 Middle of System".
- 2) Remove the 8 screws of the LCD Front Cover using the (+) screwdriver and separate it.
- 3) Remove the 8 screws of the Track Ball using the (+) screwdriver.
- 4) Remove the 4 screws of the LCD Inverter using the (+) screwdriver and separate it.
- 5) Remove the 2 screws of the Track Ball using the (+) screwdriver and separate it.
- 6) Separate the cables from the LCD module.
- 7) Remove the 4 screws of the LCD Panel using the (+) screwdriver and separate it.



[Picture 8-9-a] LCD Module





[Picture 8-9-b] LCD Module

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 C 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 overcurrent 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 C degrees Celsius in the event of a single fault failure.

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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.

9.2.1 **Probe Application and Preset**

Probes, applications and settings available for this product are as follows:

| Probe | Application | Preset |
|-------|----------------------|--------------------------------|
| | Abdomen | General, Renal |
| C3-7 | ОВ | General, Fetal Heart, OB Early |
| | Gynecology | General |
| | Musculoskeletal | General |
| L5-12 | Small Parts | Breast, General |
| | Vascular | General |
| | Abdomen | General |
| P2-4 | Cardiac | General |
| 1 2-4 | Pediatric Cardiology | General |
| | TCD | General |
| | Gynecology | General |
| EV4-9 | ОВ | General |
| | Urology | General |
| | Abdomen | Renal, General |
| 3D2-6 | Gynecology | General |
| | ОВ | General, Fetal Heart, OB Early |

9.2.2 **Function list**

Some functions depend on probe and its application. See following table.

| Probes | Applications | Presets | Q Scan | Har | PI | PPI | TDI | СМ | Biopsy |
|-------------------|-------------------------|----------------|--------|-----|----|-----|-----|----|--------|
| | Abdomen | Renal | 0 | 0 | 0 | Χ | Х | Х | |
| | Abdomen | General | 0 | 0 | 0 | Χ | Χ | Χ | |
| | Gynecology | General | 0 | 0 | 0 | Χ | Χ | Χ | |
| C3-7 | | OB Early | 0 | 0 | 0 | Х | Χ | Χ | 0 |
| | ОВ | Fetal Heart | 0 | 0 | 0 | Х | Х | 0 | |
| | | General | 0 | 0 | 0 | Χ | Χ | Χ | |
| | Musculoskeletal | General | 0 | Χ | Χ | Χ | Χ | Χ | |
| L5-12 | Small Dorto | Renal | 0 | Χ | Χ | Χ | Χ | Χ | |
| L3-12 | Small Parts | General | 0 | Х | Х | Х | Х | Χ | 0 |
| | Vascular | General | 0 | Х | Х | Х | Х | Х | |
| | Abdomen | General | 0 | 0 | 0 | 0 | Χ | Χ | |
| | Cardiac | General | 0 | 0 | 0 | 0 | 0 | 0 | |
| P2-4 | Pediatric Cardiology | General | 0 | 0 | 0 | 0 | 0 | 0 | X |
| 1 Z- 4 | TCD | General | 0 | 0 | 0 | 0 | Χ | Χ | |
| | Gynecology | General | 0 | Х | Х | Х | Х | Х | |
| EV4-9 | ОВ | General | 0 | Χ | Χ | Χ | Χ | Χ | 0 |
| | Urology | General | 0 | Χ | Χ | Χ | Х | Χ | |
| | Λ la al a ma a m | Renal | 0 | 0 | 0 | Χ | Χ | Χ | |
| | Abdomen | General | 0 | 0 | 0 | Χ | Χ | X | |
| | Gynecology | General | 0 | 0 | 0 | Х | Х | Х | |
| 3D2-6 | | OB Early | 0 | 0 | 0 | Χ | Х | Χ | 0 |
| | ОВ | Fetal Heart | 0 | 0 | 0 | Х | Х | 0 | |
| | | General | 0 | 0 | 0 | Χ | Χ | Χ | |

NOTE Q Scan: Quick Scan

Har: Harmonic imaging

PI: Pulse Inversion

PPI: Power Pulse Inversion TDI: Tissue Doppler Imaging

CM: Color M mode



Thermal Index (TI) Tables 9.3

TI(TI;Thermal Index) values displayed on the screen title bar can change depending on probes and applications. ACCUVIX V20 decides automatically which TI value will be displayed out of TIs(TI;Thermal Index System), TIb(TI;Thermal Index Bone), and Tlc(TI;Thermal Index Cranium). The TI values are as follows,

| Application Probes | Obstetrics | Gynecology | Abdomen | Cardiac | Pediatric Cardiology | Urology | Vascular | Small Parts | Musculoskeletal | TCD |
|-----------------------|------------|------------|---------|---------|----------------------|---------|----------|-------------|-----------------|-----|
| C3-7 | Tlb | Tls | TIs | | | | | | | |
| L5-12 | | | | | | | TIs | Tls | Tls | |
| P2-4 | | | Tls | TIs | Tls | | | | | TIs |
| EV4-9 | Tlb | Tls | | | | Tls | | | | |
| 3D2-6 | Tlb | Tls | Tls | | | | | | | |

Ultrasound Transmission Gel 9.4

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.

WARNIN



- 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
 - lodine
 - Lanolin
 - Any lotions or gels containing perfume



Sheaths 9.5

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 in the ultrasound gel. If necessary, secure the sheath to the probe and the probe cable.
- 4) Dispose of the sheath after use.

WARNIN





- 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



Sufficient washing and disinfecting must be carried out for preventing infection. This is the responsibility of the user who manages and maintains the disinfection procedures for the equipment. Always use legally approved detergents and sheaths.



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 Service 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)

| | | Disinfectants | | | | | | | | | |
|-------|-----------------|---------------|----------------------|------------|---------------------------|--------------------------|-------------------------|----------|---------|-------------------------------|-------------------|
| Names | | T-Spray II | T-Spray | Sani-Cloth | Cidex OPA ^{2,3)} | Cidex Plus ²⁾ | Metricide ²⁾ | Omnicide | Nuclean | Wavicide -01 ³⁾ | Sekusept Extra |
| | Type | | ray | Wipe | Liquid | | | | | | |
| Ac | tive Ingredient | | Quaterna onium (N | - | | | Gluta | raldehy | de | | |
| CA | C3-7 | | 0 | Ο | 0 | 0 | | | | | |
| LA | L5-12 | | 0 | 0 | 0 | 0 | | | | 0 | |
| PA | P2-4 | 0 | | 0 | 0 | 0 | | | | 0 | |
| EC | EV4-9 | | | | - | | | | | | |
| 3D | 3D2-6 | 0 | 0 | X | 0 | 0 | 0 | | | 0 | |



| | | | Disinfectants | | | | | Cleaner | | | |
|-------------------|-------|------------------------|---------------|-------------------|-----------------------------------|---------------|--|------------------------|-----------------------------|------------------|---------------------------------|
| | Names | Milton | Vircon | Sporox II | Gigasept AF ³⁾ | Gigasept FF | Enzol | Klenzyme | lsoproppyl alcohol (70%) | Metrizyme | Aquasonics 100 ³⁾ |
| | Type | Liquid | | | | | | NA | Lic | uid | |
| Active Ingredient | | Sodium Hypochlorite | NA | Hydrogen Peroxide | Succindialdehyde, Formaldehyde | Bersteinsaure | Dodeylphenoleth oxylate, Sodium Xylene Sulfonate | Proteolytic Enzymes | Alcohol | Propylene Glycol | Gel |
| CA | C3-7 | | | Х | | | 0 | 0 | | 0 | 0 |
| LA | L5-12 | | | 0 | | | 0 | 0 | | 0 | 0 |
| PA | P2-4 | | | 0 | | | 0 | 0 | | 0 | |
| EC | EV4-9 | | | | | | | | | | |
| 3D | 3D2-6 | | | X | | Ο | | Ο | | Ο | Ο |

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 reusable and can be disinfected).
- 3) Discard sheaths. (Sheaths are single-use items).
- 4) Use a soft cloth lightly dampened with mild soap or compatible cleaning solution to remove any particulate matter and body fluid that remain on the probe or cable.
- 5) To remove remaining particulates, rinse with water up to the immersion point.
- 6) Wipe with a dry cloth.
- 7) If necessary, wipe first with a water-dampened clothe to remove soap residue.

Disinfection 9.7.3

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

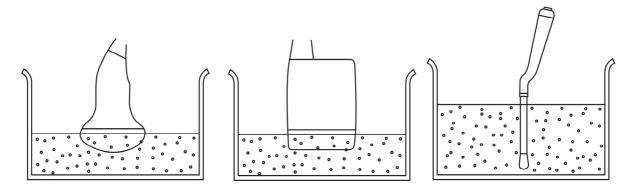


- If a pre-mixed solution is used, be sure to observe the solution expiration date.
- The type of tissue it will contact during use dictates the level of disinfection required for a device. Ensure that the solution strength and duration of contact are appropriate for disinfection.

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.



[Picture 9-1] Disinfection

10 User Maintenance

10.1 Overview

Chapter 10 describes how to extend the life of MySono U5.

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.

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10.2 Operating Environment

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° C ~ 35° C and humidity of 30° ~ 75° K.
- 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.

10.3 System Maintenance

Using inappropriate detergents or disinfectants may damage the product. Please read the following carefully

WARNING



- Make sure to turn off and unplug the product before cleaning or disinfecting it. Otherwise, it may result in electric shock or fire.
- Always use protective eyewear and gloves when cleaning and disinfecting the equipment.

10.3.1 Cleaning

- 1) Console: Use a soft cloth lightly dampened in a mild soap or detergent solution to clean the exterior surfaces of the system.
- 2) Monitor: Wipe the LCD surface with a soft dry cloth. If the LCD panel is dirty, wipe it 2 3 times or more in one direction

CAUTION



- Do not use a spray directly on the product exterior. It may cause cracking or color degradation.
- Do not use chemical substances such as wax, benzene, alcohol, thinner, mosquito repellant, deodorant, lubricant or detergent.

NOTE

For information on cleaning and disinfection of the probe & biopsy kit, please refer to Chapter 9 'Probes' in this manual.



10.3.2 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 | Туре | 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.

10.4 Battery Pack Maintenance

Because the battery pack is an expendable supply, its life is shortened after a long use. When the battery life decreases to less than half of its original life, you should replace the battery.

CAUTION



- Battery packs are normally guaranteed for a period of 6 months.
- MEDISON recommends you replace the battery pack once a year.

NOTE

To purchase a battery pack, please contact a Local sales or service representative.

10.4.1 Disconnecting the Battery Pack

Perform the following procedure to disconnect the battery pack:

- 1) Turn off and unplug the product.
- 2) Open the battery pack cover at the bottom of the console and remove the battery pack.

WARNING



Always remove the battery pack if you do not use the product for more than a month. If the product is left unplugged for an extended period of time, the battery may become completely discharged. If this happens, a problem may occur in the product's communication.

10.4.2 Connecting a Battery Pack

Perform the following procedure to connect a battery pack:

- 1) Turn off and unplug the product.
- 2) Open the battery cover at the bottom of the console and insert a battery pack

CAUTION



When inserting the battery pack, make sure that its polarity is not reversed.

3) After the battery pack has been put in place, wait about 10 seconds before turning on the product.



10.4.3 Charging Battery Pack

The battery pack is automatically charged when you connect the AC adapter to it. MySono U5 charges faster if it is turned off or in Power Saving Mode than when it is turned on.

WARNING



- When you see the message saying that the product is out of battery power while using it, immediately save the content of the diagnosis and connect the AC adapter to the product.
- Do not charge the battery pack by using a method different from the one provided in this manual. It may cause a fire or explosion.

Charging and discharging of the battery pack must be done in the temperature ranges shown below.

| Status | Ambient Temperature |
|-------------|---------------------|
| Charging | 0 ~ 45℃ |
| Discharging | -10 ~ 50℃ |

CAUTION



It is recommended that you charge the battery when the ambient temperature is between 0 and $40\,^{\circ}$ C. If the battery pack is charged in a place where the temperature is too high, it can overheat. If the battery pack is charged in a place where the temperature is too low, the charging takes too long.

NOTE

When supplying power from the battery pack, you should check the remaining battery level from the battery icon on the screen. For detailed information on battery icons, refer to the "Battery" section of Chapter 3, "Installing the Product."

10.4.4 Storing Battery Pack

If you do not use MySonoU5 for more than a month, you must remove the battery pack from the product and store it. The temperature ranges for specific storage periods are shown below.

| Storage Period | Ambient Temperature |
|-------------------------|---------------------|
| Less than one month | -10 ~ 60℃ |
| One to three months | -10 ~ 45 ℃ |
| Four months to one year | -10~ 30℃ |

For more information on storage and operating environment, please refer to "Operating Environment" of this chapter

CAUTION



If you use the battery pack for the first time or you have not used it for three months or longer, repeat the "full charging and discharging" process several times.

Full charging and discharging

- Connect the charged battery pack to MySono U5, and leave the system on until the battery is fully discharged and turned off.
- A fully charged battery pack will take about an hour until it is fully discharged.
- The lamp indicator showing the status of battery changes from green to orange according to the progress of discharging.
- Connect the AC adapter to the battery pack and fully charge it. The battery indicator turns green when the battery is fully charged.
- 3) Discharge the battery once again until the system is turned off.

10.4.5 Discarding Battery Pack

The battery pack must be replaced and disposed of by a MEDISON service engineer or an authorized dealer.

WARNING



Do not discard the battery pack without thought. In particular, if it is incinerated there is a risk of fire or explosion.



10.5 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.

10.5.1 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'.

10.5.2 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'.

10.5.3 Software

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

Service Part List

Overview 11.1

This chapter 11 contains information on the MySono U5 Service Part.

Please refer to the MySono U5 Part Catalogue 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

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11.2 Cover



[Picture 11-1] MySono U5 Cover

| PART NAME | PART NUMBER | DESCRIPTION |
|----------------|-------------|-----------------------------------|
| CASE A | 213-D-069A | CASE A MYSONOU5 (LCD back cover) |
| CASE D | 213-D-070A | CASE D MYSONOU5 (Bottom cover) |
| CASE B | 213-M-145A | CASE B MYSONOU5 (LCD front cover) |
| CASE C | 213-M-146A | CASE C MYSONOU5 (Middle cover) |
| COVER CP | 215-M-534A | COVER CP MYSONOU5 |
| COVER HINGE | 215-M-535A | COVER HINGE MYSONOU5 |
| COVER BATTERY | 215-M-536A | COVER BATTERY MYSONOU5 |
| COVER HDD | 215-M-537A | COVER HDD MYSONOU5 |
| COVER CW | 215-M-538A | COVER CW MYSONOU5 |
| BRACKET PSA AY | A235-092A | BRACKET PSA AY MYSONOU5 |
| CASE A | 213-D-069A | CASE A MYSONOU5 (LCD back cover) |

[Table 11-1] MySono U5 Cover



11.3 **System**



[Picture 11-2] System

| PART NAME | PART NUMBER | DESCRIPTION |
|------------|--------------------------|--|
| SPEAKER AY | A231-023A | HOLDER SPEAKER AY MYSONOU5 |
| FAN AY | A235-090A | BRACKET FAN AY MYSONOU5 |
| ADAPTER | ADAPTER-PMP150-13 | MYSONOU5 ADAPTER 19V/7.9A PMP150-13-2 |
| MAIN AY | AY-350-MAIN | MYSONOU5 MAIN BD, PSA BD, DDM PWR ASSY |
| DDM POWER | AY-350-PWR-DDM | MYSONOU5 POWER AY DC-DC MODULE |
| BATTERY BD | BD-350-BATTERY | MYSONOU5 SUB BATTERY BD |
| CP BD | BD-350-CP | MYSONOU5 CONTROL PANEL BD |
| HDD BD | BD-350-HDD | MYSONOU5 SUB HDD BD |
| MAIN BD | BD-350-MAIN | MYSONOU5 MAIN BD |
| PSA BD | BD-350-PSA | MYSONOU5 PSA BD |
| BATTERY | BT-14.4V-5.2A | MYSONOU5 BATTERY 14.4V 5200mA Li402SX-5200 |
| HDD | HDD-160G- ST9160314AS | SEAGATE 160G HDD |
| SPEAKER AY | A231-023A | HOLDER SPEAKER AY MYSONOU5 |
| FAN AY | A235-090A | BRACKET FAN AY MYSONOU5 |
| ADAPTER | ADAPTER-PMP150-13 | MYSONOU5 ADAPTER 19V/7.9A PMP150-13-2 |

[Table 11-2] System



11.4 **Control Panel**



[Picture 11-3] Control Panel

| PART NAME | PART NUMBER | DESCRIPTION |
|-----------------|-------------|---------------------------------|
| PWR | 264-M-001A | BUTTON POWER MYSONOU5 |
| FUNCTION | 264-M-002A | BUTTON FUNCTION MYSONOU5 |
| CLEAR | 264-M-003A | BUTTON CLEAR MYSONOU5 |
| MENUE CHANGE | 264-M-004A | BUTTON MENU CHANGE MYSONOU5 |
| 2D/DUAL/M | 264-M-005A | BUTTON 2D/DUAL/M MYSONOU5 |
| C/PD/PW | 264-M-006A | BUTTON C/PD/PW MYSONOU5 |
| CLIP/PRINT/3D4D | 264-M-007A | BUTTON CLIP/PRINT/3D4D MYSONOU5 |
| SAVE/FREEZE | 264-M-008A | BUTTON SAVE/FREEZE MYSONOU5 |
| ENCORDER | 264-M-009A | BUTTON ENCORDER MYSONOU5 |
| MENU | 264-M-010A | BUTTON ENCORDER MENU MYSONOU5 |
| QSCAN | 264-M-011A | BUTTON ENCORDER QSCAN MYSONOU5 |
| ZOOM | 264-M-012A | BUTTON TOGGLE ZOOM MYSONOU5 |
| FOCUS | 264-M-013A | BUTTON TOGGLE FOCUS MYSONOU5 |
| DEPTH | 264-M-014A | BUTTON TOGGLE DEPTH MYSONOU5 |
| TGC KNOB | 267-M-084A | KNOB TGC MYSONOU5 |
| SENSOR CAP | 269-M-504A | CAP SENSOR MYSONOU5 |
| TRACK BALL | 335-C-011A | TRACKBALL 1.4 INCH ORACOM |

[Table 11-3] Control Panel



LCD 11.5



MNT-15-LCD-350







INVERT-LCD.KT2150MD

[Picture 11-4] Monitor

| PART NAME | PART NUMBER | DESCRIPTION |
|------------------|---------------------|----------------------------------|
| LCD AY | MNT-15-LCD-350 | MYSONOU5 15" LCD MNT ASSY COSTEK |
| LCD MNT | MNT-LCD/M150XN07 | U5 LCD MNT M150XN07 |
| LCD MNT INVERTER | INVERT-LCD/KT2150MD | U5 LCD MNT INVERTER KT-2150MD |

[Table 11-4] Monitor

11.6 Mechanism and Chassis



[Picture 11-5] Mechanism & Chassis

| PART NAME | PART NUMBER | DESCRIPTION |
|-------------------|-------------|-----------------------------|
| GUIDE CABLE | 227-P-116A | GUIDE CABLE MYSONOU5 |
| BRACKET LCD LEFT | 235-P-574A | BRACKET LCD LEFT MYSONOU5 |
| BRACKET LCD RIGHT | 235-P-575A | BRACKET LCD RIGHT MYSONOU5 |
| HANDLE | 252-M-041A | HANDLE MYSONOU5 |
| LOCK CATCH MAGNET | 254-Z-006A | LOCK CATCH MAGNET MYSONOU5 |
| HINGE HANDLE LEFT | A257-010A | HINGE HANDLE LEFT MYSONOU5 |
| HINGE HANDLE RIGH | A257-011A | HINGE HANDLE RIGHT MYSONOU5 |
| HINGE LCD LEFT | A257-012A | HINGE LCD LEFT MYSONOU5 |
| HINGE LCD RIGHT | A257-013A | HINGE LCD RIGHT MYSONOU5 |

[Table 11-5] Mechanism & Chassis

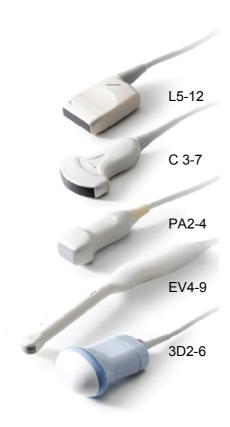


11.7 Option

| PART NAME | PART NUMBER | DESCRIPTION |
|-----------|------------------|------------------------|
| AUTOIMT | S/W-350-AUTOIMT | MYSONOU5 AUTOIMT S/W |
| LIVE3D | S/W-350-LIVE3D | MYSONOU5 LIVE3D S/W |
| 3DXI | S/W-350-3DXI | MYSONOU5 3DXI S/W |
| CARDICAC | S/W-350-CARDICAC | MYSONOU5 CARDICA S/W C |
| DICOM | S/W-350-DICOM | MYSONOU5 DICOM S/W |
| DICOMSR | S/W-350-DICOMSR | MYSONOU5 DICOMSR S/W |
| DMR-LITE | S/W-350-DMR-LITE | MYSONOU5 DMR-LITE S/W |
| COLOR3D | S/W-350-COLOR3D | MYSONOU5 COLOR3D S/W |
| CART | OPT-350-CART | MYSONOU5 CART |

[Table 11-6] Option

11.8 **Probe**



[Picture 11-6] Probe

| PART NAME | PART NUMBER | DESCRIPTION |
|-----------|---------------|-------------|
| Probe | PBTZ-C3-7EP | C 3-7 |
| Probe | PBTZ-EV4-9ED | EV4-9 |
| Probe | PBTZ-L5-12EP | L5-12 |
| Probe | PBTZ-AXP2-4AH | PA2-4 |
| Probe | PBTZ-3D2-6ET | 3D2-6 |

[Table 11-7] Probe



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