

UGEO ^{H60}

Operation Manual

Volume 1



WARRANTY

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

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

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

Parts with cosmetic defects or deterioration will not be replaced. Replacement of batteries, training materials, and supplies are not covered.

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

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

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

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

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

CAUTION: United State federal law restricts this device to sale by or on the order of physicians.



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UGEO H60

Diagnostic Ultrasound System

Operation Manual

Version 1.00.00

English

MI68-02334A

PROPRIETARY INFORMATION AND SOFTWARE LICENSE

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

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

:: 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:

- ▶ Medical Electrical Equipment, Part 1: General Requirements for Basic Safety and Essential Performance **IEC 60601-1:2005**
- ▶ Medical Electrical Equipment, Part 1-2: General Requirements for Basic Safety and Essential Performance- Collateral Standard: Electromagnetic Compatibility - Requirements and Tests **IEC 60601-1-2:2007**
- ▶ Medical Electrical Equipment, Part 1-6: General Requirements for Basic Safety and Essential Performance- Collateral Standard: Usability **IEC 60601-1-6:2006**
- ▶ Medical Electrical Equipment, Part 2-37: Particular Requirements for the Basic Safety and Essential Performance of Ultrasonic Medical Diagnostic and Monitoring Equipment **IEC 60601-2-37:2007**
- ▶ Medical Electrical Equipment, Part 1: General Requirements for Safety **IEC 60601-1:1988 with A1:1991 and A2:1995**
- ▶ Medical Electrical Equipment, Part 1: General Requirements for Safety - 1 Collateral Standard: Safety Requirement for Medical Electrical Systems **IEC 60601-1-1:2000**
- ▶ Medical Electrical Equipment, Part 1: General Requirements for Safety - 2 Collateral Standard: Electromagnetic Compatibility - Requirements and Test **IEC 60601-1-2:2001, A1:2004**
- ▶ Medical Electrical Equipment, Part 1: General Requirements for Safety - 4 Collateral Standard: Programmable Electrical Medical Systems **IEC 60601-1-4: 1996, A1:1999**

- ▶ Medical Electrical Equipment, Part 2: Particular Requirements for Safety - 37 Ultrasonic Medical Diagnostic and Monitoring Equipment **IEC60601-2-37: 2001 with A1:2004, A2:2005**
- ▶ Medical Devices - Application of Risk Management to Medical Devices **ISO 14971:2007**
- ▶ Medical Electrical Equipment, Part 1: General Requirements for Safety **UL60601-1:2003**
- ▶ Medical Electrical Equipment - Part 1: General Requirements for Safety **CAN/CSA 22.2 No.601.1-M90:1990, with R2003, with R2005**
- ▶ Biological Evaluation of Medical Devices **ISO10993:2009**
- ▶ Standard Means for the Reporting of the Acoustic Output of Medical Diagnostic Ultrasonic Equipment **IEC61157:2007**

■ Declarations



This is the CSA symbol for Canada and United States of America.



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



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



This is the GMP symbol that shows that the product complies with the Korean Good Manufacturing Practice quality regulation system.

:: Precautions For Use

Be sure to read this manual thoroughly to familiarize yourself with the operation of the product and the relevant safety information before attempting to use the product.

- Keep this manual near the product and refer to it when using the product.
- 'Chapter 1. Safety' and 'Chapter 4. Maintenance', in particular, contain important safety information and must be thoroughly understood.
- This manual does not include diagnosis results or opinions. Also, check the reference information for the measured area of the body before using the application's measurement results in any diagnosis.
- This product is an ultrasound diagnosis device and cannot be used with your PC. The manufacturer is not responsible for any problems that may be caused by such attempts.
- This product must only be used by persons who are trained and/or certified to operate clinical diagnostic devices. Unqualified persons must not use this product.
- The manufacturer is not responsible for any damage to this product caused by user carelessness and/or neglect.
- The contents and specifications described in this manual may be changed without notice.
- Products that are not manufactured by Samsung Medison are indicated with the trademarks of their respective owners.
- The following terms are used to highlight safety precautions that the user must be aware of:



DANGER: Disregarding this instruction may result in death, serious injury, or other dangerous situations.



WARNING: Follow these instructions to prevent a serious accident or damage to property.



CAUTION: Follow these instructions to prevent a minor accident or damage to property.



NOTE: The accompanying information covers an installation, operation, or maintenance procedure that requires careful attention from the user, but has little chance of leading directly to a dangerous situation.

If You Need Assistance

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

:: Revision History

The revision history of this manual is as follows.

VERSION	DATE	NOTE
v1.00.00-00	2012-04-02	Initial Release

Product Upgrade and Manual Update

Upgrades to this product can include upgrades to its hardware or software components. Revised versions of this manual will be published to reflect any upgrades to the product.

Please make sure that your operation manual is appropriate for your product version. If not, please contact Samsung Medison's Customer Service Department.

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****Reference Manual**

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:: Indication for Use

The UGEO H60 Diagnostic Ultrasound System and transducers are intended for diagnostic ultrasound imaging and fluid analysis of the human body.

The clinical applications include: Fetal, Abdominal, Pediatric, Small Organ, Neonatal Cephalic, Trans-rectal, Trans-vaginal, Muscular-Skeletal (Conventional, Superficial), Peripheral vessel.

❏ Contraindications

The UGEO H60 system is not intended for ophthalmic use or any use causing the acoustic beam to pass through the eye.

**CAUTION:**

- ▶ Federal law restricts this device to sale by or on the order of a physician.
- ▶ The method of application or use of the device is described in the manual 'Chapter 6. Starting Diagnosis' and 'Chapter 7. Diagnosis Modes'.

:: Safety Information

Please read the following safety information before using this product. It is relevant to the ultrasound system, the probes, the recording devices, and any of the optional equipment.











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




















This equipment should not be used by any healthcare professional or individual who is not properly qualified to operate it. Prolonged use of three-dimensional ultrasound (3D, 4D) by an unqualified individual, such as to produce a commemorative photograph or video of the fetus, may have an adverse effect on the fetus.

Please use the 3D ultrasound diagnostic imaging system for appropriate purposes only, since using it for non-diagnostic purposes such as recording videos of the fetus may adversely affect the fetus.

Safety Symbols

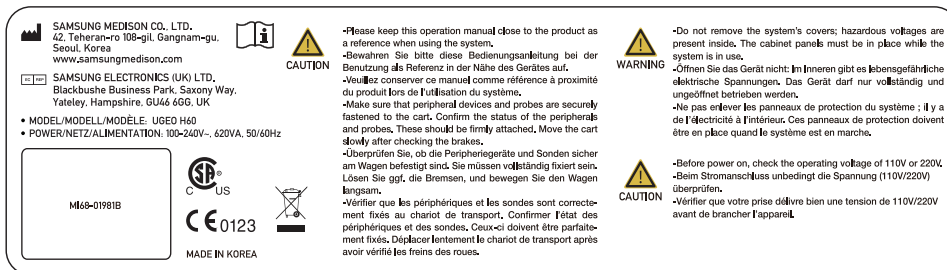
The International Electro Technical Commission (IEC) has established a set of symbols for medical electronic equipment, which classify a connection or warn of potential hazards. The classifications and symbols are shown below.

Symbols	Description	Symbols	Description
	AC (alternating current) voltage source		Data Input/Output port
	Electric shock warning		Left and right Audio / Video input
	Isolated patient connection (Type BF applied part).		Left and right Audio / Video output
	Isolated patient connection (Type CF applied part).		Remote print output
	Power switch (Supplies/cuts the power for product)		Foot switch connector

Symbols	Description	Symbols	Description
	OFF (Cuts the power to a part of the product)		USB connector
	WARNING: Follow this information to prevent a serious accident or damage to property.		Protection against the effects of immersion
	CAUTION: Hazards or unsafe practices that may result in minor personal injury or property damage.		Protection against long periods of immersion under pressure
	Refer to the operation manual		Probe connector
	ON (Supplies power to a part of the product)		ESD (Electrostatic discharge) caution symbol
	Identifies an equipotential ground.		Do not sit on control panel
	Indicates dangerous voltages over 1000V AC or over 1500V DC.		Do not push the product
	Protective earth connected to conductive parts of Class I equipment for safety purposes.		Do not lean against the product
	Data Output port		Follow the operation manual
	Data Input port		

Labels

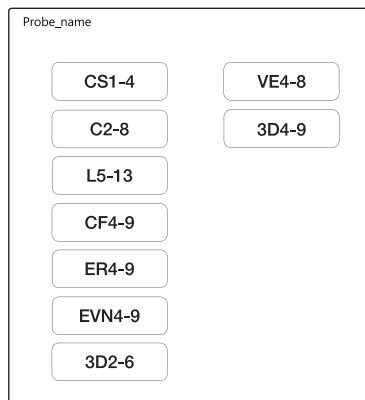
Warning and caution labels that contain information and instructions concerning the protection of the product can be found on the exterior of the product.



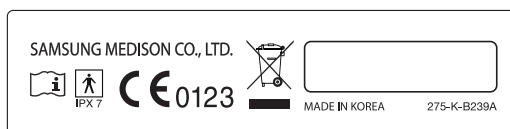
[Label 1. ID label]



[Label 2. Cautions on "TIP-OVER"]



[Label 3. Probe ID Label]



[Label 4. Probe label]

:: Electrical Safety

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

Prevention of Electric Shocks

Additional equipment connected to medical electrical equipment must comply with the respective IEC standards (e.g. IEC60950/EN60950 for data processing equipment, IEC60601-1/EN60601-1 for medical devices). Furthermore, all configurations shall comply with the requirements for medical electrical systems (see IEC60601-1-1/EN60601-1-1). Anybody connecting additional equipment to signal input and output ports of medical electrical equipment should make sure that the equipment complies with IEC60601-1-1/EN60601-1-1.



WARNING:

- ▶ Electric shock may result if this system, including all of its externally mounted recording and monitoring devices, is not properly grounded.
- ▶ Never open the cover of the product. Hazardous voltages are present inside. All internal adjustments and replacements must be made by qualified Samsung Medison Customer Support Department personnel.
- ▶ Always check the product's housing, cables, cords, and plugs before using the product. Disconnect the power source and do not use the equipment if the housing is damaged such as cracked, and chipped, or if the cable is worn.
- ▶ Always disconnect the system from the wall outlet prior to cleaning the system.
- ▶ All patient contact devices, such as probes and ECG leads, must be removed from the patient prior to application of a high voltage defibrillation pulse.
- ▶ The use of flammable anesthetic gas or oxidizing gases (N₂O) should be avoided. There is a risk of explosion.
- ▶ Avoid installing the system in such a way that it is difficult for the operator to disconnect it from the power source.
- ▶ Do not use HF surgical equipment with the system. Any malfunctions in the HF surgical equipment may result in burns to the patient.
- ▶ The System must only be connected to a supply mains with protective earth to avoid risk of electric shock.



CAUTION:

- ▶ The system has been designed for 100-240VAC; you should select the input voltage of any connected printer and VCR. Prior to connecting a peripheral power cord, verify that the voltage indicated on the power cord matches the voltage rating of the peripheral device.
- ▶ An isolation transformer protects the system from power surges. The isolation transformer continues to operate when the system is in standby.
- ▶ Do not immerse the cable in liquids. Cables are not waterproof.
- ▶ The auxiliary socket outlets installed on this system are rated 100-240VAC with maximum total load of 150VA. Use these outlets only for supplying power to equipment that is intended to be part of the ultrasound system. Do not connect additional multiple-socket outlets or extension cords to the system.
- ▶ Do not connect any peripheral devices that are not listed in this manual to the auxiliary socket outlet of the system. It may cause an electrical hazard.
- ▶ Do not touch SIP/SOP and the patient simultaneously. There is a risk of electric shock from leakage current.

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. The static shock or ESD is a discharge of the electrical energy build-up from a charged individual to a less or non-charged individual or object. An ESD occurs when an individual with an electrical energy build-up comes into contact with conductive objects such as metal doorknobs, file cabinets, computer equipment, and even other individuals.



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 to 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 ESD-related warning symbols and preventive procedures.

EMI

Although this system has been manufactured in compliance with existing EMI (ElectroMagnetic Interface) requirements, use of this system in the presence of an electromagnetic field can cause degradation of the ultrasound image or product damage.

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



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

EMC

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

Guidance and Manufacturer's Declaration - Electromagnetic Emission

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

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

■ Approved Cables, Transducers and Accessories for EMC

■ Approved Cable for Electromagnetic Compliance

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

Cable	Type	Length
VGA	Shielded	Normal
USB	Shielded	Normal
LAN(RJ45)	Twisted pair	Any
S-Video	Shielded	Normal
Foot Switch	Shielded	< 3m
e-Motion Marker	Shielded	< 3m
Audio R.L	Shielded	Normal
Parallel	Shielded	Normal
HDMI	Shielded	Normal

■ Probes

Probes listed in 'Chapter 5. Probes' meet the Group 1 Class B requirements of the CISPR 11 standard.


■ Approved Accessories for Electromagnetic Compliance

Accessories used with this product may affect its emissions.



CAUTION: When connecting a VCR or other customer-supplied accessory to the system, it is the user's responsibility to ensure the electromagnetic compatibility of the system. Only use devices that are compliant with CISPR 11 or CISPR 22, CLASS B.

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	0.01 V	<p>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.</p> <p>Recommended separation distance</p> $d = \left[\frac{3,5}{V_1} \right] \sqrt{P}$ $d = \left[\frac{3,5}{E_1} \right] \sqrt{P} \quad 80\text{MHz to } 800\text{MHz}$ $d = \left[\frac{7}{E_1} \right] \sqrt{P} \quad 800\text{MHz to } 2.5\text{GHz}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	<p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol :</p> 
<p>NOTE 1: At 80MHz and 800MHz, the higher frequency range applies.</p> <p>NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
<p>^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.</p> <p>^b Over the frequency range 150kHz to 80MHz, field strengths should be less than V_1 V/m.</p>			

❏ Recommended separation distances between portable and mobile RF communications equipment and UGEO H60

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 to prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and this product as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter [W]	Separation distance according to frequency of transmitter [m]		
	150kHz to 80MHz $d = [\frac{3,5}{V_1}] \sqrt{p}$	80MHz to 800MHz $d = [\frac{3,5}{E_1}] \sqrt{p}$	800MHz to 2.5GHz $d = [\frac{7}{E_1}] \sqrt{p}$
	$V_1=0.01$ Vrms	$E_1=3$ V/m	$E_1=3$ V/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
<p>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.</p> <p>NOTE 1: At 80MHz and 800MHz, the separation distance for the higher frequency range applies.</p> <p>NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			

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 ensure that they meet the minimum specification.



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

Avoiding Electromagnetic Interference

Typical interference on Ultrasound Imaging Systems varies depending on Electromagnetic phenomena. Please refer to the following table:

Imaging Mode	ESD ¹	RF ²	Power Line ³
2D	Change of operating mode, system settings, or system reset. Brief flashes in the displayed or recorded image.	For sector imaging probes, white radial bands or flashes in the centerlines of the image. For linear imaging probes, white vertical bands, sometimes more pronounced on the sides of the image.	White dots, dashes, diagonal lines, or diagonal lines near the center of the image.
M		Increase in the image background noise or white M mode lines.	White dots, dashes, diagonal lines, or increase in image background noise
Color		Color flashes, radial or vertical bands, increase in background noise, or changes in color image.	Color flashes, dots, dashes, or changes in the color noise level.
Doppler		Horizontal lines in the spectral display or tones, abnormal noise in the audio, or both.	Vertical lines in the spectral display, popping type noise in the audio, or both.
<div>1. ESD caused by discharging of electric charge build-up on insulated surfaces or persons.</div> <div>2. RF energy from RF transmitting equipment such as portable phones, hand-held radios, wireless devices, commercial radio and TV, and so on.</div> <div>3. Conducted interference on powerlines or connected cables caused by other equipment, such as switching power supplies, electrical controls, and natural phenomena such as lightning.</div>			

A medical device can either generate or receive electromagnetic interference. The EMC standards describe tests for both emitted and received interference.

Samsung Medison's ultrasound products do not generate electromagnetic interference in excess of standard levels established for such devices.

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 sources of interference are medical devices, 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 transducer operating at the same frequency or with several transducers?
- ▶ Do two different transducers 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 resides with the system or the scanning environment. After you answer the questions, contact the Samsung Medison Customer Support Department.

:: Mechanical Safety

Moving the Equipment



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

- Before transporting the product, check that the brakes on the wheels are unlocked. Also, make sure to retract the monitor arm completely so that it is secured in a stationary position.
- Always use the handles at the back of the console and move the product slowly.

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

If the system operates abnormally after repositioning, please contact the Samsung Medison Customer Support Department.

❑ Foot Lock

Brakes are mounted to the wheels of the console. To lock the brakes, press the bottom part of the brake with your foot. To unlock them, press the part labeled OFF at the top of the brake with your foot.

You can use the brakes to control the movement of the product. We recommend that you lock the brakes when using the product.

❑ Precautions on Ramps

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



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

Leaving the CART unattended on an inclined surface may cause the CART to topple, even if you engage the foot lock. Do not rest the product on ramps.

Precautions for Use

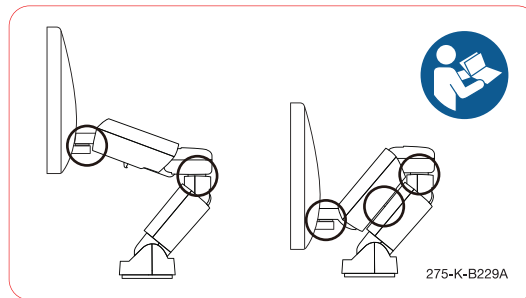
**CAUTION:**

- ▶ Do not press the control panel excessively.
- ▶ Never attempt to modify the product in any way.
- ▶ Check the operational safety when using the product after a prolonged break in service.
- ▶ Make sure that other objects, such as metal pieces, do not enter the system.
- ▶ Do not block the ventilation slots.
- ▶ Do not pull on the power cord to unplug the product. Doing so might damage the cord and cause the product to short-circuit, or the cord itself to break. Unplug the cord by pulling on the plug itself.
- ▶ Excessive bending or twisting of cables on patient-applied parts may cause failure or intermittent operation of the system.
- ▶ Improper cleaning or sterilization of a patient-applied part may cause permanent damage.
- ▶ Servicing the product, including repairs and replacement of parts, must be done by qualified Samsung Medison service personnel. Assuming that the product is used in accordance with the guidelines contained in this manual and maintained by qualified service personnel, the expected lifespan of the product is approximately 7 years.

Please refer to 'Chapter 4. Maintenance' for detailed information on protection, cleaning, and disinfecting the equipment.

Caution for Using Monitor

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



[Figure 1.1 Safety note for monitor]

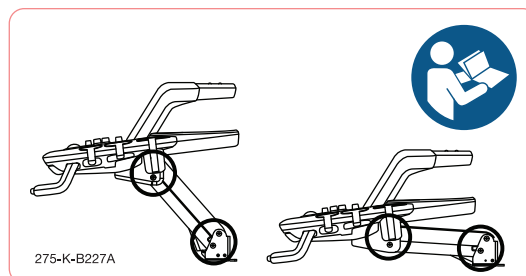
Caution for Using Control Panel



CAUTION:

- ▶ Do not push the control panel with excessive force or lean on it.
- ▶ Do not sit on the control panel or exert excessive force on it.

When adjusting the height or position of the control panel, pay attention to the space between the control panel and the lift. Catching your fingers or other body parts in it may result in injury.



[Figure 1.2 Safety note for Control Panel]

:: Biological Safety

For safety information on the probe and biopsy kit, refer to 'Chapter 5. Probes' in 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. Write down the message displayed on screen, turn the power off, and contact the Samsung Medison Customer Support Department.
- ▶ Do not use a system that exhibits erratic or inconsistent updating. Discontinuities in the scanning sequence are an indication 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.

The ALARA Principle

Performing diagnoses using an ultrasound device is defined by the "As Low As Reasonably Achievable" (ALARA) principle. The decision as to what is reasonable should be 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 based on various ultrasound output data to provide that important information for executing the ALARA principle.

There are a number of variables that 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 supports the ALARA principle.

Applying ALARA

The system-imaging mode used depends upon the information needed. 2D-mode and M-mode imaging provide anatomical information, while Doppler, 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 controls.

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 priorities 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. Samsung Medison's systems provide both automatic and user-definable settings.

Output has a 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 that are lower than the defined maximum. Prudent use dictates that you select the lowest output intensity consistent with good image quality.

Indirect Controls

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

The choice of imaging mode determines the nature of the ultrasound beam. 2D-mode is a scanning mode, while 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.

The 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, 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 intensities to scan at a deeper depth. To scan deeper at the same output intensity, a lower probe frequency is required. Using more gain and output beyond a point, without corresponding increases in image quality, can mean that a lower frequency probe is needed.

■ Receiver Controls

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

■ Additional Considerations

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

■ Output Display Features

The system output display comprises two basic indices: a mechanical index and a thermal index. The thermal index consists of the following indices: soft tissue (TI_s), bone (TI_b) and cranial bone (TI_c). One of these three thermal indices will be displayed at all times. Which one is determined by 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 three indices, and only one of these is displayed all the time. Each probe application has an appropriate default selection. The TI_b or TI_s is continuously displayed over the range of 0.0 to maximum output, based on the probe and application, in increments of 0.1.

The default setting of the application-specific nature is also an important factor of index selection. 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 the 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: TI_s is used for imaging soft tissue, and TI_b for a focus at or near a 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 lower than the thermal index displays.

The selection of scanned modes or unscanned modes of operation also affects 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 through scanning. Ensure that the indices are kept to a minimum, and that exposure time is limited without compromising diagnostic sensitivity.

■ Mechanical Index (MI) Display

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

■ Thermal Index (TI) Display

The TI informs the user about the potential for temperature increase occurring 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. 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, such as the skeletal structure of a 2~3 months old fetus. 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. Tlc is displayed when you select a trans-cranial application.

You can select the TI to display at Setup>Imaging>Display.

■ 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 of 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 to calculate 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 acoustic output values measured underwater 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 a steady state to be reached.

A number of factors are considered when estimating the accuracy of display values: Hardware deviation, algorithm accuracy, and measurement deviation. Deviation among probes and systems in particular is an important factor. Probe deviation results from piezoelectric crystal efficiencies, process-related impedance differences, and sensitive lens focusing parameter variations. Differences in the system pulse voltage control and efficiencies also contribute to deviation. 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 underwater 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 underwater measurements, non-linear propagation and saturation losses occur as pulse voltages increase.

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

❏ Control Effects - Control Affecting the Indices

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

■ Power

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

In combined modes, such as simultaneous 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.

❏ 2D Mode Controls

■ 2D-mode size

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

■ Zoom

Increasing the zoom magnification may increase frame rate. This 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.

■ Number of Focal Zones

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

■ Focus

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

■ Color and Power Controls

■ Color Sensitivity

Increasing the color sensitivity may increase the TI, and more time is spent scanning for color images. Color pulses are the dominant pulse type in this mode.

■ Color Sector Width

Narrower color sector width will increase the color frame rate, and so 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.

■ 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.

■ 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 maximum. A decrease in pulse voltage will also decrease MI.

■ 2D-mode size

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 the dominant mode and the TI change will be small.

■ M Mode and Doppler Controls

■ 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 additional. During auto-update and duplex, the TI will display the dominant pulse type. The displayed MI will be from the mode with the largest peak pressure.

■ Sample Volume Depth

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

■ Other

■ 2D, Color, M-Mode, PW and CW Modes

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 the MI is the value for the focal zone of the mode with the largest de-rated intensity. If a mode is turned off and then reselected, the system will return to the previously selected settings.

■ Probes

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

■ Depth

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

■ Application

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

Related Guidance Documents

For more information about ultrasonic bioeffects and related topics, refer to the following;

- ▶ Medical Ultrasound Safety (AIUM, 2009). (A copy of this AIUM Clinical User Education Brochure is shipped with each system.)
- ▶ AIUM Consensus Report on Potential Bioeffects of Diagnostic Ultrasound: Executive Summary, J. Ultrasound in Medicine, 2008, Vol. 27, Num. 4.
- ▶ WFUMB. Symposium on Safety of Ultrasound in Medicine: Conclusions and Recommendations on Thermal and Non-thermal Mechanisms for Biological Effects. Ultrasound in Med. & Biol; 1998, 24: Supplement 1.
- ▶ Bioeffects and Safety of Diagnostic Ultrasound (AIUM, 1993)
- ▶ Guidelines for the safe use of diagnostic ultrasound equipment. (BMUS, 2009)
- ▶ Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers (U.S. FDA – 2008)
- ▶ Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment. (IEC, 2007)
- ▶ Acoustic Output Labeling Standard for Diagnostic Ultrasound Equipment (AIUM, 2008)
- ▶ Standard Means for the Reporting of the Acoustic Output of Medical Diagnostic Ultrasonic Equipment. (IEC, 2007)
- ▶ Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices On Diagnostic Ultrasound Equipment (AIUM / NEMA, 2004)
- ▶ Ultrasonics - Field characterization -Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields (IEC, 2005)
- ▶ Measurement and Characterization of Medical Ultrasonic Fields up to 40 MHz. (IEC, 2007)
- ▶ Ultrasonics-Power Measurements- Radiation Force Balances and Performance Requirements. (IEC, 2006)
- ▶ Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment. (AIUM / NEMA, 2004)

■ 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: 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. In addition, periodically updated reports on biological effects, results, and guidelines on safe usage have been published by groups such as WFUMB (World Federation of Ultrasound in Medicine and Biology), AIUM, and BMUS.

The Acoustic output for this system has been measured and calculated in accordance with the Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices On Diagnostic Ultrasound Equipment (AIUM / NEMA, 2004) and Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment (AIUM / NEMA, 2004)

■ In Situ, De-rated, and Water Value Intensities

All intensity parameters are measured in water. Since water does not absorb acoustic energy, these water measurements represent the largest possible value. Biological tissue absorbs 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:

$$In\ Situ = Water [e^{-(0.23\ a\ l\ f)}]$$

where: *In Situ* = *In Situ* Intensity Value

Water = Water Value Intensity

e = 2.7183

a = Attenuation Factor

Tissue	a(dB/cm-MHz)
--------	--------------

Brain	.53
-------	-----

Heart	.66
-------	-----

Kidney	.79
--------	-----

Liver	.43
-------	-----

Muscle	.55
--------	-----

l = skin line to measurement depth (cm)

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

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

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

Since this value is not the true *In Situ* intensity, the term “de-rated” is used.

The maximum de-rated and the maximum water values do not always occur under the same operating conditions. Therefore, the reported maximum water and de-rated values may not be related to the *In Situ* (de-rated) formula. For example, a multi-zone array transducer has the greatest water value intensities in its deepest zone. The same transducer may have its largest de-rated intensity in one of its shallowest focal zones.

Terms and Symbols Related to Acoustic Output and Measurement

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

A_{aprt}	-12dB OUTPUT BEAM AREA, ultrasonic beam area induced by -12dB output beam size (unit: cm ²)
d_{eq} at max. I_{pi}	EQUIVALENT BEAM DIAMETER, the acoustic beam's diameter at the location where the PULSE-INTENSITY INTEGRAL is maximal, expressed as an equivalent beam area (unit: cm)
$d_{eq}(Z_b)$	EQUIVALENT BEAM DIAMETER, the acoustic beam's diameter at Z_b location, expressed as an equivalent beam area (unit: cm ²)
Dim of A_{aprt}	-12dB OUTPUT BEAM DIMENSIONS, the dimensions of an ultrasound beam (whose pulse beam width is -12dB) from a specific direction that is perpendicular to the transducer output plane and the beam alignment axis (unit: cm)
f_{awf}	ACOUSTIC WORKING FREQUENCY, the arithmetic average of f_1 and f_2 that are farthest from each other among the frequencies of the pressure spectrum of the acoustic signal whose amplitudes are lower than the peak amplitude, i.e. maximum amplitude, by 3dB (unit: MHz)
Focal Length	The focal length in a direction parallel to the beam alignment axis in the defined operational state of the ultrasound system (unit: cm).
I_{pa} at max. MI	The average attenuated pulse strength at the location where Mechanical Index (MI) is maximal (unit: W/cm ²)
I_{ta} (z)	Attenuated time average strength at a specific focal length (z) (unit: mW/cm ²)

MI	MECHANICAL INDEX, a variable representing potential cavitations within the human body (unit: N/A)
P	OUTPUT POWER, time average power of an ultrasonic transducer's emissions into a free field through specified media such as water (unit: mW)
$P_a(z)$	ATTENUATED OUTPUT POWER, the power of ultrasonic output calculated at a specific distance from the transducer after attenuation occurs (unit: mW)
$P_{r,\alpha}$	ATTENUATED PEAK-RAREFACTIONAL ACOUSTIC PRESSURE, the peak rarefactional acoustic pressure calculated at a specific distance after attenuation occurs (unit: MPa)
P_r at max. I_{pi}	The peak rarefactional acoustic pressure at the location where PULSE-INTENSITY INTEGRAL is maximal (unit: MPa)
pr	PULSE REPETITION RATE, the inverse number of the time interval between two contiguous acoustic pulse (unit: Hz)
TIB	BONE THERMAL INDEX, a thermal index for a focal zone formed near a bone after the ultrasound beam passes through soft tissue, e.g. applied to a fetus (2nd or 3rd trimester) or to the head of a neonate (through the fontanel) (unit: N/A)
TIC	CRANIAL BONE THERMAL INDEX, a thermal index for an ultrasound beam entering the body and passing through a bone, e.g. skull of children or adults (unit: N/A)
TIS_{scan}	Soft tissue thermal index in scanning mode (unit: N/A)
$TIS_{non-scan}$	Soft tissue thermal index in non-scanning mode (unit: N/A)
t_d	PULSE DURATION (unit: us)
$z_{at_max_I_{pi},\alpha}$	The location where PULSE-INTENSITY INTEGRAL is maximal (unit: cm)
z_b	DEPTH FOR BONE THERMAL INDEX (unit: cm)
z_{bp}	BREAK-POINT DEPTH, which is EQUIVALENT APERTURE DIAMETER multiplied by 1.5 (unit: cm)
z_s	DEPTH FOR SOFT-TISSUE THERMAL INDEX, the distance from a plane where the product of minimum attenuated output power, ATTENUATED SPATIAL-PEAK TEMPORAL-AVERAGE INTENSITY, and 1 cm^2 is maximal at the distance range that is equal to, or greater than, the equivalent aperture diameter multiplied by 1.5, when the beam dimension of -12dB output is defined along the beam alignment axis (unit: cm)

■ Acoustic Measurement Precision and Uncertainty

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

Quantity	Precision	Total Uncertainty
$I_{pi,\alpha}$ (attenuated pulse intensity integral)	3.2 %	+21 % to - 24 %
P (acoustic power)	6.2 %	+/- 19 %
$P_{r,a}$ (attenuated rarefaction pressure)	5.4 %	+/- 15 %
f_{awf} (acoustic working frequency)	< 1 %	+/- 4.5 %

■ Systematic Uncertainties

For the pulse intensity integral, de-rated rarefaction pressure $P_{r,3}$, 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.

Acoustic power measurements using a Radiation Force for systematic uncertainties are measured through the use of calibrated NIST acoustic power sources.

We also refer to a September 1993 analysis carried out 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.

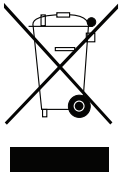
Training

The users of this ultrasound system must familiarize themselves with the ultrasound system to optimize the performance of the device and to detect possible malfunctions. It is recommended that all users receive proper training before using the device. You can receive training on the use of the product from the Samsung Medison VGAservice department, or any of the customer support centers worldwide.

:: Protecting the Environment

**CAUTION:**

- ▶ For disposal 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 Samsung Medison Co., Ltd service engineer or an authorized dealer.



Waste Electrical and Electronic Equipment

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

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

Chapter 2

Introduction

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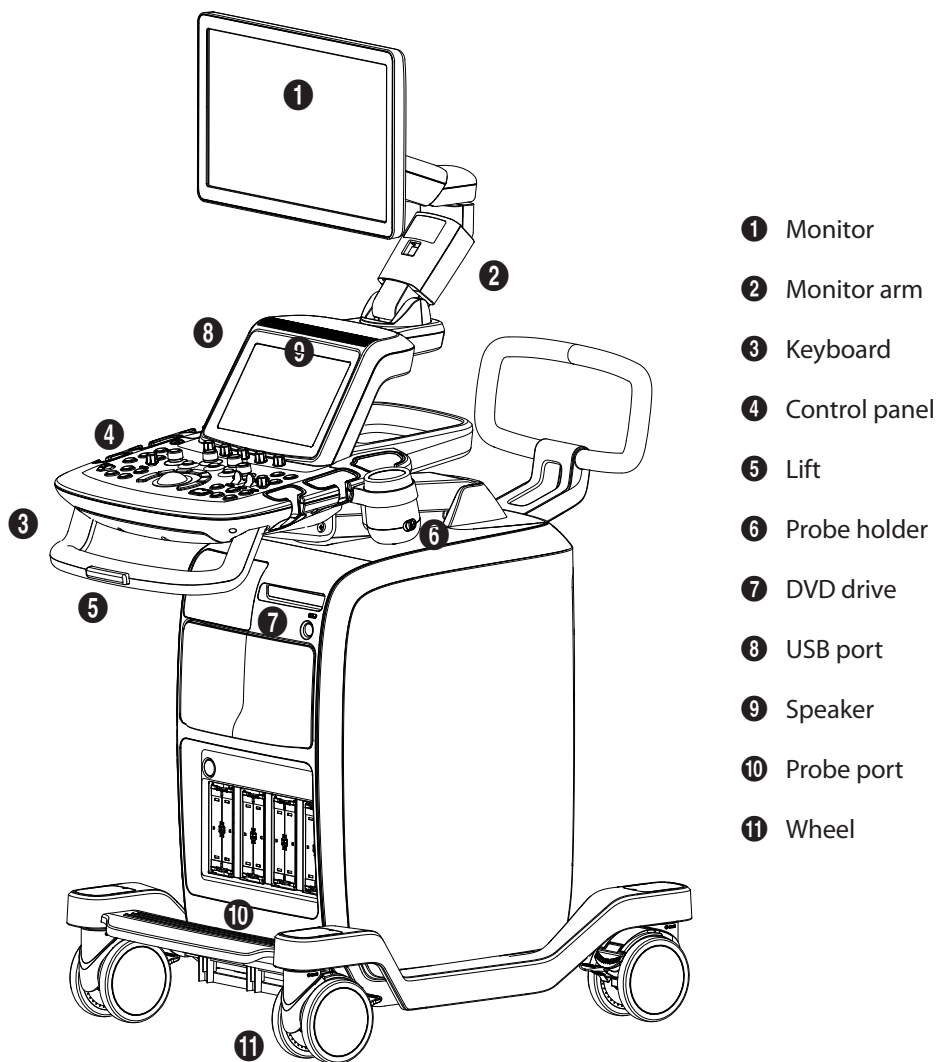
:: Product Specifications

Physical Dimensions	Height: 1660 mm (with Monitor) Width: 550 mm Depth: 980 mm(with Keyboard) Weight: 103.2 kg (without accessories)
Imaging modes	2D-Mode M-Mode Color Doppler Pulsed Wave (PW) Spectral Doppler Power Doppler (PD) 3D/4D imaging mode Dual Modes Quad Modes Combined Modes Simultaneous Mode Zoom mode S-Flow mode
Gray Scale	256 (8 bits)
Focusing	Transmit focusing, maximum of eight points (four points simultaneously selectable) Digital dynamic receive focusing (continuous)
Probes (Type BF / IPX7)	Linear Array L5-13 Curved Array CS1-4, C2-8, CF4-9, ER4-9, EVN4-9 3D 3D2-6, 3D4-9, VE4-8
Probe connections	3 Probe Connectors 4 Probe Connectors for option
Monitor	Main Monitor Display area: 18.5 inch Resolution: 1366 x 768 LED Backlight Digital brightness/contrast adjustment Touch Screen Monitor Display area: 10.1 inch Resolution: 1280 x 800 LED Backlight called "LCD monitor" henceforth
Rear Panel Input/Output Connections	Audio Output Port(Right/Left) VGA monitor LAN USB Port HDMI Output HDMI Input (HDMI Input is currently not supported.)

Image Storage	Maximum 45000 frames for Cine memory Maximum 14000 Lines for LOOP memory Image filing system
Application	Obstetrics, Gynecology, Urology, Abdomen, Vascular, Small Part, MSK Pediatric
Electrical Parameters	100-240VAC, 620VA, 50/60Hz
Measurement Packages	Abdomen, Obstetrics, Fetal Echo, Gynecology, MSK, Pediatric Hips, Small Part, Urology, Vascular * Refer to Chapter 5 for additional information
Signal processing (Pre-Processing)	Acoustic Power Control Analog TGC Control Dynamic Aperture Control Dynamic Apodization Control Dynamic LPF Control
Signal processing (Post-Processing)	Digital TGC Control Slider TGC Control Mode-Independent Gain Control Black Hole/Noise Spike Filtering 1D Lateral/Axial Filtering 2D Edge/Blurring Filtering Frame average M/D Mode Sweep Speed Control Zoom Image View Area Control Image Orientation (left/right and up/down)
Measurement	Trackball operation of multiple cursors 2D mode: Linear measurements and area measurements using elliptical approximation or trace M mode: Continuous readout of distance, time, and slope rate Doppler mode: Velocity and trace
Auxiliary	DVD Multi-Drive Digital B/W Video Printer Digital Color Video Printer USB Printer DVD Recorder Foot switch (IPX8) e-Motion Marker (IPX7) USB Flash Memory Media USB HDD Monitor
User Interface	English, German, French, Spanish, Italian, Russian, Chinese
Pressure Limits	Operating: 700-1060 hPa Storage: 700-1060 hPa
Humidity Limits	Operating: 30% to 75% Storage & Shipping: 20% to 90%
Temperature Limits	Operating: 10°C ~ 35°C Storage & Shipping: -25°C ~ 60°C

Product Configuration

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



[Figure 2.1 Front of the product]

Tips!

Principles of Operation

Medical ultrasound images are created by computer and digital memory from the transmission and reception of mechanical high-frequency waves applied through a probe. The mechanical ultrasound waves spread through the body, producing an echo where density changes occur. For example, in the case of tissue, an echo is created where a signal passes from an adipose tissue region to a muscular tissue region. The echoes return to the probe where they are converted back into electrical signals.

These echo signals are highly amplified and processed by analog and digital circuits having filters with many frequency and time response options, transforming the high-frequency electrical signals into a series of digital image signals which are stored in memory. Once in memory, the image can be displayed in real-time on the image monitor. All signal transmission, reception and processing characteristics are controlled by computer.

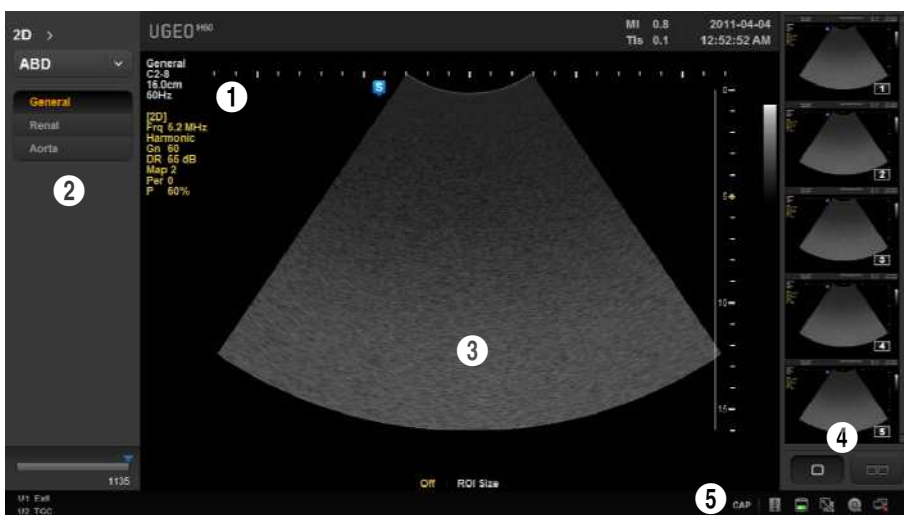
The Monitor

Ultrasound images and other information are displayed on the color LCD monitor.

Screen Layout

The monitor displays ultrasound images, operation menus and a variety of other information.

As shown in the image below, the screen layout consists of **1** Title area, **2** Measurement Menu area, **3** Image area, **4** Thumbnail area, and **5** User Information area.



[Figure 2.2 Monitor Display]

■ **Title Area**

Patient information (name, ID, GA), names of the clinic and the operator, acoustic output information, date, and time are displayed.

■ **Measurement Menu Area**

During measurement, displays the measurement menus.

■ **Image Area**

Displays ultrasound images. Image information, annotation, and measurement information are also displayed.

■ **Thumbnail Area**

The images saved by pressing the **Store** button are displayed. Click a thumbnail to enlarge. Up to 16 can be displayed at once.












In BodyMarker mode, BodyMarkers are displayed.

■ **User Information and Status Information Area**

The user information area provides a variety of information necessary for system use. States of the current storage media (HDD, USB, CD), Caps Lock, DICOM, U1 and U2 are displayed.

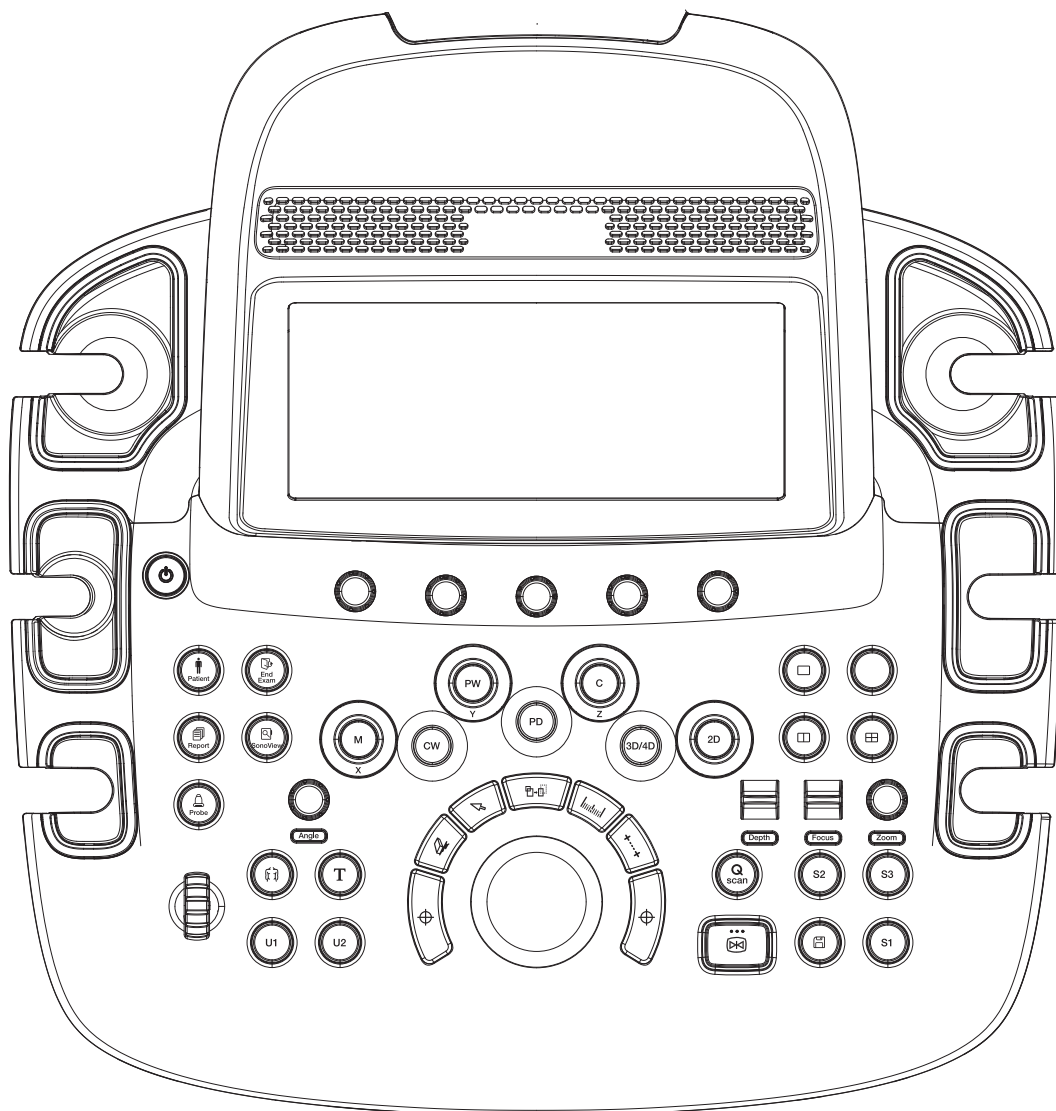


Current System Status

-  Indicates that Caps Lock is on.
-  Indicates that CD/DVD storage media is available.
-  Indicates that CD/DVD storage media is not available.
-  Indicates that USB storage media is not available.
-  Indicates that the HDD has 10% or more free space.
-  Indicates that the HDD has less than 10% free space.
-  Indicates that the DICOM spooler is empty.
-  Indicates that the DICOM spooler is busy.
-  Indicates that the DICOM spooler has failed a task.
-  Indicates that the LAN is connected.
-  Indicates that the LAN is not connected.

The Control Panel

The system can be controlled by using the control panel.








[Figure 2.3 Control Panel]





The control panel consists of a keyboard, soft menus, buttons, dials, dial-buttons, a slider, and a trackball.





The dial-button can be used both as a dial and a button.

Functions of the Control Panel

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

 On/Off	Button	Turns the system on/off.
Patient	Button	Displays the Patient Information screen for patient selection and information entry.
Probe	Button	Displays the <i>Probe Selection</i> screen to select or change the probe and application.
SonoView	Button	Displays the screen for viewing and managing stored images.
End Exam	Button	Finishes the exam of the currently selected patient and resets the related data.
Report	Button	Displays the Report screen that shows the measurement results of the current application and other information.
	Button	Enter a BodyMarker over an image.
T	Button	Allows the user to place text on an image.
U1	Button	This button is used to assign user-defined function. The function for each button can be assigned in Setup > Peripherals > Customize Key.
U2	Button	This button is used to assign user-defined function. The function for each button can be assigned in Setup > Peripherals > Customize Key.
	Button	In this mode, only the image is displayed on the screen.
	Button	Compares two independent images.
	Button	Compares four independent images.
Depth	Switch	Adjusts the scanning depth of the image.
Focus	Switch	Moves the focus to the target area for observation.
Zoom	Dial-button	Makes the Zoom Box appear. In order to close the Zoom mode, press the Exit button.

Angle	Dial-button	Adjusts the angle of the sample volume in Spectral Doppler mode. It is also used to adjust the Arrow's angle or the probe angle for a BodyMarker. In 3D View, using the Angle dial-button moves the Reference Slice horizontally. Use the Angle dial-button to enter Biopsy Guide Edit mode.
Q Scan	Button	Press this button to turn the Quick Scan function on.
 Store, S1, S2, S3	Button	Each button may be assigned one of the following functions: Save image, print image, or send image to the DICOM server. To assign a function to each button, go to Setup > Peripherals > Customize Keys.
 Freeze	Button	Pauses/resumes scanning.
M	Dial-button	Start or end M Mode. Rotate this dial-button to adjust Gain. Also, turning this dial-button when in 3D View rotates the image along the x-axis.
PD	Button	Press this dial-button to start/stop Power Doppler mode.
Color	Dial-button	Press this dial-button to start/stop Color Doppler mode. Rotate this dial-button to adjust Gain. Also, turning this dial-button, when in 3D View, rotates the image along the z-axis.
2D	Dial-button	Press this dial-button to start 2D mode. Rotate this dial-button to adjust Gain.
PW	Dial-button	Press this dial-button to start/stop PW Spectral Doppler mode. Rotate this dial-button to adjust Gain. Also, turning this dial-button, when in 3D View, rotates the image along the y-axis.
CW	Button	This button is currently not supported.
3D/4D	Button	Press this button to turn 3D/4D Mode on/off.
 Set / Exit	Button	Set or Exit function may be assigned to this button. The function for each button can be assigned in Setup > Peripherals > Customize Keys. ► Set: Select an item or value using the trackball. Also used to change the function of the trackball. ► Exit: Exit the function currently being used and return to the previous state.
 Pointer	Button	An arrow marker appears to point to parts of the displayed image in scan mode.

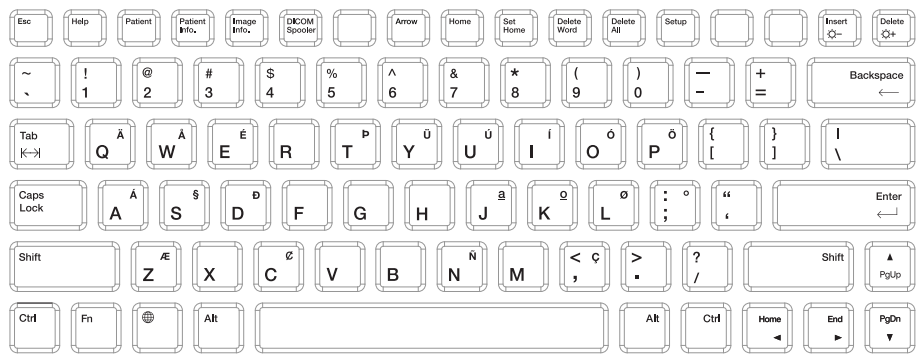
 Clear	Button	Deletes text, Arrow, BodyMarker, measurement result, etc. displayed on an image.
 Change	Button	Switch the trackball's current function to the next supported function.
 Calculator	Button	Start measurements for the application.
 Caliper	Button	Start basic measurements of distance, volume, circumference, and area.
Trackball	Trackball	Moves the cursor on the screen. Also scrolls through Cine images.





CAUTION: Too great a difference in the gain value settings of adjacent TGC sliders may cause stripes to appear in an image.

■ Keyboard

The keyboard is used to type in text.



[Figure 2.4 Keyboard]

Help	Displays the Help Manual on the screen.
Patient	Displays the General Information on the screen.
Patient Info.	Shows or hides the patient information on the screen.
Image Info.	Shows or hides the Image Parameters on the screen
DICOM Spooler	Displays the DICOM Spooler on the screen.
Arrow	Initiates Arrow mode.
Home	Moves the cursor to the Home position in Annotation mode.
Set Home	Specifies the Home position in Annotation mode.
Delete Word	Deletes the last text entered in Annotation mode.
Delete All	Deletes all the text that has been entered in Annotation mode.
Setup	This displays the Setup screen.
Insert 	Select an input method. Press in conjunction with the Fn key to reduce the brightness of the monitor.
Delete 	Deletes text. Press in conjunction with the Fn key to increase the brightness of the monitor.

Touch Screen

The touch screen is an operating tool that can be touched by the user to input data. The functions that are available in the current mode are shown in the form of buttons or a dial-button.

Touch screen display

- 1 Information Area: Shows the title of the touch screen currently displayed.
- 2 TGC: Adjust TGC Slide when TGC Curve is activated on the touch screen.



[Figure 2.5 TGC]

- 3 Menu Area: The menu items that are available in the current input mode are shown in the form of buttons. The user can access the desired menu item by pressing the corresponding button. The menu currently in use is shown in yellow.
- 4 Soft Menu Area: The Soft Menu items that are available in the current input mode are shown. Press or rotate the dial-buttons right below each menu.



When there are two Soft Menus

When there are two menus available – upper and lower, both menus can be adjusted with the corresponding dial-button. Or tap the button for the menu you want to use on the touch screen and then use the dial-button.



[Figure 2.6 Touch Screen]

Adjusting the Control Panel



CAUTION:

- ▶ Do not apply excessive force to the control panel.
- ▶ Use the handle at the back of the product when moving it.

Adjusting to the right and left

Hold the control panel handle and move it carefully to the right or left.

Adjusting the height

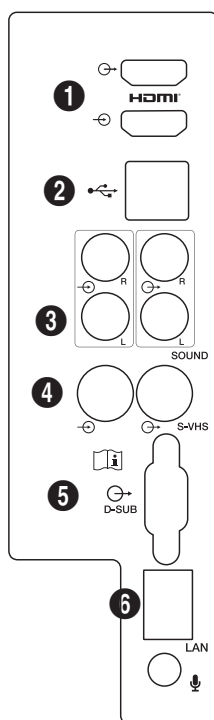
Press the lever on the handle of the control panel and move it carefully up or down.

The Console

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

Rear Panel

A monitor and other peripheral devices, like a printer, are connected via the rear panel at the back of the system.

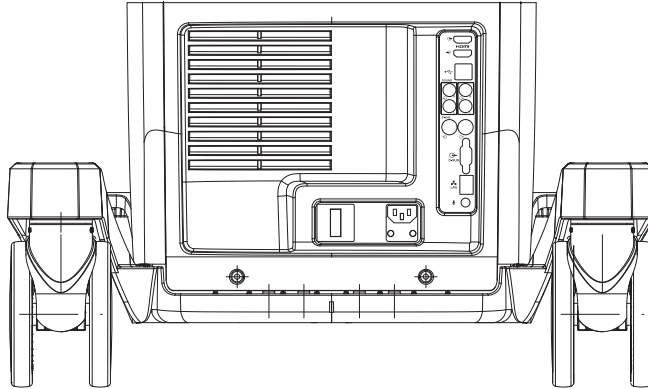


- ❶ HDMI: Simultaneously transmits video and audio signals in digital format via a single cable.
- ❷ USB port: Connects the USB peripheral devices.
- ❸ Audio port (Output): Used to output audio signals.
- ❹ S-VHS port (I/O): Connects the VCR in S-VHS mode.
- ❺ D-SUB port: Outputs the analog signal to the monitor.
- ❻ Network port: Connects to the network.

[Figure 2.7 Rear Panel]

Power Connection Part

The power connection part is located at the bottom on the rear panel.



[Figure 2.8 Power Connection Part]

1. Power inlet: For the power cable to connect to external power
2. Power outlet: Supplies peripheral devices and external devices with power; maximum capacity is 150 VA. Outlet port is located on the DC power assembly.
3. Power switch/breaker: Turns on the power of the product, and cuts off power if overcurrent or overvoltage occurs.

Probe Holder

Probe holders are mounted at the left and right-hand sides of the control panel.

Peripheral Devices



NOTE: Refer to the operation manual of the peripheral device for its operating information.

■ Internal Peripheral Devices

These are peripheral devices mounted in the system.

■ DVD-Multi

DVD±R, DVD±RW, DVD-RAM, CD-R, CD-RW

■ Hard Disc Drive

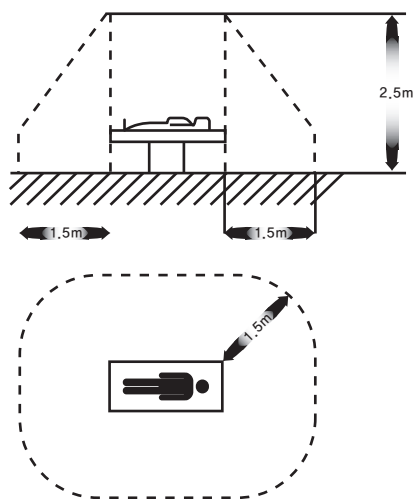
Min. 500GB SATA-2 2.5" HDD

External Peripheral Devices

These are peripheral devices that can be connected for use when needed and are connected via the USB port located at the rear panel.



CAUTION: Do not place peripheral devices that are not listed in this manual in the vicinity of the patient. If you place them in the patient environment, it may cause an electrical hazard.



[Figure 2.9 Patient Environment]



CAUTION: When using a peripheral device via a USB port, always turn the power off before connecting/disconnecting the device. Connecting or disconnecting a USB device while power is turned on may cause the system and/or the USB device to malfunction.



Tips!

When there are two Soft Menus

The console's USB ports are located on the side panel of the control panel, as well as on the rear panel of the console.

We recommend that you connect USB storage devices (flash memory media, etc.) to the ports on the side panel, and connect USB peripheral devices to the rear panel for convenience.

The following products are recommended:

■ Digital Video Printer

- ▶ Black and White: Sony UP-D897, Mitsubishi P95DE
- ▶ Color: Sony UP-D25MD, Mitsubishi CP30DW

■ USB Printer

HP Officejet 4500, Samsung CLP-620NDK

■ DVD Recorder

Sony DVO-1000MD



CAUTION:

- ▶ You must install a printer and drivers that are compatible with Microsoft Windows 7 (English version). Contact Samsung Medison customer support division for inquiries about printer driver installation.
- ▶ When connecting the printer, ensure that the printer is configured under Microsoft Windows™ or system setup and has been chosen as the default printer.
- ▶ Please check the port that the printer uses before connecting. Printers should be connected to the printer port while the USB printer should be connected to the USB port.

■ Foot Switch

To configure the Foot Switch function, go to Setup > Peripherals > Customize Keys > Foot Switch. You can select from Exit, Freeze, Store, S1, S2, S3, or Update.

Probes

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



NOTE: For detailed information, refer to 'Chapter 5. Probes'.

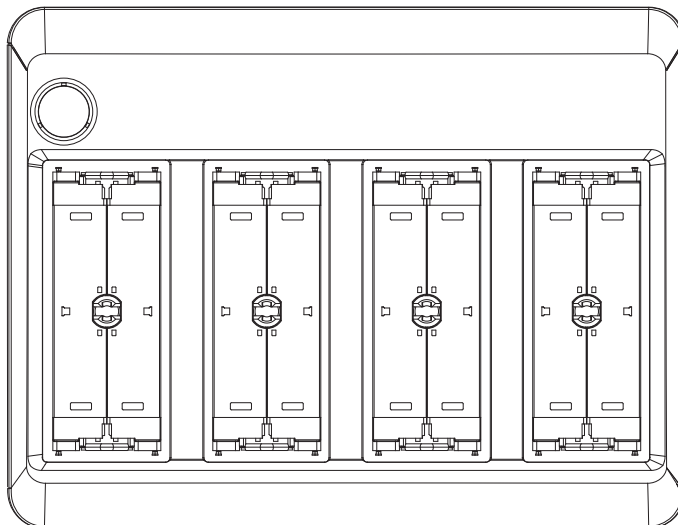
Connecting Probes

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

1. Connect probes to the probe connectors on the front panel of the system. Up to four probes (options inclusive) may be connected.
2. Turn the connector-locking handle clockwise.



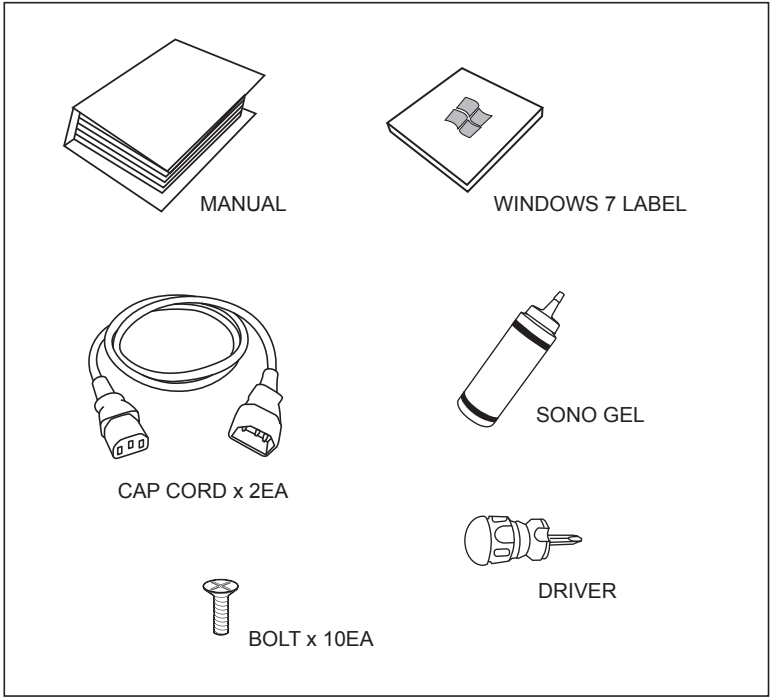
NOTE: If the probe does not connect properly, try reconnecting it after removing any foreign objects.



[Figure 2.10 Probe Connector]

Accessories

An accessory box containing the items below is supplied with the product.



[Figure 2.11 Accessories]

Optional Functions

This product has the following optional functions:

- ▶ SDMR
- ▶ Spatial Compound Imaging (SCI)
- ▶ DICOM
- ▶ 4D
- ▶ 3D XI
- ▶ Volume NT/IT
- ▶ Gel warmer
- ▶ Foot switch
- ▶ 4 probe ports
- ▶ e-Motion Marker
- ▶ Network Isolator

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

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:: System Settings

General system settings that do not have direct bearing on imaging are explained. The setup may be modified depending on specific needs or preferences.

1. Press **Setup** button on the keyboard.
2. The **Setup** screen will appear on the monitor and the touch screen. Select a tab that has items to specify.

Tips!

Selecting a tab

You can select a desired tab in either one of two ways. Select the method that suits you.

Use the trackball and the **Set** button to select a tab.

Tap a corresponding button on the touch screen.

3. Specify settings for each item.
4. Save settings and exit. Click **Exit** on the monitor screen, or tap **Exit** on the touch screen, or press **Exit** button on the control panel to switch to Scan mode.



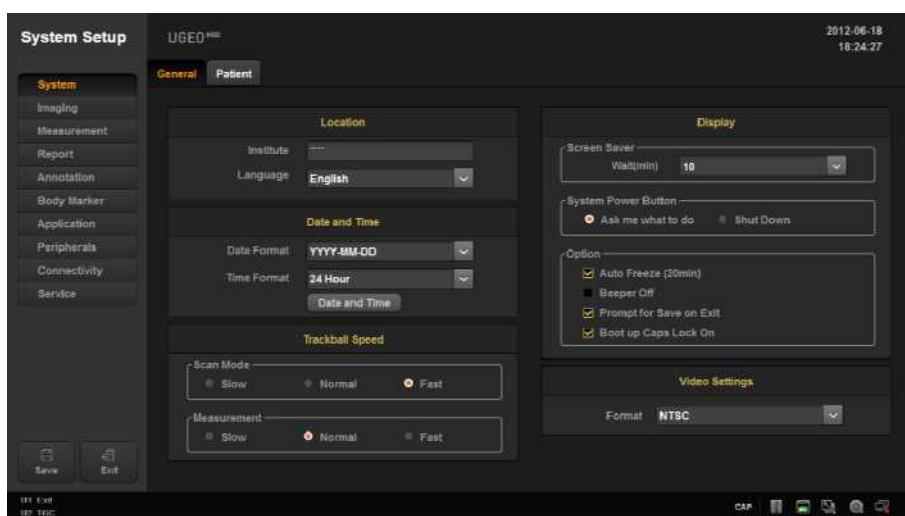
[Figure 3.1 Setup – Touch Screen]

General System Settings

In the *Setup* screen, select the **System** tab. Or tap **System** on the touch screen. You can specify general settings such as title settings.

General

In the *Setup* screen, select the **General** tab in the **System** category.



[Figure 3.2 Setup – System – General]

Location

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

Institute

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

Language

Select the system language.

(Supported languages: English, German, French, Spanish, Italian, Russian, Simplified Chinese)

❏ Date and Time

The current date is displayed. To change the date, click **Date and Time**.



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

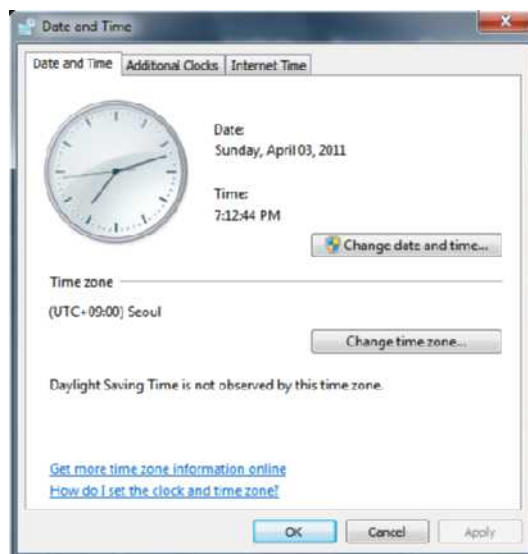


How to set the date and time

Click **Date and Time** next to the Date (or Time) field.

Click **Change date and time settings**. Set the date and time by using the trackball and the **Set** button on the control panel. To change the time zone, click **change time zone settings**.

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



[Figure 3.3 Date & Time]

■ Date Format

Specify the date format. Select a date format using the combo button. The selected date format will be applied to various date fields in *Patient Information*.

■ Time Format

Specify the time format. Select a desired time format (12 Hour or 24 Hour) by pressing the combo button.

✦ Trackball Speed

■ Scan Mode

Specify the trackball speed as Slow, Normal, or Fast.

■ Measurement

Specify the trackball speed as Slow, Normal, or Fast.

Slower speeds allow more precise measurements.

✦ Display

■ Screen Saver

Select the wait time (in minutes) for the screen saver.

■ System Power Button

► Ask me what to do: Select from Shut Down, Restart or Cancel.

► Shut Down: The power will turn off.

■ Option

► Auto Freeze (20min): The screen automatically freezes in 20 minutes.

► Beeper Off: Turn beeper Off.

► Show Save Prompt on Exit: Use the check box to select whether to save or not.

► Boot up Caps Lock On: Use the checkbox to select whether to enter capital letters.

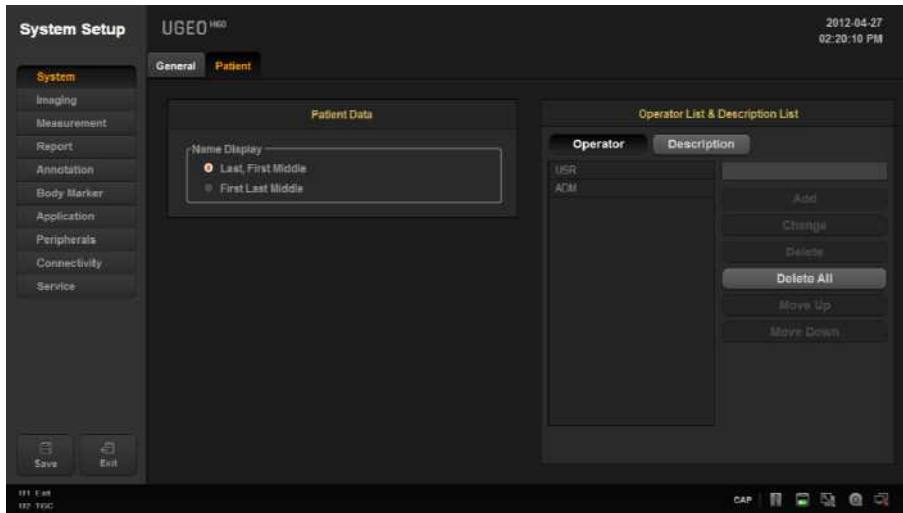
✦ Video Settings

■ Format

Select either NTSC or PAL.

Patient

In the *Setup* screen, select the **Patient** tab in the **System** category.



[Figure 3.4 Setup – System – Patient]

■ Patient Data

■ Name Display

- ▶ Last, First Middle: Display the name of the patient in the order of last name, first name, then middle name.
- ▶ First Last Middle: Display the name of the patient in the order of first name, last name, then middle name.

■ Operator List & Description List

■ Operator List

The names of up to 20 sonographers who scanned the patient may be added, edited, deleted, or repositioned.

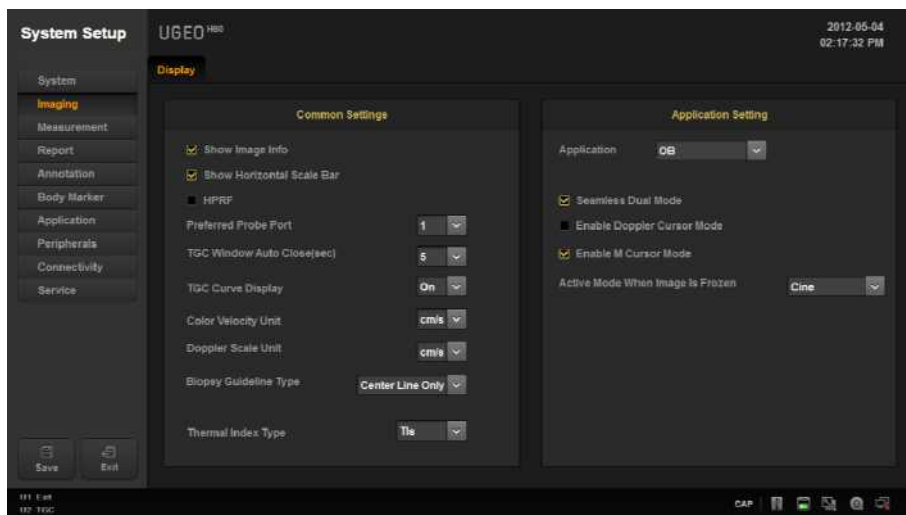
■ Description List

Save up to 20 diagnostic memos per application. Use the button on the right side of the screen to add, edit, delete, or reposition.

Screen Display Settings (Imaging)

In the *Setup* screen, select the **Imaging** tab. Or tap **Imaging** on the touch screen. Specify display-related options.

Display



[Figure 3.5 Setup – Imaging – Display]

Common Settings

Common settings apply to all applications.

You can select multiple items. Use the trackball and the **Set** button to select and check or uncheck an item.

■ Show Image Info

Show or hide the image information. If the image is obscured by the image information, disable this option to hide the image information.

■ Show Horizontal Scale Bar

Show or hide the Horizontal Scale Bar in the Scan UI.

■ HPRF

In PW Spectral Doppler mode, this detects blood flow with a velocity that exceeds the maximum speed at the depth you want to obtain the Sample Volume from.

■ Preferred Probe Port

Select the Probe Port that takes the highest priority when the system starts or when you select a probe.

■ Touch Window Auto Close (sec)

Specify how much time must elapse before the TGC Control Window in the touch screen automatically closes because of a lack of user input. If set to Off, the window will not time out.

■ TGC Curve Display

Specify how long the TGC Curve is displayed for in Scan UI (On: Always displayed, Off: Never displayed, Auto: Displayed for a specific length of time and then disappears).

■ Color Velocity Unit

Select the units of velocity in Color Mode.

■ Doppler Scale Unit

Select the units of measurement for the axis scale in Spectral Doppler Mode.

■ Biopsy Guideline Type

Select the type of Biopsy Guide Line displayed.

■ Thermal Index Type

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

■ Application Settings

These settings are applied specifically to the selected application.

You can select multiple items. Use the trackball and the **Set** button to select and check or uncheck an item.

■ **Application**

Select the application.

■ **Seamless Dual Mode**

Select whether or not to use Seamless Dual Mode in Dual Mode.

■ **Enable Doppler Cursor Mode**

Select whether or not to enter Cursor mode before Doppler mode.

■ **Enable M Cursor Mode**

Select whether or not to enter Cursor mode before M mode.

■ **Activated Mode When Image Is Frozen**

Select the mode to activate upon freezing an image.

One of the following modes may be selected: Cine, Measurement, Annotation, or Body Marker.

Measurement Settings

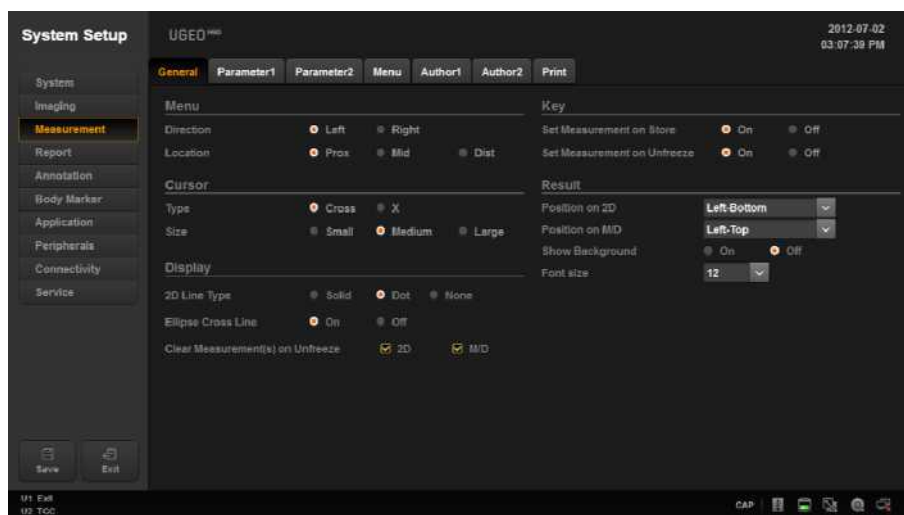
Specify various setup options for measurements. The setup may be modified depending on specific needs or preferences.

1. Press **Setup** on the keyboard. When the *Setup* screen is displayed, select the **Measurement** tab.
2. When the *Measurement* screen appears, select the tab that contains the items you wish to configure.
3. Specify settings for each item.
4. Press the **Save** button to save the settings. You can click **Exit** on the monitor screen or tap **Exit** on the touch screen to exit the *Setup* screen and switch to Scan Mode.

General Settings

In the *Setup* screen, select the **General** tab in the **Measurement** category.

You can specify basic measurement options.



[Figure 3.6 Setup – Measurement – General]

Menu

- **Directions:** Select the Direction Type applied to the target to measure in the initial system status. The options are Left and Right.
- **Location:** Select the Location Type applied to the target to measure in the initial system status. The options are Prox, Mid, and Dist.

Cursor

■ Cursor Type

Select the shape of the default caliper cursor displayed on the screen. Select between 'Cross' shape (+) and 'X'.

■ Cursor Size

Select the size of the default caliper cursor displayed on the screen. The options are Small, Medium, and Large.

Display

■ 2D Line Type

Select the type of line to use for measurement in 2D mode (Solid: Solid line, Dot: Dotted line, None: Start and end points).

■ Ellipse Cross Line

Show (On) or hide (Off) the long axis and the short axis of an ellipse while taking Ellipse measurements.

■ Clear Measurement(s) on Unfreeze

Select 2D Mode or M/D Mode to choose whether to keep (On) or discard (Off) the measurements displayed on screen when the image switches to Scan Mode.

Key

■ Set Measurement on Store

Turn on or off the function that automatically completes measurements when the Store key on the control pad is pressed while a measurement is being taken.

■ Set Measurement on Unfreeze

Turn on or off the function that automatically completes measurements when the image switches to Scan mode while a measurement is being taken.

Result

Select how measurement results are displayed.

■ Position On 2D:

Reposition the measurement results when 2D mode is selected.

- ▶ Left-Top: Measurement results are displayed in the top left corner of the screen.
- ▶ Left-Bottom: Measurement results are displayed in the bottom left corner of the screen.
- ▶ Right-Bottom: Measurement results are displayed in the bottom right corner of the screen.
- ▶ Right-Top: Measurement results are displayed in the top right corner of the screen.
- ▶ Custom: Measurement results are displayed in a location selected by the user.

■ Position on D/M

Moves the measurement results.

- ▶ Left-Top: Moves the measurement results towards the top left corner of the screen.
- ▶ Left-Bottom: Moves the measurement results towards the bottom left corner of the screen.
- ▶ Right-Bottom: Moves the measurement results towards the bottom right corner of the screen.
- ▶ Right-Top: Moves the measurement results towards the top right corner of the screen.
- ▶ Custom: Measurement results are moved to a location selected by the user.

■ Show Background

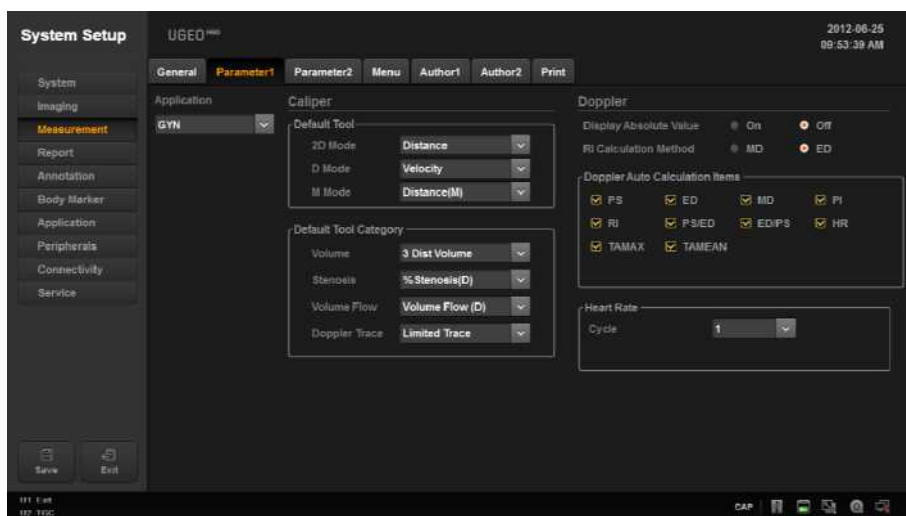
Turn the background of the measurement results transparent (On) or opaque (Off).

■ Font Size

Select the size of the font used for the measurement results.

Parameter1 (Tool & Calculation Settings)

In the *Setup* screen, select the **parameter1** tab in the **Measurement** category.



[Figure 3.7 Setup – Measurement – Parameter1]

■ Application

Select an application.

Caliper

■ Default Tool

Select the default tool that functions in the measurement cursor state for each Image mode.

- ▶ 2D Mode : Distance, Trace Length, Open Spline, Ellipse, Trace, Closed Spline, Angle, Distance Steno(D), Trace Steno(D), Ellipse Steno(A), Trace Steno(A), Spline Steno(A), 1 Dist Volume, 2 Dist Volume, 3 Dist Volume, Ellipse Volume, Ellipse+ Dist Vol
- ▶ D Mode : Velocity, Acc, Manual Trace, Limited Trace, HR, RI, Dist Vol.Flow(D), Trace Vol. Flow(D), Spline Vol. Flow(D), Ellipse Vol. Flow(A), Trace Vol. Flow(A), Spline Vol.Flow(A), Time
- ▶ M Mode : Distance(M), Slope, HR, Time(M)

■ Default Tool Category

Select the default tool for each measurement category.

- ▶ Volume: 1 Dist. Volume, 2 Dist. Volume, 3 Dist. Volume, Ellipse Volume, Ellipse + Dist. Vol
- ▶ Stenosis: %Stenosis(D), %Stenosis(A)
- ▶ Volume Flow: Volume Flow(D), Volume Flow(A)
- ▶ Doppler Trace: Manual Trace, Limited Trace

Doppler

■ Display Absolute Value

The doppler measurement is displayed as an absolute value.

■ RI Calculation Method

Select whether to use ED or MD when calculating the value of RI.

■ Doppler Auto Calculation Items

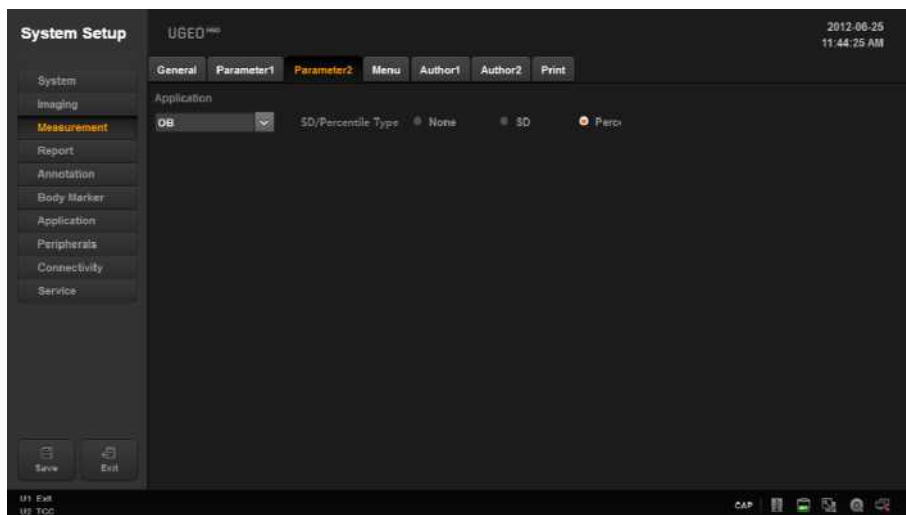
Select which value to measure and display on the screen in measurement mode using the Auto Doppler Trace Tool.

■ Heart Rate

Cycle: Select the number of heart rate (HR) cycles.

Parameter2

In the *Setup* screen, select the **parameter2** tab in the **Measurement** category.



[Figure 3.8 Setup – Measurement – Parameter2]

■ Application

Select an application.

■ SD/Percentile Type

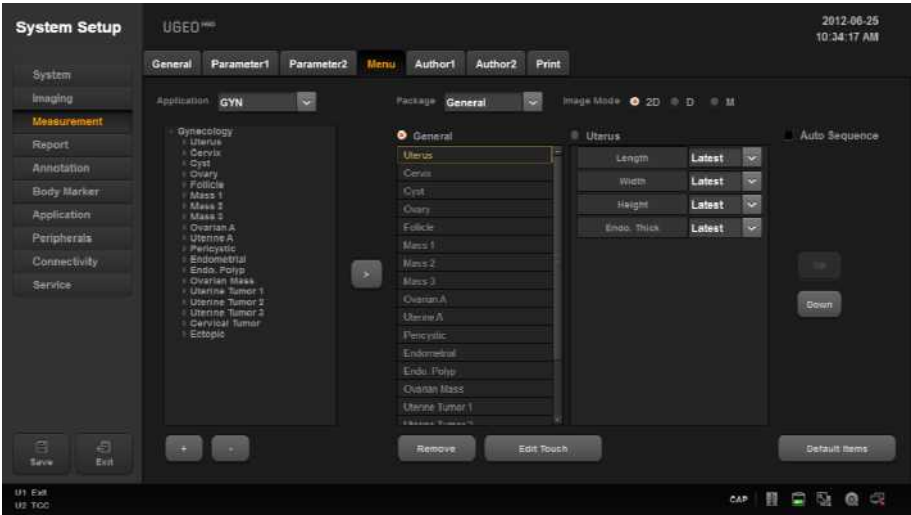
Select None, SD, or Percentile.



NOTE: This can only be selected if the application is OB.

Menu

In the *Setup* screen, select the **Menu** tab in the **Measurement** category.



[Figure 3.9 Setup – Measurement – Menu]

Available Menu List

Application

Select the application you want to load the Available Menu List for. Once a selection is made, the Available Menu List shown on screen will change.

Available Menu View

Available Menu View displays the Labels that can be measured in the selected application in tree form. Use the +, - buttons in the bottom left corner to add or remove Group, Measurement, and Calculation.

■ Add Item

- ▶ In Available Menu View, select a Group or an Item and click the > button to enter the selected Group or Item in the Available List Box on the right side.
- ▶ After you save a Group or Item you have entered by clicking the **Save** button on the left side of the screen, it will be shown in the Menu.
- ▶ It will be entered into the Label Menu and the Touch Menu simultaneously. In this case, a Group or Item will added after the last Group or Item displayed.

■ Group View

Group View lists the groups shown in the Menu. When Group View is activated, you can delete any of the groups shown, and change the layout of the groups shown in the Menu and the Touch Menu.

■ Item View

Item View lists the items shown in the Menu. When Item View is activated, you can delete any of the items shown, and change the layout of the items shown in the Menu and the Touch Menu. Latest, Average, Max, or Min may be selected for each item.

■ Package

Select the Packages that are supported by each application.

■ Image Mode

View the Menu and the Touch Menu for each Image mode.

■ Remove

Delete the group and item selected in Group View or Item View.

■ Edit Touch

Place groups and items shown in Group View or Item View on the touch screen.

- ▶ Click the **Edit Touch** button to display a dialog box that shows the Touch Buttons.
 - Clear All: Clear all groups and items.
 - Add Page: Add a page.
 - Remove Page: Remove a page.
- ▶ Click a Touch Button to display the groups and items that may be assigned to the button.
- ▶ Select Empty to delete the group and item currently assigned to the Touch Button.
- ▶ If you delete a group or item from a Touch Button and click the **Save** button to exit the dialog box, that group or item will be also deleted from Group View or Item View.

■ Auto Sequence

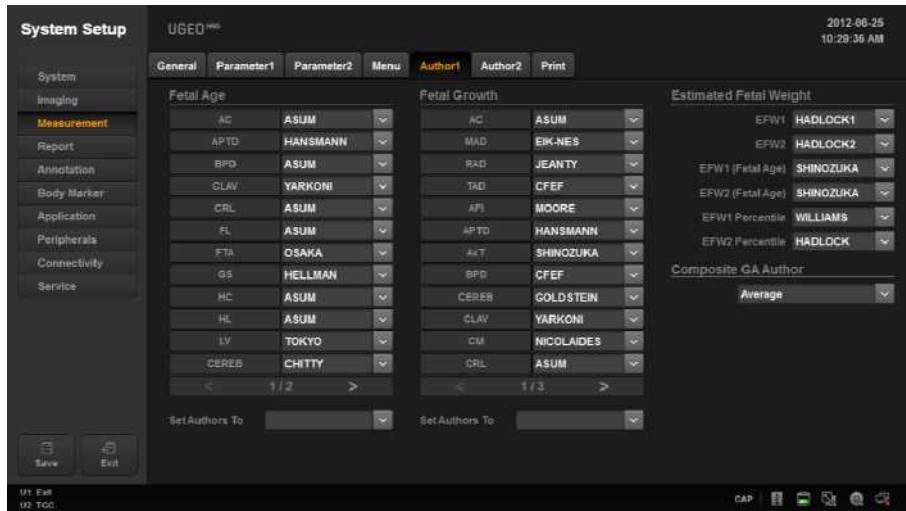
Place a check mark in the Auto Sequence box to activate it. It supports the ability to activate all the items within a Group in sequence. It also supports the sequential measurement function for measuring AFI and Volume in OB.

■ Default Items

Press the Default Items button and then select OK to revert to the initial state.

Author1 Settings

In the *Setup* screen, select the **Author1** tab in the **Measurement** category.



[Figure 3.10 Setup – Measurement – Author1]

■ Fetal Age

Specify the Fetal Age Author for each Label.

■ Fetal Growth

Specify the Fetal Growth Author for each Label.

■ Estimated Fetal Weight

Specify the EFW or EFW percentile Author.

■ Composite GA Author

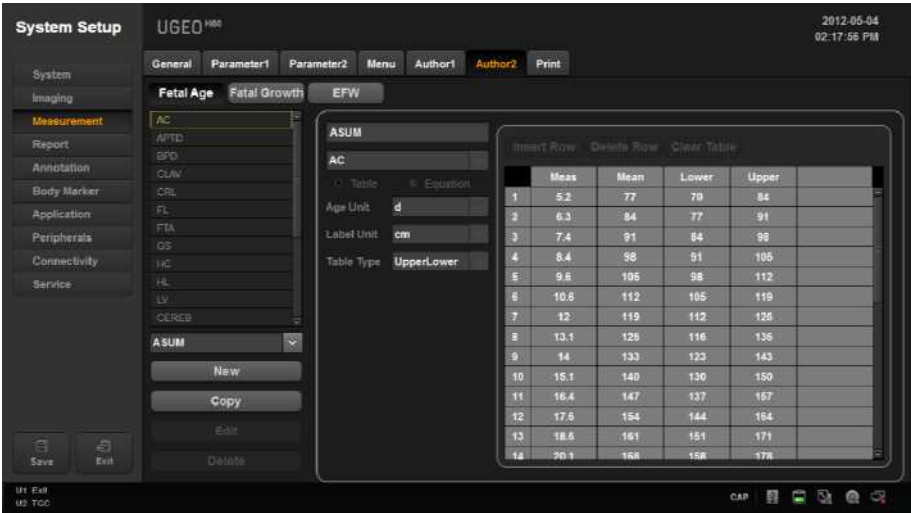
Specify the Author to use for calculating Composite GA.

■ Set Authors To

Specify the same Author for all Labels.

Author2 (Tables & Equations) Settings

In the *Setup* screen, select the **Author2** tab in the **Measurement** category. View and edit the Tables and Equations to be used in each measurement item of OB.



[Figure 3.11 Setup – Measurement – Author2]

Select Category

Select a category from Fetal Age, Fetal Growth, and EFW (Estimated Fetal Weight) to view and edit tables and charts for that category.

Select Label

Select a Label in the list box; that Label's Author List will be filled into the combo box and the first Author data will be displayed on screen.

Select Author

Select Author in the combo box, and the Author data will be displayed on screen.

New

Create new Author data.

Copy

Copy the currently selected Author data to create new Author data.



NOTE: If Author data created by the user is selected, Copy button becomes inactive and cannot be selected.

■ Delete

Delete the currently selected Author data.



NOTE: Only the Author data created by the user may be deleted.

■ Author Name

Represents the currently selected Author's name. Author's name may be entered when creating new Author data.



NOTE: When creating new Author data, you cannot save data without entering the Author's name.

■ Author Data Label

Represents the label that the currently selected Author data belongs to. Label may be changed when creating new Author data.

■ Author Data Type

Represents the currently selected Author data type.



NOTE: The Author data type may be changed when creating new Author data using the New button. Note that Table type data cannot be created for EFW.

■ Age Unit

Represents the Fetal Age unit for the currently selected Author data. The Age Unit may be changed when creating new Author data.

■ Valid GA Range

Represents the valid range of the Gestational Age (GA) for the currently selected Author data. The valid GA range may be changed when creating new Author data.

■ Label Unit

Represents the Label Unit for the currently selected Author data. Label unit may be changed when creating new Author data.

■ Valid Label Value Range

Represents the valid range of the Label value for the currently selected Author data. The valid Label value range may be changed when creating new Author data.

■ Table Type

Represents the deviation type of the Table for the currently selected Fetal Age Author data. The deviation type of the Table may be changed when creating new Author data.

■ SD Type

Represents the deviation type of the Table for the currently selected Fetal Growth Author data. The deviation type of the Table may be changed when creating new Author data.

■ EFW Unit

Represents the EFW unit of the currently selected EFW Author data. The EFW unit may be changed when creating new Author data.

■ Equation

Represents the currently selected Author Equation data. The equation may be changed using the Input Parameter list box or the Calculator buttons when creating new Author data.

**NOTE:**

- ▶ If the Equation contains a formulaic error, the data cannot be saved.
- ▶ If you enter a Label that is not found in the Input Parameter list box, the data cannot be saved.

■ Table

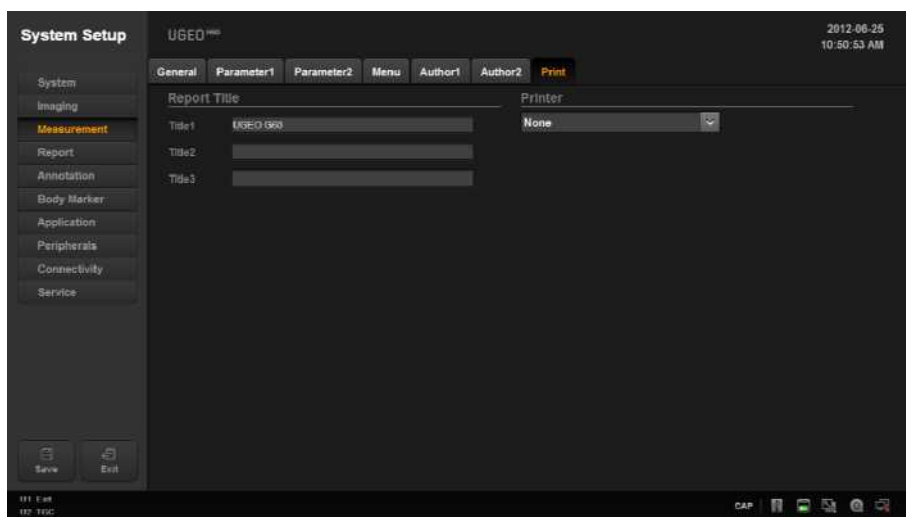
Represents the currently selected Author Table data. The table may be changed using the Insert Row, Delete Row, and Clear Table buttons when creating a new Author data.



NOTE: At least one row of data must be entered into the Table before data can be saved.

Print Settings

In the *Setup* screen, select the **Print** tab in the **Measurement** category. Select a type of printer to assign settings.



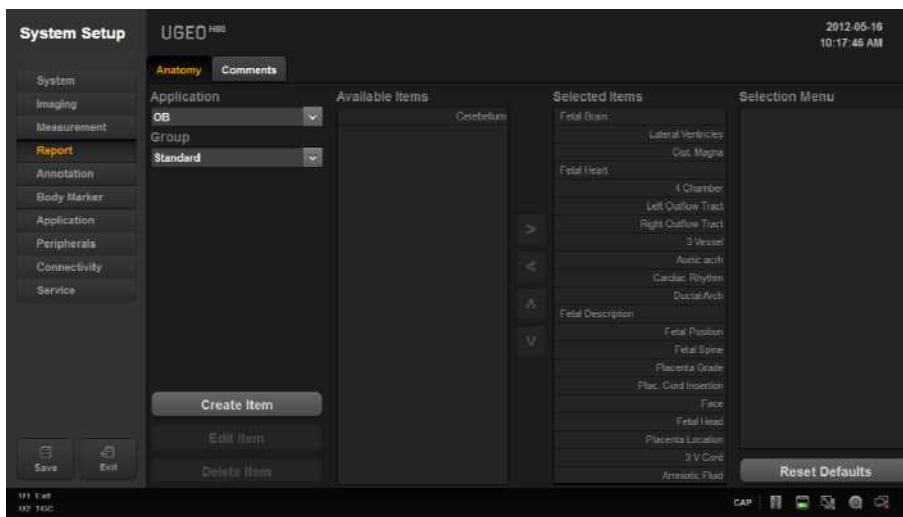
[Figure 3.12 Setup – Measurement – Print]

Report

In the *Setup* screen, select the **Report** tab. Or tap **Report** on the touch screen. Specify display-related options.

Anatomy

In the *Setup* screen, select the **Anatomy** tab in the **Report** category.



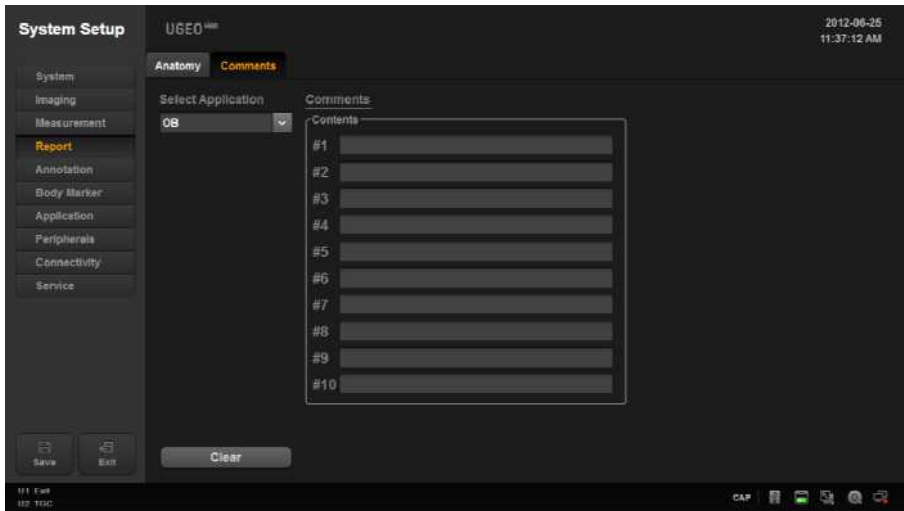
[Figure 3.13 Setup – Report – Anatomy]

Press **Create Item** to add a new item, press **Edit Item** to edit an item, or press **Delete Item** to delete an item. Press **Reset Defaults** to reset to the default settings.

- Application: Select the application.
- Group: Setup the preset for the measurement application.
- Available Items: This is a category or item list that can be added to the Anatomy page.
- Selected Items: This is a category or item list that has been added to the Anatomy page.
- Selection Menu: This is the lower-tier item list belonging to an item you have selected that has been added to the Anatomy page.

Comments

In the *Setup* screen, select the **Comments** tab in the **Report** category.



[Figure 3.14 Setup – Report – Comments]

■ Select Application

Display all information for the measured application and select the application to show in Report.

■ Comments

The user enters comments manually.

■ Clear

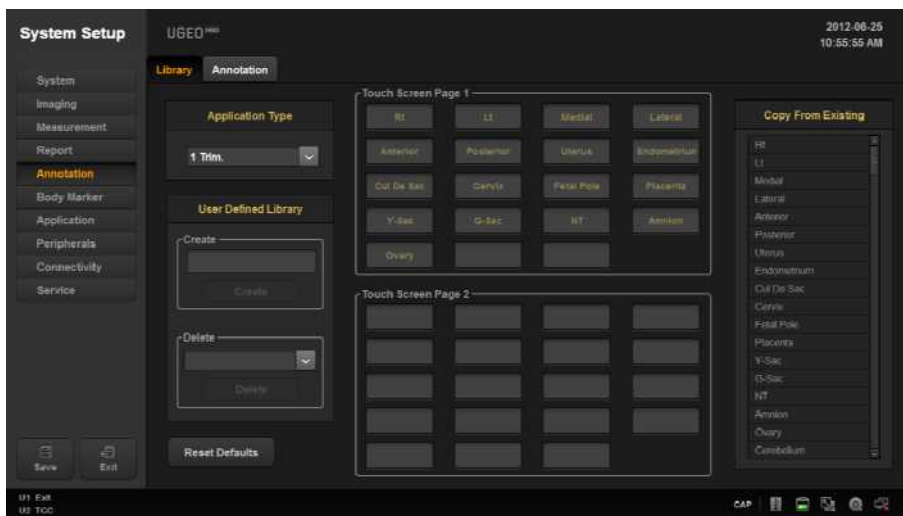
Delete saved comments.

Annotation

In the *Setup* screen, select the **Annotation** tab. Or tap **Annotation** on the touch screen. Setup options for entering an opinion or a diagnosis.

Library

In the *Setup* screen, select the **Library** tab in the **Annotation** category. You can create, edit, or delete an Annotation library.



[Figure 3.15 Setup – Annotation - Library]

Application Type

Select an application type.

User Defined Library

The user creates or deletes text.

Create

Creates text.

Delete

Deletes text.

Reset Default

Reverts to default settings.

Touch Screen Page 1

Specify items to be displayed on the first page of touch screen.

Touch Screen Page 2

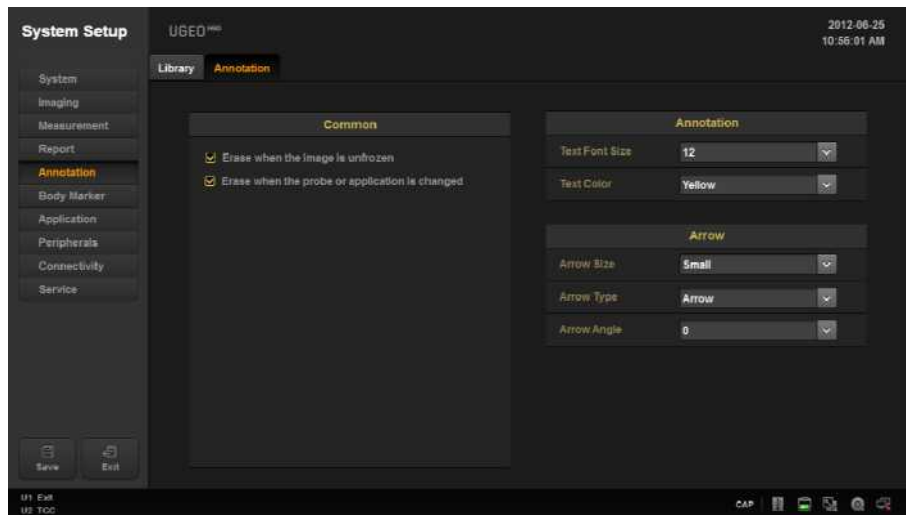
Specify items to be displayed on the second page of touch screen.

Copy From Existing

You can select the items provided by the system to set up.

Annotation

In the *Setup* screen, select the **Annotation** tab in the **Comments** category. Select whether or not to discard annotations from the screen when in Scan Mode or when the probe or application is changed.



[Figure 3.16 Setup – Annotation – Annotation]

Common

■ Erase When the Image is Unfrozen

Select whether or not to erase annotations in Image Scan mode.

■ Erase When the Probe or Application is Changed

Select whether or not to erase annotations when the probe or application is changed.

Annotation

■ Text Font Size

Select the font size to use.

■ Text Color

Select the font color to use.

Arrow

■ **Arrow Size**

Select the size of the arrow.

■ **Arrow Type**

Select the shape of the arrow.

■ **Arrow angle**

Select the angle of the arrow.

Body Marker

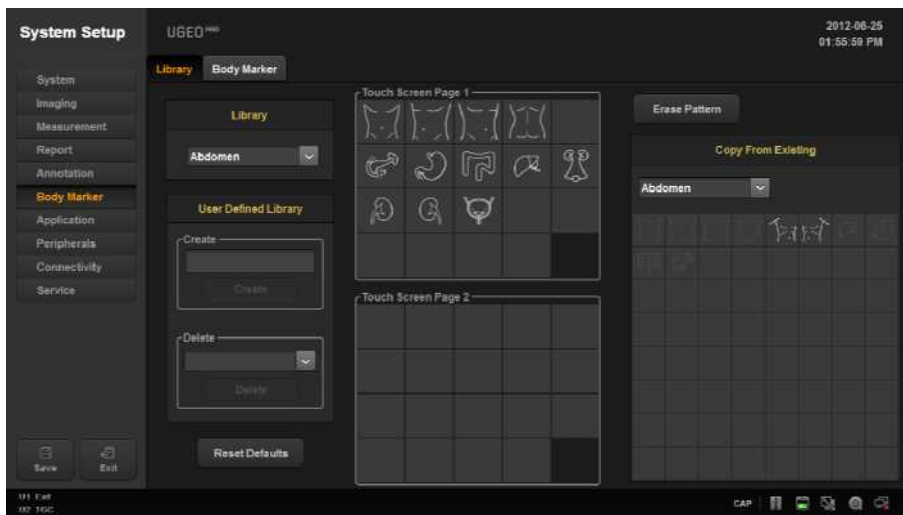
In the *Setup* screen, select the **Body Marker** tab. Or tap **Body Marker** on the touch screen.

Library

In the *Setup* screen, select the **Library** tab in the **Body Marker** category.

You can create, edit, or delete a Body Marker library.

1. On Touch Screen Page 1 or Touch Screen Page 2, use the trackball to select a desired location; once selected, it will be marked in yellow.
2. In Copy From Existing, select the Body Marker you want; the Body Marker will be created at the location marked in yellow.
3. On Touch Screen Page 1 or Touch Screen Page 2, use the trackball to select a Body Marker to display it in yellow; tap **Erase Pattern** to delete the Body Marker.



[Figure 3.17 Setup – Body Marker - Library]

Library

Select an application.

User Defined Library

The user can create or delete a Library.

Create

Create a new library.

Delete

Delete a Body Marker.

Reset Default

Reverts to default settings.

Touch Screen Page 1

Specify items to be displayed on the first page of touch screen.

Touch Screen Page 2

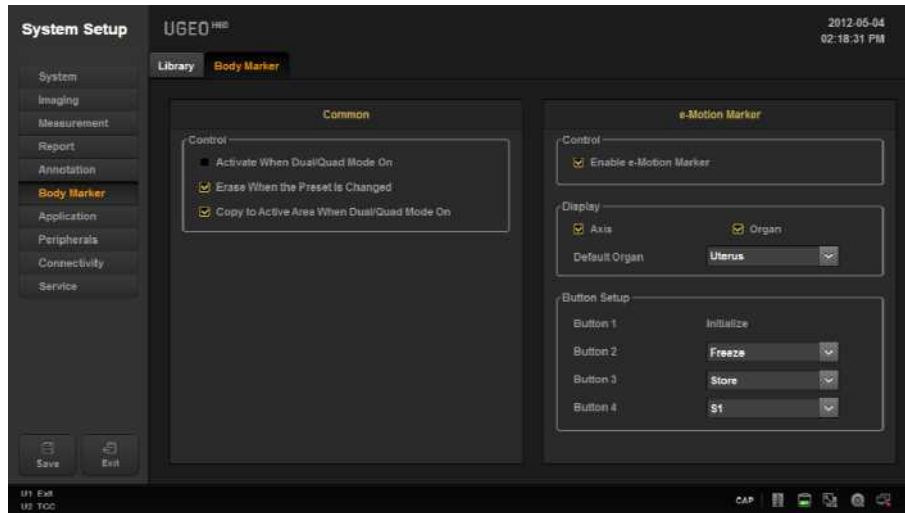
Specify items to be displayed on the second page of touch screen.

Copy From Existing

You can select the Body Markers provided by the system to set up.

Body Marker

In the *Setup* screen, select the **Body Marker** tab in the **Body Marker** category.



[Figure 3.18 Setup – Body Marker- Body Marker]

Common

■ Activate When Dual/Quad Mode On

Select whether or not to display the BodyMarker when Dual or Quad mode is activated.

■ Erase When the Preset Is Changed

Select whether or not to erase the BodyMarker when the Preset is changed.

■ Copy to Active Area When Dual/Quad Mode On

Select whether or not to copy the BodyMarker to the active area when Dual or Quad mode is activated.

e-Motion Marker

Select this if you are using e-Motion Marker, which is an optional feature for this product.



NOTE:

- ▶ e-Motion Marker can be used only if the following conditions are met:
 - Probe: EVN4-9
 - Application: Gynecology
 - Preset: Uterus
- ▶ General Body Markers cannot be used while e-Motion Marker is being used.
- ▶ Refer to the installation guide that comes with the e-Motion Marker package for instructions on installing e-Motion Marker.
- ▶ It is not available in USA and CANADA.

■ Control

Enable e-Motion Marker: If this checkbox is selected, pressing the **Body Marker** button on the control panel runs e-Motion Marker.

■ Display

- ▶ Axis: Select this checkbox to display the axes on the monitor screen.
- ▶ Organ: Select this checkbox to display the shape of the organ on the monitor screen.
- ▶ Default Organ: Press the combo button to select the type of organ to use.

■ Button Setup

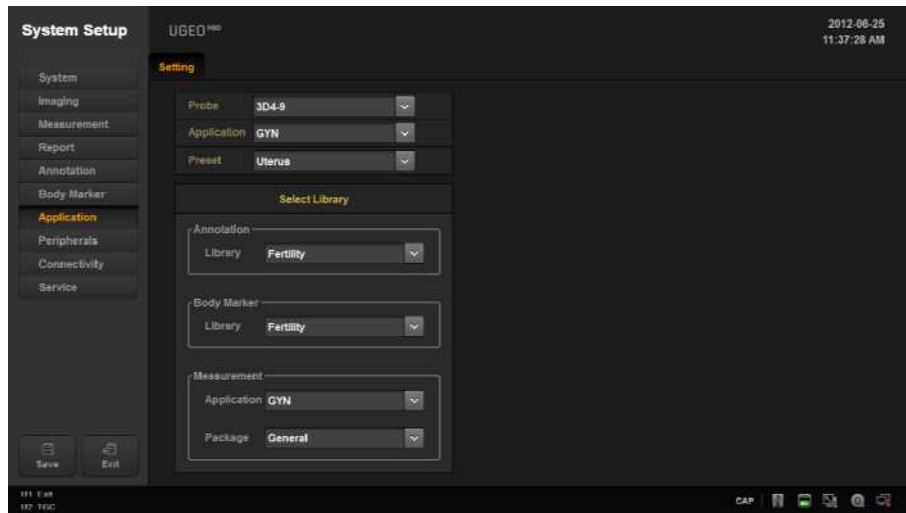
Assign functions to the buttons on the main body of e-Motion Marker.

- ▶ Button 1: Initializes the e-Motion Marker sensor. The user may not assign another function to this button.
- ▶ Button 2-4: Press the combo button to select the function to use. Select from Freeze, Store, S1, S2, and S3.

Application

In *Setup* screen, select **Application** tab. Or tap **Application** on the touch screen.

Settings



[Figure 3.19 Setup – Application – Setting]

Probe

Select a probe.

Applications

Select an application.

Preset

Select the Preset that is supported by the selected application.

Select Library

■ **Annotation**

Set up a text library.

■ **BodyMarker**

Set up a BodyMarker library.

■ **Measurement**

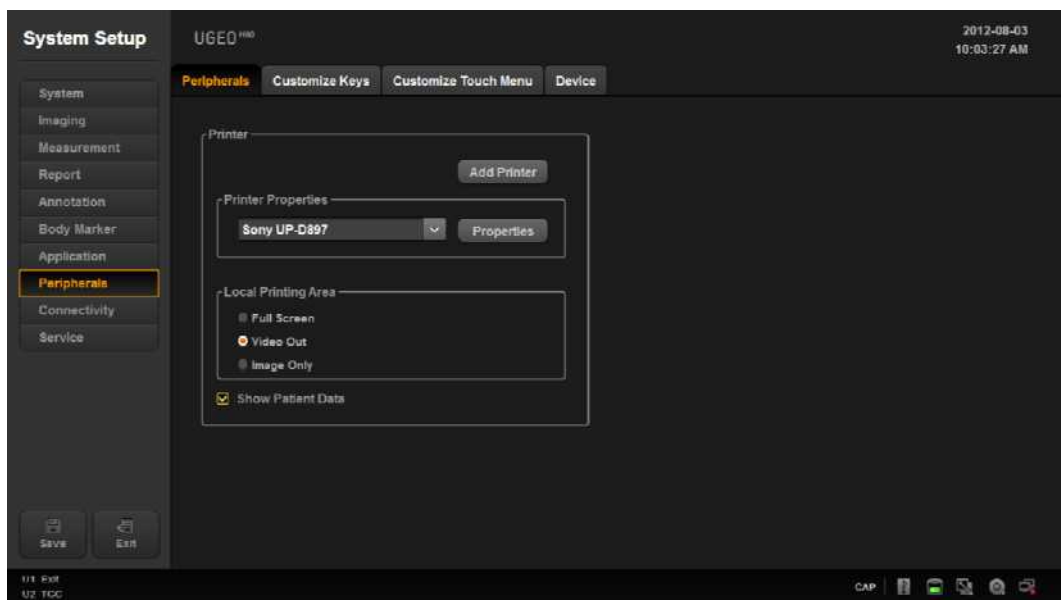
- ▶ Application: Select the application.
- ▶ Package: Set up the preset for the measurement application.

Peripheral Device Settings

Select the **Peripherals** tab on the *Setup* screen. Or tap **Peripherals** on the touch screen. You can configure keys, buttons and the peripheral devices connected to the product.

❏ Peripherals

In the *Setup* screen, select the **Peripherals** tab in the **Peripherals** category. You can configure peripheral devices connected to the product.



[Figure 3.20 Setup – Peripherals – Peripherals]

Printer

Press the **Add Printer** button to start installing an additional printer. The system must be rebooted before the additional printer can be used.

■ **Printer Properties**

Press the **Properties** button to specify the type of printer and its properties. Select the size and orientation of the paper. Select either Landscape or Portrait. Select the printer to use by using the combo button.

■ **Local Printing Area**

Set the area that will be printed.

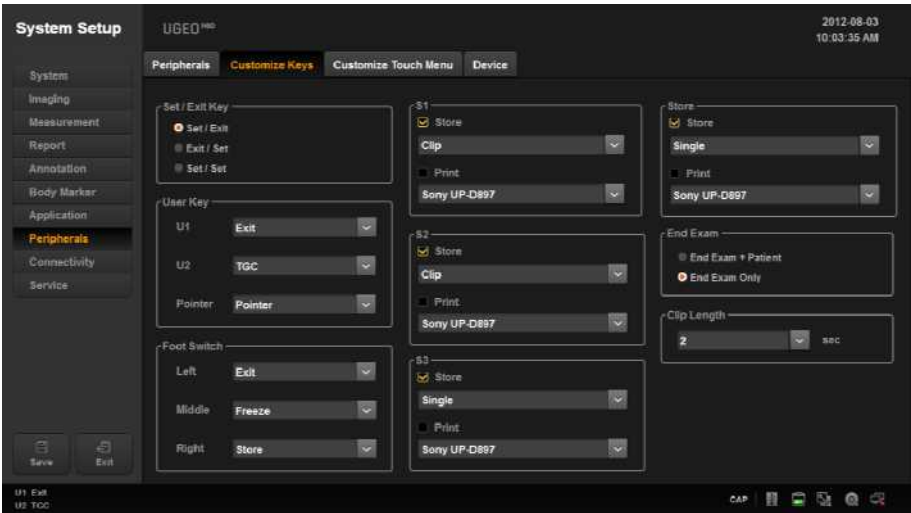
- ▶ Full Screen: Prints the entire contents of the monitor screen.
- ▶ Video Out: Prints only a certain area of the screen, including the Image area.
- ▶ Image Only: Prints the image area only.

■ **Show Patient Data**

Select whether or not to display the patient information.

User Defined Keys (Customize Keys)

In the *Setup* screen, select the **Customize Keys** tab in the **Peripherals** category. You can set the functions of the keys and buttons on the product.



[Figure 3.21 Setup – peripherals – Customize Keys]

Set/Exit Key

Set the functions of the buttons to the left and right of the trackball on the control panel.

- ▶ Set/Exit: The left button is set to **Set** and the right button is set to **Exit**.
- ▶ Exit/Set: The left button is set to **Exit** and the right button is set to **Set**.
- ▶ Set/Set: Both the left and the right keys are set to the **Set** function.

User Key

Assign functions to the **U1, U2** buttons and pointer on the control panel. The functions that can be assigned are as follows:

U1, U2	
Exit	TGC
Q Scan	Harmonic
Dual	Quad
Dual Live	Biopsy
Simultaneous	EFW Measure
Pointer	Arrow

Pointer	
Pointer	Arrow

Foot Switch

Assign functions to the Foot Switch's left, middle, and right pedals. The functions that can be assigned are as follows:

Foot Switch Functions	
Exit	Freeze
Store	S1
S2	S3
Update	

S1, S2, S3, Store Key

- Set up Store (Single, Clip) and Print functions.
- If both Store and Print are selected, the image will be stored and then printed.

End Exam

■ End Exam + Patient

Pressing the **End Exam** button on the control panel switches the screen to the *Patient Information* screen.

■ End Exam Only

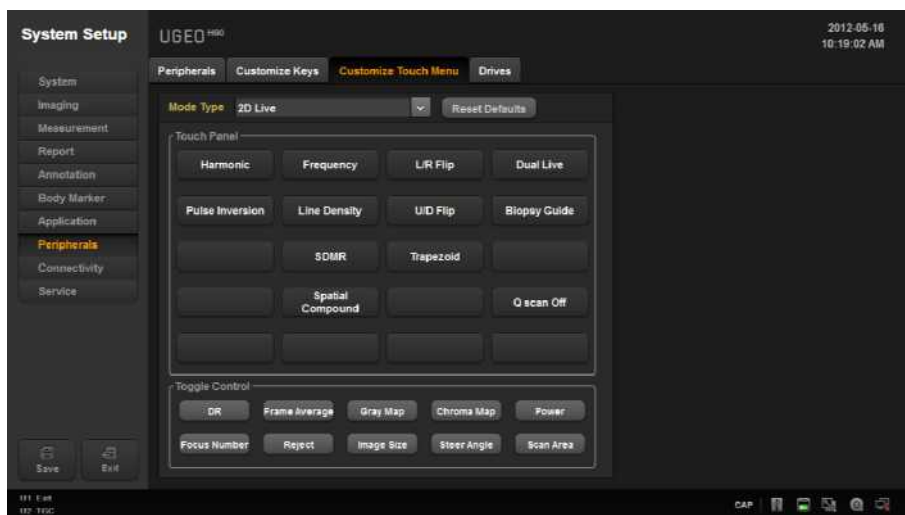
Pressing the **End Exam** button on the control panel exits Exam Mode and switches the screen to the B Mode Scan screen.

Clip Length

Specify the time to be saved.

Customize Touch Menu

In the *Setup* screen, select the **Customize Touch Menu** tab in the **Peripherals** category. You can configure the touch screen and the Toggle Control button.



[Figure 3.22 Setup – peripherals – Customize Touch Menu]

Mode Type

Select 2D Live, 2D Freeze, C Live, C Freeze, D Live, D Freeze, M Live, or M Freeze.

Touch Panel

Specify items to be included on the touch screen and their positions.

Toggle Control

Specify the dial-button activated items to be included in the bottom menu on the touch screen and their positions.

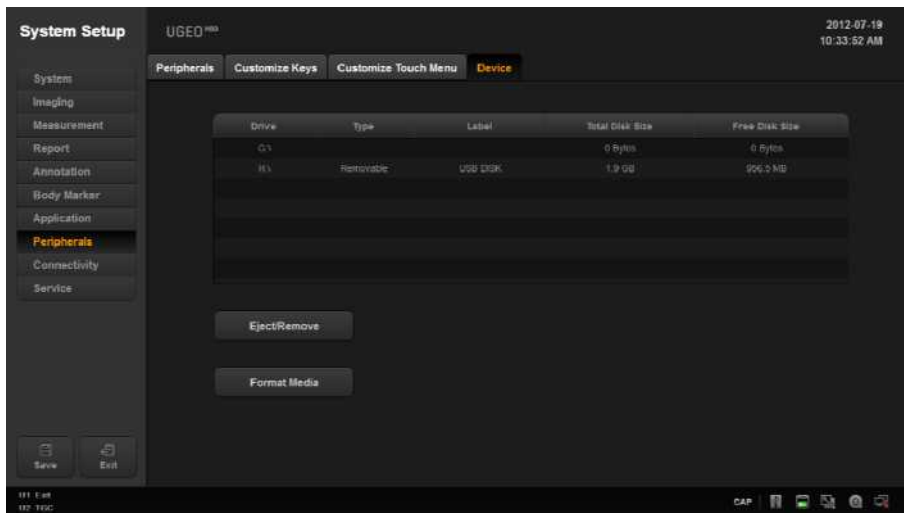
Reset to Default

Reverts to default settings.

Device

On the *Setup* screen, select the **Device** tab in the **Peripherals** category.

Press the **Eject/Remove** button to eject or remove the disk from the device. Press the **Format Media** button to erase the CD/DVD.



[Figure 3.23 Setup – Peripherals – Device]

Connectivity Settings

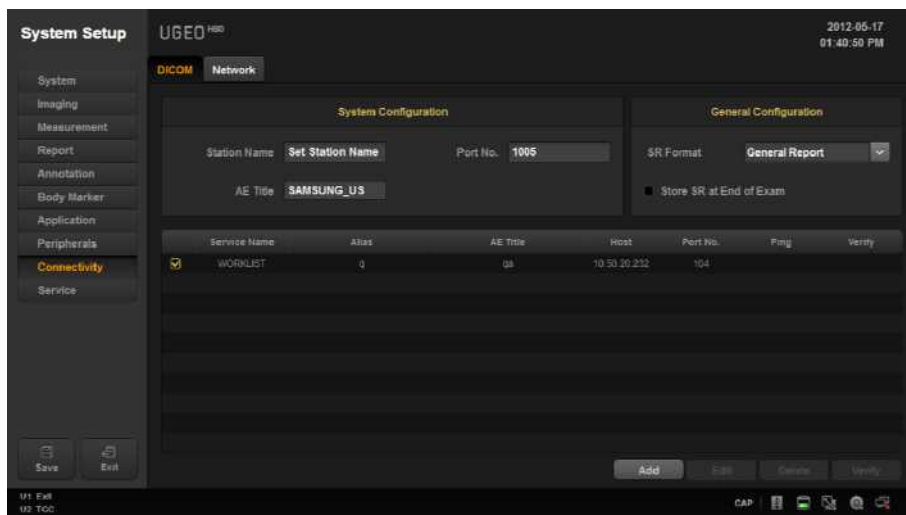
Tap **Connectivity** on the touch screen. You can perform DICOM administration tasks or manage DICOM server settings and network information for your system.

DICOM Settings

In the *Setup* screen, select the **DICOM** tab in the **Connectivity** category. Used to configure DICOM (Digital Imaging and Communication in Medicine) operation and server.



NOTE: For more information, please refer to the server's user manual, or the DICOM Conformance Statement.



[Figure 3.24 Setup – Connectivity – DICOM]

❏ System Configuration

Information about 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 the DICOM for the system within a network. It is also used to transfer data to other DICOM servers.



NOTE: For IP Address, AE Title, and Port No. settings, contact your organization's network administrator.

■ Station Name

Enter the name of the system. Along with AE Title, it is often used to identify the system in the DICOM network.

■ AE Title

Enter the name of the DICOM AE (Application Entity). The title is used to identify devices that use DICOM within a network.

■ Port No.

Enter the port number on the server being used.

❏ General Configuration

■ SR Format

Select the format to save SR in. The options are General Report and Viewpoint.

■ Store SR at End of Exam

Select whether to store SR at the end of the exam. When you select this checkbox, SR is automatically stored at the end of the exam. Otherwise, it is not stored.

❏ Adding DICOM Services

Click **Add** on the screen. A screen is displayed where you can enter a DICOM service to add. After adding a service, click **Apply** to save the information. Click **Cancel** to cancel.

■ DICOM Services Options

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

■ Alias

Enter the name of the DICOM server.

■ AE Title

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

■ IP Address

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

■ Port No.

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

■ Connection Timeout

The connection will time out if there is no response within the configured time period. You can specify this time period in seconds.

■ Read Timeout

Specify the Read Timeout time limit for the server you are adding.

■ Retry Interval

Specify how many seconds the system will wait before it retries a failed transmission. You can specify this time period in seconds.

■ Maximum Retries

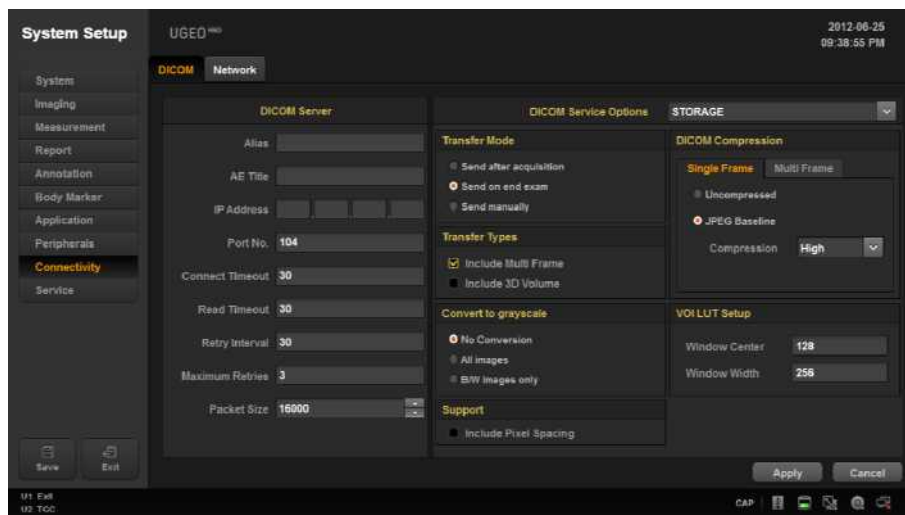
Specify how many times a failed transmission will be retried.

■ Packet Size

Specify the size of the transfer packet.

Storage Server Information

Select 'STORAGE' as the **DICOM Service Options** item. Configure the Image Storage Service using DICOM.



[Figure 3.25 DICOM Configuration – Storage]

■ Transfer Mode

Select a transfer method:

- ▶ Send after acquisition: Send an image whenever you press the **Store** button to save it.
- ▶ Send on end exam: Send all saved images when you press the **End Exam** button.
- ▶ Send manually: Send an image the user selects from the Exam List or in Review.

■ Transfer Types

- ▶ Include Multi Frame: Select this checkbox to transfer Cine Loops.
- ▶ Include 3D Volume: Select whether to send 3D volume data together with the 3D images.



NOTE: Only select this option if you use a storage service that supports the 3D volume data format used by Samsung Medison.

■ Convert to Grayscale

Select the grayscale conversion type for the image to apply the DICOM service to.

- ▶ No Conversion: Send the original image without converting it.
- ▶ All Images: Convert all images to grayscale before sending them.
- ▶ B/W Images only: Only the images that do not have color are converted to grayscale before being sent.

■ Support

Include Pixel Spacing: In addition to the area information used in ultrasonography, the area information used in CT or radiography is also included. You can take measurements in a PACS system that does not support ultrasound area information.



NOTE: However, only 2D and 2D Color Mode images are supported. In Dual and Quad Mode, the depths of the included images must be identical.

■ DICOM Compression

Select whether or not to compress the images for the DICOM service. Use the combo button to select the image type and the compression type (Uncompressed or JPEG Baseline). When you select Uncompressed, the images are saved without compression.

- ▶ Single Frame: Specify the compression type for still images.
- ▶ Multi Frame: Specify the compression type for Cine images.
- ▶ If you select JPEG Baseline, you need to select from Lossy Low, Lossy Medium, or Lossy High (TBD). You can prioritize either the quality or the compression ratio. You can specify the compression type, compression ratio, and frame rate. You can select Full, 10, 20, or 30 as the frame rate.

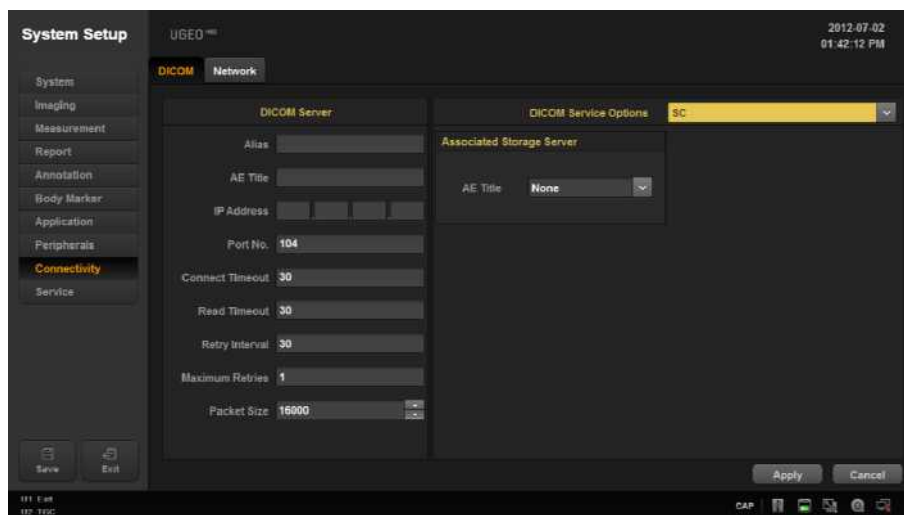
■ VOI LUT Setup

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

- ▶ **Window Center:** 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. The image is getting darker if the value is set to 128 or higher. Note that this function can be used only when it is supported by the storage service.
- ▶ **Window Width:** Enter a value for the DICOM Tag (0028, 1051) setting. The setting value indicates the brightness of an image that is displayed by the storage service. Relative to 256, higher values result in lower contrast. Note that this function is available only when it is supported by the storage service.

STORAGE CMT Server Information

Select 'STORAGE CMT' (Storage Commitment) as the **DICOM Service Options** item. 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 sent.



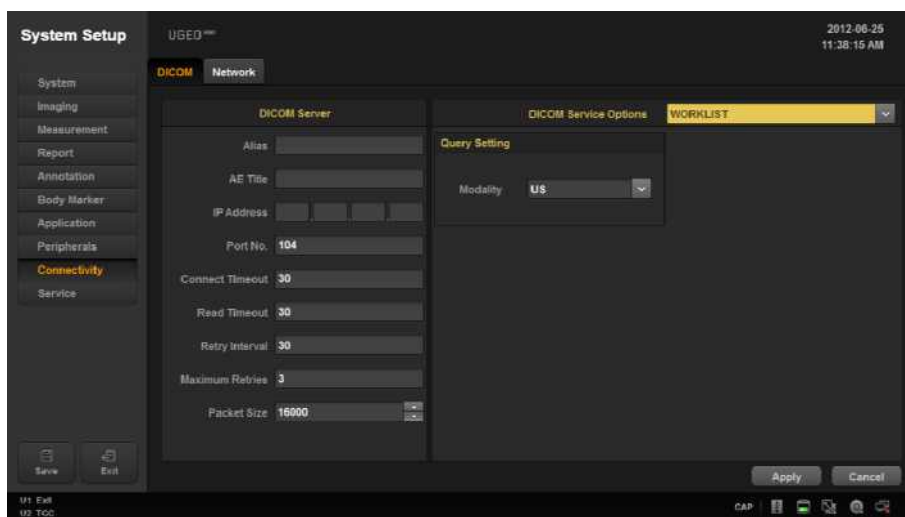
[Figure 3.26 DICOM Service Options – STORAGE CMT]

■ Associated Storage Server

Select an Image Storage server to connect to.

Worklist Server Information

Select 'WORKLIST' as the **DICOM Service Options** item. Configure the Modality Worklist Service using DICOM.



[Figure 3.27 DICOM Service Options – Worklist]

■ Query Setting

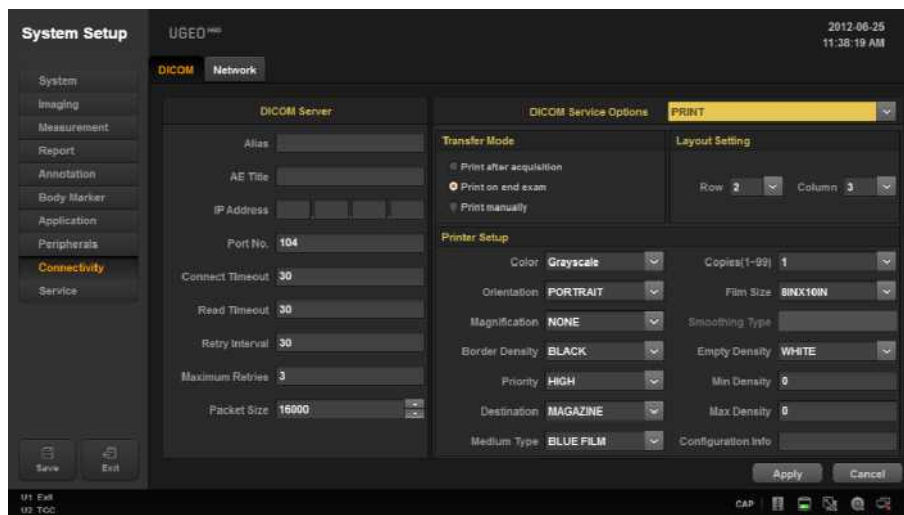
- ▶ Select the type of Modality to retrieve when updating the worklist.
- ▶ Modality: Select from ultrasound images (US) or all images (All).

Tips!

After setting up the Worklist service, press the **Patient** button on the control panel to go to the Worklist page.

Print Server Information

Select 'PRINT' as the **DICOM Service Options** item. Configure the Print Service using DICOM.



[Figure 3.28 DICOM Configuration – Print]



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 the printer service, refer to the printer's user manual or its DICOM Conformance Statement.

■ Transfer Mode

Select a printing method:

- ▶ Print after acquisition: Print an image whenever you press the **Store** button to save it.
- ▶ Print on end exam: Print all saved images when you press the **End Exam** button.
- ▶ Print manually: Print an image the user selects from the Exam List or in Review.

■ Layout Settings

Specify the paper layout. Between 1 and 6 rows and 1 and 4 columns may be selected.

■ Color

Specify whether to use color for printing. Select either Grayscale or Color.

■ Orientation

Specify the orientation of the paper. Select either Landscape or Portrait.

■ Magnification Type

Specify the type of interpolation to use to resize an image to print. Select from Replicate, Bilinear, Cubic and None.

■ Border Density

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

■ Print Priority

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

■ Film Destination

Specify the paper pathway. Select Magazine or Processor.

■ Medium Type

Specify the material type for the printout. Select from Paper, Clear Film, Blue Film, Mammo Clear Film, and Mammo Blue Film.

■ Number of Copies

Enter the number of copies between 1 and 99.

■ Film Size ID

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

■ Smoothing Type

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

■ Empty Image Density

Select the background color for the printed area. Select Black or White.

■ Min. Density

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

■ Max. Density

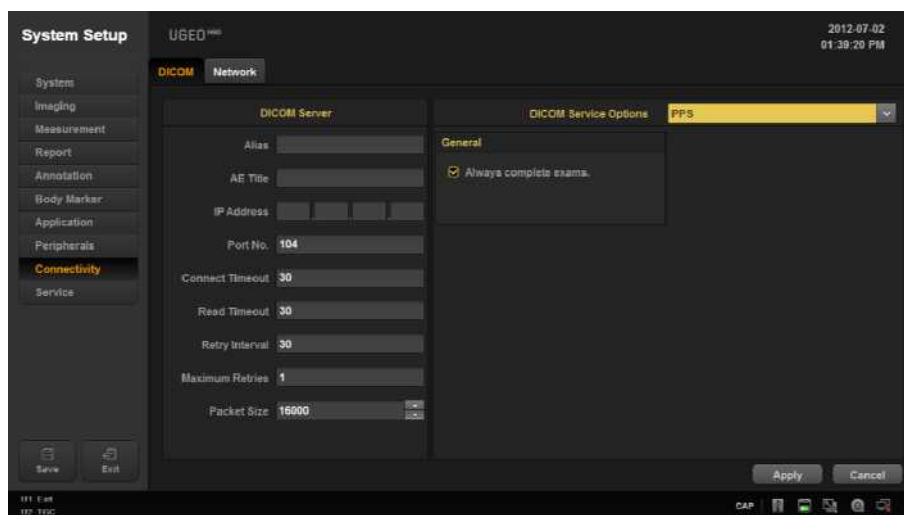
Specify the maximum brightness of an image to print. If this option is not specified, the default value is applied.

■ Configuration Info

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

MPPS Server Information

Select **DICOM Service Options** as the 'MPPS' (Modality Performed Procedure Step). Configure the Modality Performed Procedure Step Service using DICOM.



[Figure 3.29 DICOM Service Options - MPPS]

■ Always complete exams

When you check this checkbox, exams are always reported in complete condition. If you press the **End Exam** button without selecting a checkbox, the selected cancellation message will be sent to the RIS server.

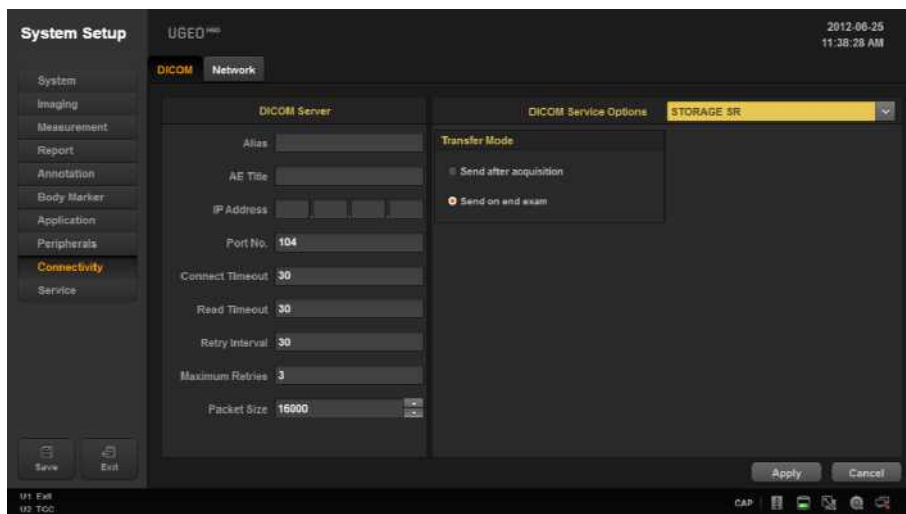
Storage SR Server Information

Select 'Storage SR' (Storage Structured Report) as the **DICOM Service Options** item. Configure the Report Storage Service using DICOM.

■ Transfer Mode

Select a printing method:

- ▶ Send after acquisition: Whenever the **Store** button is pressed, the measurement data in the report will be sent as an SR.
- ▶ Send on end exam: Whenever the **End Exam** button is pressed, the measurement data in the report will be sent.



[Figure 3.30 DICOM Service Options – Storage SR]

■ Changing DICOM Information

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

After changing the information, click **Apply** to save the changes. Click **Cancel** to cancel.

■ Deleting DICOM Services

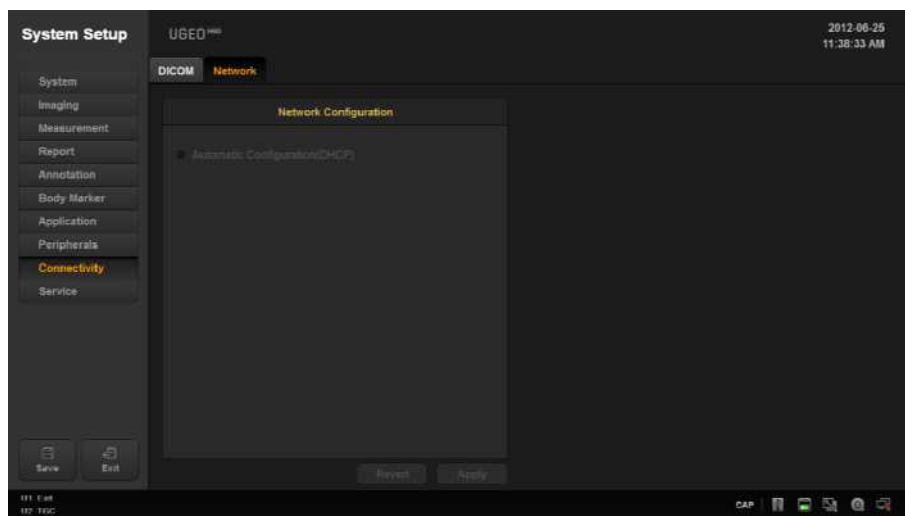
Select a service and click **Delete** on the screen.

Testing DICOM Servers

Select a service and click **Verify** on the screen. The connection with the selected service is tested and the results are shown under the Verify items. If the result is Success, the connection is normal.

Network Settings

In the *Setup* screen, select the **Network** tab in the **Connectivity** category. Or tap **Connectivity** on the touch screen. You can manage the network information for the current equipment.



[Figure 3.31 Setup – Connectivity – Network]

Network Configuration

Setup the network information for the current equipment.

Automatic Configuration (DHCP)

If the checkbox is selected, the IP information is configured automatically.

Static Configuration

If the checkbox is cleared (Automatic Configuration), you can enter the fixed IP information. Specify IP Address, Subnet Mask, Gateway, and DNS information.

■ Revert

Clear the currently entered information and revert to the default settings.

■ Apply

Use the currently entered information to set up the IP.

Service



NOTE:

- ▶ The following actions should not be performed by a user. Users must make a request to a customer support representative of Samsung Medison, who will then perform the action for users.
- ▶ Such services as restoring patient information and images, modifying the software, etc. are performed.
- ▶ Enable or disable the use of optional software and hardware.
 - Name: This shows the types of optional software that can be installed on the product.
 - Status: This shows the current status of optional software. Registered means that the software can be used until the date specified by the Expired Date is reached. Unregistered means that the software cannot be used now.
- ▶ Information about the system software version will be displayed.
- ▶ Built in self test function is provided.

Help

Press the **Help** button on the keyboard. The electronic manual appears on the monitor screen.



NOTE: There is no **Return** key on the *Help* screen.

Chapter 4

Maintenance and Storage

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:: Operational Environment

When installing the product, please pay attention to the following:



CAUTION: Placing the system near generators, X-ray machines or broadcast cables may result in screen noise and abnormal visual images. Sharing the power source with other electrical devices may also induce noise.

- Avoid excess humidity.
- Avoid direct sunlight.
- Avoid excessive fluctuation in temperature.
- Optimal conditions for the system are a temperature of 10-35° and a humidity of 30-75%.
- Avoid installing the product near a heating appliance.
- Avoid dusty and/or poorly ventilated locations.
- Avoid locations that are subject to reverberation.
- Avoid a location where chemical substances or harmful gases are present.

:: Product Maintenance

Cleaning and disinfecting

Using an inappropriate cleaning or sterilizing agent may damage the product. Pay attention to the following:

**WARNING:**

- ▶ Turn off the system and disconnect the power cord from the wall outlet before cleaning and disinfecting, otherwise, there is a risk of electric shock or fire.
- ▶ Always use protective eyewear and gloves when cleaning and disinfecting the product.

■ Cleaning

**CAUTION:**

- ▶ Do not spray detergent directly onto the product's exterior. Doing so may discolor or crack the surface.
- ▶ Do not use chemical substances such as wax, benzene, alcohol, paint thinner, insecticide, aerosol deodorant, lubricant, or detergent.

■ Console

Use a soft cloth lightly dampened with a mild soap or detergent solution to clean the exterior surfaces of the system.

■ Cleaning Monitor

Wipe the LCD surface with a soft dry cloth. When the LCD panel has dirt on it, wipe it two to three times or more in one direction.



NOTE: For information on cleaning and disinfecting the probe, please refer to 'Chapter 5. Probes.'

Disinfection



CAUTION: Use only disinfectants recommended by Samsung Medison on system surfaces.

A disinfectant qualified by the FDA 510(k) process is recommended. The following disinfectants are qualified through the FDA 510(k) process and are recommended for this product:

Solutions	Country	Type	Active ingredient	FDA 510(k)
Cidex	USA	Liquid	Gluteraldehyde	K934434
Cidex Plus	USA	Liquid	Gluteraldehyde	K923744

1. Turn off the system and disconnect the power cord from the wall outlet.
2. Mix the disinfectant solution that is compatible with your system to the solution strength specified on the instruction label.
3. Clean the exterior surface of the product in compliance with the instructions provided with the disinfectant.
4. Air dry or towel dry the surface with a sterile cloth according to the instructions on the disinfectant label.

Fuse Replacement

The power protection fuse protects the product from overcurrent. If the power monitoring protection circuit detects excess current, it shuts off the current to the product in order to prevent overheating and to restrict the ultrasound power output. If the fuse blows, replace it as shown below.



DANGER: To avoid risk of electric shock, always disconnect the plug from the system prior to fuse replacement.

1. Turn off the system and disconnect the power cord from the wall outlet.
2. Press down on the middle part of the used fuse and pull out.
3. Remove the old fuse and replace it with a new one.
4. After installing the new fuse, connect the plug to the system.

Fuse information is shown in the following table.

Input Ratings	Fuse Ratings	Maker	Order No.	Description
100-240VAC	6.3AH/250V	Littelfuse	021506.3P	F1 for DC power assy
100-240VAC	4A/H250V	Littelfuse	0215004P	F2 for AUX Outlet



- ▶ The fuse of this product is intended for outlets.
- ▶ Fuse is located under the control board of AC Power Assembly.
- ▶ Fuses are marked as F1 and F2.

Cleaning Air Filters

The air filters minimize the intake of dust. When the air filter is clogged with dust, it may cause the product to overheat and generate noise; it may also reduce the reliability and the system performance.

Clean the filter once every three months to maintain the system in optimal condition.



CAUTION: Be sure to lock the brakes on the front wheels before cleaning the air filters to avoid injury by any unexpected movement of the product.

1. Pull out the filter under the front of the console and take it away from the product.
2. Shake the filter to remove the dust and wash it in a mild, soapy solution.
3. Afterwards, dry the filter with a cloth, then air dry it in the shade.
4. Slide the filter back into the product.



NOTE: Allow the wet filter to dry thoroughly before reinstalling it. A wet filter can cause the system to malfunction.

Accuracy Checks



NOTE: The user must ensure that safety inspections are performed every 2 years according to the requirements of safety standard EN60601-1. Only trained personnel are allowed to perform these safety inspections.

The product's maintenance status may affect the measurements obtained when using the product. The product should be maintained in an optimal state to ensure reliable measurements.

To ensure optimal operation of the product, perform an accuracy check every year. The equations and table related to measurement accuracy are included in 'Chapter 8. Measurements and Calculations' in this manual.

:: Information Maintenance



CAUTION: You may lose information files on user settings or patients because of physical shocks to the product or internal errors. Therefore, you should back up information on a regular basis.

User Settings Backup

Always keep a backup copy of all information related to the user settings in case of data loss. Users should not attempt to back up the user settings of the product on their own; they must contact the customer support department of Samsung Medison, so that its representative may perform the backup procedure for them.

Backing Up Patient Information

The SONOVUE program can be used to back up patients' basic information and scanned images. The data is saved in the system by default, and the user can also choose to save the data to a specific location. If the system needs to be reinstalled because of product failure, etc., Samsung Medison customer support staff will restore the patients' basic information and scanned images that are saved in the system. For a more detailed description, see 'Chapter 9. Image Management'.

Software

The software may be changed to improve the product's performance. Software may not be altered by the user; any alterations to the software must be made with the help of a representative of Samsung Medison customer support department.



CAUTION: Minor software updates may be carried out without prior notice from the manufacturer.

If errors occur in the operating system (WindowsTM), or you desire to upgrade the operating system, please follow the instructions of the operating system manufacturer.

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:: Probes

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

The system limits patient contact temperature to 43 degrees Celsius, and acoustic output values to their respective U.S. FDA limits. A power protection fuse circuit protects against over-current conditions. If the power monitor protection circuit senses an over-current condition, then the drive current to the probe is shut off immediately, preventing overheating of the probe surfaces and limiting acoustic output.

■ 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.

■ Applications and Settings for Probes

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

Probes	Application	Preset
CS1-4	Abdomen	General, Aorta, Renal
	OB	1st Trimester, 2nd-3rd Trimester, Fetal Heart
	Gynecology	Uterus, Pelvis
C2-8	Abdomen	General, Aorta, Renal
	OB	1st Trimester, 2nd-3rd Trimester, Fetal Heart
	Gynecology	Uterus, Pelvis
CF4-9	Pediatric	Abdomen, Neohead
	Vascular	Carotid, Arterial, Venous
L5-13	Small Parts	Thyroid, Testicle, Breast
	Vascular	Arterial, Carotid, Venous
	Musculoskeletal	Shoulder, Hand/Foot, Knee/Elbow

Probes	Application	Preset
ER4-9	OB	1st Trimester, 2nd-3rd Trimester
	Gynecology	Uterus, Pelvis
	Urology	Prostate
EVN4-9	OB	1st Trimester, 2nd-3rd Trimester
	Gynecology	Uterus, Pelvis
	Urology	Prostate
VE4-8	Abdomen	General, Aorta, Renal
	OB	1st Trimester, 2nd-3rd Trimester, Fetal Heart
	Gynecology	Uterus, Pelvis
3D2-6	Abdomen	General, Aorta, Renal
	OB	1st Trimester, 2nd-3rd Trimester, Fetal Heart
	Gynecology	Uterus, Pelvis
3D4-9	OB	1st Trimester, 2nd-3rd Trimester
	Gynecology	Uterus, Pelvis
	Urology	Prostate



NOTE:

- ▶ In addition to the standard presets, users can also create up to five of their own, which can be accessed by selecting User 1-5.
- ▶ For information on the selection and setting of probes, refer to 'Chapter 6. Starting Diagnosis'.

■ Function list

The functions available in this product for various probes and applications are as follows:

Probes	Application	Q Scan	Har	PI	SCI	SDMR	Biopsy
CS1-4	Abdomen	O	O	O	X	O	O
	OB	O	O	O	X	O	O
	Gynecology	O	O	O	X	O	O
C2-8	Abdomen	O	O	O	X	O	O
	OB	O	O	O	X	O	O
	Gynecology	O	O	O	X	O	O
CF4-9	Pediatric	O	X	X	X	O	X
	Vascular	O	X	X	X	O	X
L5-13IS	Small Parts	O	O	X	O	O	O
	Vascular	O	O	X	O	O	O
	Musculoskeletal	O	O	X	O	O	O
ER4-9	Abdomen	O	X	X	X	O	O
	OB	O	X	X	X	O	O
	Gynecology	O	X	X	X	O	O
EVN4-9	Abdomen	O	X	X	X	O	O
	OB	O	X	X	X	O	O
	Gynecology	O	X	X	X	O	O
VE4-8	Abdomen	O	O	O	X	O	O
	OB	O	O	O	X	O	O
	Gynecology	O	O	O	X	O	O
3D2-6	Abdomen	O	O	O	X	O	O
	OB	O	O	O	X	O	O
	Gynecology	O	O	O	X	O	O

Probes	Application	Q Scan	Har	PI	SCI	SDMR	Biopsy
3D4-9	OB	O	O	X	X	O	O
	Gynecology	O	O	X	X	O	O
	Urology	O	O	X	X	O	O



NOTE:

Legend

- ▶ Q Scan: Quick Scan
- ▶ Har: Harmonic Imaging
- ▶ PI: Pulse Inversion
- ▶ SCI: Spatial Compound Imaging
- ▶ SRI(SDMR): Speckle Reduction Imaging

Thermal Index (TI) Tables

The Thermal Index (TI) is displayed in the Title area of the screen, and represents the probability of temperature rise in a particular area of the body. The thermal index consists of the following indices: Soft tissue (TIs), bone (Tlb), and cranial bone (Tlc). This product automatically displays an appropriate thermal index for the current probe and application. Refer to the following table:

Probes	Application											
	Abdomen	Obstetrics	Gynecology	Cardiac	Vascular	Urology	Musculoskeletal	Pediatric	Small Parts	TCD	Contrast	Intraoperative
CS1-4	TIs	TIs	TIs									
C2-8	TIs	TIs	TIs									
CF4-9					TIs			TIs				
L5-13IS					TIs		TIs		TIs			
ER4-9		TIs	TIs			TIs						
EVN4-9		TIs	TIs			TIs						
VE4-8	TIs	TIs	TIs									
3D2-6	TIs	TIs	TIs									
3D4-9		TIs	TIs			TIs						

Ultrasound Transmission Gel

Using an inappropriate ultrasound gel may damage the probe. For proper transmission of the acoustic beam, only use ultrasound transmission gels approved by Samsung Medison.

**WARNING:**

- ▶ Do not use mineral oil, oil-based solutions, or other non-approved materials, as they may cause damage to the probe.
- ▶ Do not use ultrasound gels that contain one or more of the following substances:
 - Acetone
 - Methanol
 - Denatured alcohol
 - Mineral oil
 - Iodine
 - Lanoline
 - All lotions or gels that contain aromatic substances

■ Gel Warmer (Optional)

The Gel Warmer keeps the ultrasound gel warm. Warming up ultrasound gel takes approximately 5 minutes.

**WARNING:**

- ▶ Always turn the Gel Warmer off when it is not in use.
- ▶ Do not put your hands inside the Gel Warmer, as it may burn your skin.

**CAUTION:**

- ▶ Do not use the Gel Warmer for purposes other than to control the temperature of ultrasound gel.
- ▶ Do not place the probe or any other equipment inside the Gel Warmer.
- ▶ Do not touch the power terminal of the Gel Warmer while you are examining a patient. There is a risk of electric shock from leakage current.
- ▶ Do not apply excessive force to the Gel Warmer, or you may damage its support parts.

MODEL : UGEO GEL WARMER
RATE : 12V $\overline{=}$ 0.5 A
MANUFACTURER : JCWell



[Figure 5.1 Gel Warmer label]

Sheaths

Sheaths are recommended for clinical applications of an invasive nature, including intraoperative, transrectal, transvaginal, and biopsy procedures. Using a sheath also prevents contamination from blood or other bodily fluids during operations or biopsy.

Samsung Medison does not supply sheaths, so appropriate sheaths should be purchased independently.

**WARNING:**

- ▶ Always keep sheaths in a sterile state.
- ▶ Sheaths are disposable. Do not reuse them.
- ▶ If sheaths are torn or soiled after use, clean and disinfect the probe.
- ▶ In neurosurgical applications, a disinfected probe must be used with sterile gel and a sterile pyrogen-free sheath.
- ▶ If the sterile sheath becomes compromised during neurosurgical applications involving a patient with Creutzfeldt-Jakob disease, the probe cannot be successfully sterilized by any disinfection method.
- ▶ Some sheaths contain natural rubber latex and talc, which can cause allergic reactions in some individuals. Please refer to the FDA Medical Alert released on March 29, 1991.

❏ Installing the Sheath

1. Remove the sheath from the packaging, and fill it with ultrasound gel. Be sure to put on sterilized surgical gloves.
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 are no air bubbles trapped within the ultrasound gel. If necessary, secure the sheath to the probe and the probe cable.
4. Dispose of the sheath after use.

Probe Safety Precautions

**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.

The probe can easily be damaged by improper use or by coming into contact with 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 the probe for cracks, broken parts, leaks and sharp edges. If there is any damage, stop using the probe immediately and contact the Samsung Medison Customer Support Department. Using damaged probes may result in electric shocks and other hazards to the patients and/or users.

■ Use and Infection Control of the Probe



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 to prevent infection. This is the responsibility of the user who manages and maintains the disinfection procedures for the equipment. Always use legally approved detergents.

The ultrasonographic image scanner uses ultrasound, and 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 surgical procedure.

The most effective method of preventing 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, the safety instructions must be followed carefully in order to minimize the risk of infection among patients.

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:**

- ▶ The product should regularly be checked for electrical leakage by the Samsung Medison Customer Support Department.
- ▶ Do not immerse the probe into liquid.
- ▶ Do not drop the probe or apply mechanical shocks.
- ▶ Inspect the housing, strain relief, lens, and seal for damage, and check for any functional problem before and after each use.
- ▶ Do not apply excessive force to twist, pull or bend the probe cable.
- ▶ The power protection fuse protects the probe and the product from excess current. If the power monitoring protection circuit detects excess current, it immediately shuts off the current to the probe in order to prevent the probe surface from overheating and to restrict the ultrasound power output.
- ▶ The temperature of the product for making contact with patients is limited under 43°C. The ultrasound power output (AP&I) is in compliance with US FDA standards.

Cleaning and Disinfecting the Probe



WARNING:

- ▶ Always use protective eyewear and gloves when cleaning and disinfecting probes.
- ▶ Inspect the housing, strain relief, lens and seal for damage, and check for any functional problem after cleaning and disinfecting the probe.

Using an inappropriate cleaning or sterilizing agent may damage the probe.

Information of Detergent, Disinfectant, and Ultrasound Gel

An appropriate detergent, disinfectant or ultrasound gel should be selected based on the following tables. All probes are tested in accordance with IPX 7 Criteria.

Names	Disinfectants																
	T-Spray II	T-Spray	Sani-Cloth HB	Sani-Cloth Plus	Sani-Cloth Active	Setptiwipes	Cleanisept Wipes	Ster-Bac Blu	Transeptic Spray	Incidin Foam	Super Sani-Cloth	Sani-Cloth Germicidal	Asepti-Wipes	Asepti-Wipes II	CaviWipes	MetriWipes	Cidex 2%
Type	S	S	W	W	W	W	W	L	S	S	W	W	W	W	W	W	L
Active Ingredient	Quaternary Ammonium (N-Alkyl)								IPA								NA
CS1-4								•									•
C2-8		•	•														
CF4-9	◆	◆	◎					▣	▲								▣
L5-13IS		•							•		•						
ER4-9		•	•														•
EVN4-9		•	•														•
VE4-8	◆	◆	◎			▲	▲	▣									▣
3D2-6	•	•	×														
3D4-9		•							•		•						

Names	Disinfectants															
	Cidex OPA ^{2,3)}	Cidex Plus ²⁾	Metricide ²⁾	Omnicide (28)	Omnicide 14NS	Omnicide - FG2	Nuclear	Wavicide-01 ³⁾	Sekusept Extra	Salvanios pH 7	Salvanios pH10	Steranios 2%	Surfaces Hautes	Sekusept Plus	Milton	Bleach 5.25%
Type	L	L	L	L	L	L	L	L	L	L	L	L	S	L	L	L
Active Ingredient	Glutaraldehyde													Nonionic surfactant	Sodium Hypochlorite	
CS1-4	•	•	•					•								
C2-8	•					•	•	•							•	
CF4-9																
L5-13IS	•	•													•	
ER4-9	•	•				•	•								•	
EVN4-9	•	•				•	•								•	
VE4-8	▲		▣					▣								
3D2-6	•	•	•					•								
3D4-9	•	•														

Names	Disinfectants								Cleaner					
	Virkon	Sporox	Sporox II	Gigasept	Gigasept AF ³⁾	Gigasept FF	Hibitane	PeraSafe	Enzol	Alkazyme	Cidezyme	Klenzyme	Isopropyl alcohol(70%)	Isopropyl alcohol(80%)
Type	L	L	L	L	L	L	L	P			L	L	L	L
Active Ingredient	NA	Hydrogen Peroxide		Succindialdehyde, formaldehyde		Bersteinsäure	Chlorhexidine gluconate solution	Peracetic Acid	Dodecylphenoethoxylate, Sodium Xylene Sulfonate	NA	Proteolytic Enzymes		Alcohol	
CS1-4														
C2-8		•											•	
CF4-9					⊙	⊙	⊙	▲						
L5-13IS	•		•											
ER4-9											•	•	•	
EVN4-9											•	•	•	
VE4-8						⊙		▲						
3D2-6			×			•						•		
3D4-9			•											

Names	Cleaner			Gel							
	Ethanol 75%	Metrizyme	McKesson	Natural Image	Aquasonics 100 ³)	GE Ultrasound Contact Gel	Clear Image	Kendall	Scan	Wavelength	Sonogel
Type	L	L	L	G	G	G	G	G	G	G	G
Active Ingredient	Alcohol	Propylene Glycol	PCMX (Chloroxylenol)	Ammonium Chlorides	NA						
CS1-4					•				•		•
C2-8			•		•						
CF4-9					•				•		•
L5-13IS					•						
ER4-9		•	•		•						
EVN4-9		•	•		•						
VE4-8					•	•			•		•
3D2-6		•			•						
3D4-9					•						

Tips!

Symbols Legend

(1)	Compatible, but no EPA Registration
(2)	FDA 510(k) qualified
(3)	Has CE mark
(4)	Discontinued
(5)	Under Development
S	Spray
W	Wipe
L	Liquid
P	Powder
G	Gel
×	Not compatible (DO NOT USE)
•	Compatible
★	Staining may occur on housing parts; however, the acoustic performance and image quality are not affected.
■	Must not be used for longer than 5 minutes.
◐	Must not be used for longer than 10 minutes.
▲	Must not be used for longer than 15 minutes.
◆	Must not be used for longer than 20 minutes.
◇	Must not be used for longer than 25 minutes.
◎	Must not be used for longer than 30 minutes.
▣	Must not be used for longer than 50 minutes.
Blank	Untested (DO NOT USE)

The following is information about the manufacturers (or Distributors) of detergents, disinfectants, and ultrasound gels.

Product	Manufacturer or Distributor	Telephone number
Aquasonics	Parker Co.	+1-800-631-8888 (USA)
Cidex	CIVCO Co.	+1-800-445-6741 (USA) +1-319-656-4447 (Worldwide)
Enzol	CIVCO Co.	+1-800-445-6741 (USA) +1-319-656-4447 (Worldwide)
Gigasept AF	S&M (Schulke & Mayr) Co.	+44-114-254-3500 (UK)
Gigasept FF	S&M (Schulke & Mayr) Co.	+44-114-254-3500 (UK)
Isopropyl 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	Procter & Gamble Australia Pty. Ltd.	+61-1800-028-280 (Australia)
Nuclear	National Diagnostics Co.	+1-800-526-3867 (USA) +44(0)-148-264-6020 (UK)
Omnicide	Cottrell Ltd.	+1-800-843-3343 (USA)
Sani-cloth	PDI/Nice-Pak Products Co.	+1-914-365-1602 (USA)
Sekusept Extra	Henkel Hygiene GmbH.	+49-0211-797-0 (Germany)
Sporox II	Sultan Chemist Inc.	+1-800-637-8582 (USA)
T-Spray	CIVCO Co.	+1-800-445-6741 (USA) +1-319-656-4447 (Worldwide)
Virkon	Antec International LTD.	+1-403-286-1771 (USA)
Wavicide	Wave Energy System Inc.	+1-800-252-1125 (USA)

Cleaning

Cleaning is an important procedure that is carried out before disinfecting the probe.

The probe must be cleaned after each use.

**CAUTION:**

- ▶ Do not use a surgical brush when cleaning probes. Even the use of 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.

1. Disconnect the probe from the system.
2. Remove any biopsy adapters or needle guides. (Adapters may be reused after disinfection.)
3. Remove the sheath. (Sheaths are disposable.)
4. Use a soft cloth, lightly dampened with mild soap or compatible cleaning solution, to remove any particulate matter and bodily fluids 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 cloth to remove soap residue, and wipe with a dry cloth again.

Disinfecting

A 10^{-6} reduction in pathogens should be reached following the disinfection procedures in this manual and using the following Samsung Medison recommended solutions.



WARNING:

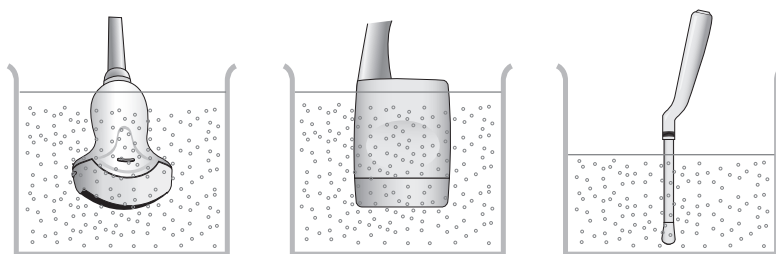
- ▶ If a pre-mixed solution is used, be sure to observe the solution expiration date.
- ▶ The type of tissue it will contact during use dictates the level of disinfection required for a device. Ensure that the solution strength and duration of contact are appropriate for disinfection.



CAUTION:

- ▶ Using a non-recommended disinfectant or not following the recommended disinfection method can damage and/or discolor the probe. This could also void the probe warranty.
- ▶ Do not immerse probes for longer than one hour, unless they are sterilizable.
- ▶ Only use liquid solutions to sterilize probes. Do not sterilize by autoclaving or using EtO gas.

1. Please refer to the user instructions of the disinfectant for details of proper storage, use, and disposal of the disinfectant.
2. Mix the disinfectant compatible with your probe according to the instructions for solution strength provided on its label.
3. Immerse the probe into the disinfectant as shown in the illustration below.
4. Follow the instructions on the disinfectant to complete the immersion procedure of the probe, and rinse the probe afterwards.
5. Air dry the probe or towel it dry with a clean cloth.



[Figure 5.2 Disinfection]

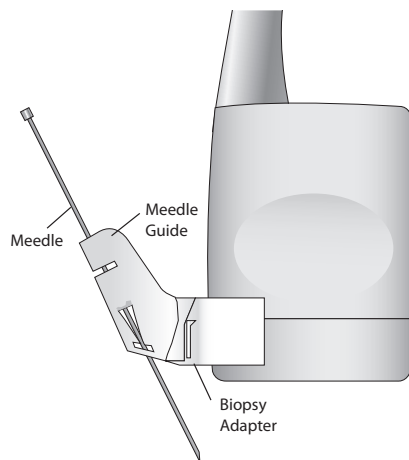
:: Biopsy

A biopsy is an examination method that surgically extracts tissue from the patient for examination. The probe and the biopsy kit are used together when conducting a biopsy with the ultrasonographic image scanner.

The ultrasound system shows the needle, which penetrates through the skin surface and veins, along with the examination location, minimizing the risk to the patient.

Biopsy Kit Components

The biopsy kit consists of the adapter, needle guide and needle. The components vary depending on the probe type. The components and accessories can be purchased from Samsung Medison.



[Figure 5.3 Biopsy Kit Components]

- ▶ Adapter: Secures the needle guide to the probe tightly.
- ▶ Needle Guide: Guides the angle (direction) of the needle so that it can reach the examination location accurately. It also secures the needle so that the needle is not loose.
- ▶ Needle: This is the needle that is inserted into the patient's body.
- ▶ Sheath: Prevents the probe and adapter from getting soiled by any unwanted substances during the examination (blood and other bodily fluids).
- ▶ Ultrasound Gel: The space between the probe and the sheath is filled with the ultrasound gel to obtain images of the best quality.

Using the Biopsy Kit



WARNING:

- ▶ Verify the condition of the biopsy needle before use. Do not use a bent biopsy needle.
- ▶ The biopsy needle may bend during tissue penetration. The precise location of the needle must be checked by monitoring the echo generated from the needle.
- ▶ Never use the biopsy kit to biopsy prostate tissue.

❑ Before Using Biopsy Kit



WARNING:

- ▶ Do not attempt to use the biopsy kit until you have read the instructions for installing the sheath and verifying alignment of the needle guide.
- ▶ Always ensure that the probe and the needle guide are secured on both the left and the right.
- ▶ Do not use in IVF, CVS, or PUBS procedures.

Ultrasonographic scanning using the biopsy kit must be conducted by medical doctors or experienced medical staff with appropriate qualifications. Always, without fail, verify all safety procedures and disinfection.

Biopsy kits not supplied by Samsung Medison may fail to fit the probe properly. Always use biopsy kits supplied by Samsung Medison, since improper setup may adversely affect the patient.

Inspect all components. Ensure that the biopsy kit you are using is the correct one for the probe, the system, and system software.

❑ Biopsy Procedure

The system generates a needle guideline through the displayed real-time ultrasound images to indicate the anticipated path of the needle. You can use this guideline to ensure that the needle or instrument is following the correct path.

1. Ready the patient according to the procedure appropriate for the examination objectives.
2. Install the sheath and the biopsy kit.
3. Set the system controls for the biopsy procedure. If necessary, apply acoustic gel to the patient.
4. Scan the patient. Adjust the patient so that the location for examination fits into the needle guideline on the screen.

5. Insert the needle into the needle guide for use. Perform the puncture by sliding the needle through the groove in the guide until the needle intercepts the target. To keep the needle securely in the needle guide, press down on the top of the biopsy adapter with your index finger.
6. When the examination location is reached, take the needle out of the needle guide.
7. Detach the needle guide, adapter and sheath from the probe.
8. Discard all disposable items following use.

Needle Guide Alignment



WARNING:

- ▶ The needle used for this alignment verification must not be used for the actual procedure. Always use a new, sterile needle for each biopsy procedure.
- ▶ To assist in accurate projection of the needle, use a straight, new needle for each alignment procedure.

Alignment of the needle guide displayed on the system is for the purpose of verifying whether the needle and the needle guide are properly installed. This must be done prior to the biopsy examination. If the needle fails to follow the accurate path while verifying the alignment of needle guide, stop using the product and contact Samsung Medison Customer Support Department.

Reverberation or other tissue artifacts may produce false needle images, which can cause confusion. Ensure the needle path is along the guideline, and that you are not using a false needle image to locate the needle.

1. Attach the biopsy kit.
2. Set the system depth for the procedure to be performed and select the Biopsy menu.
3. Immerse the probe into the water bath, and insert the needle into the needle guide.
4. Confirm that the needle image is on the needle guidelines. If it is, then the needle guide is properly aligned.
5. If the needle image is out of the needle guideline, check the needle guide or the probe adapter.

Cleaning and Disinfecting the Biopsy Kit



WARNING: Always use protective eyewear and gloves when cleaning and disinfecting biopsy kit.

Wash and disinfect the biopsy kit to reduce pathogens to the level of 10⁻⁶. Some components of the biopsy kit may be disposable. Please read the biopsy kit user manual carefully before use.

❑ Cleaning and Disinfection of Stainless Steel Biopsy Kit

■ Cleaning

1. After use, remove the biopsy kit from the probe.
2. Disassemble the biopsy kit into its component parts, if applicable.
3. Using a small brush and water, scrub each part to remove trapped material from the biopsy kit.
4. Rinse with water to remove remaining particulates.

■ Disinfection

1. Disinfect the adapter by autoclaving (Steam) or using gas (Ethylene Oxide).
2. After disinfection, follow the proper post-disinfection procedure for the disinfection method used (refer to the instructions for the disinfecting equipment).
3. Inspect the components for damage such as cracks, rust or breakage. If damage is discovered, contact the Samsung Medison Customer Support Department.

■ Cleaning and Disinfecting a plastic biopsy kit

■ Cleaning

1. After use, remove the biopsy kit from the probe.
2. Disassemble the biopsy kit into its component parts, if applicable. Discard the single-use parts. These parts cannot be disinfected.
3. Using a small brush and water, scrub each part to remove trapped material from the reusable components.
4. Rinse with water to remove remaining particulates.

■ Disinfection



CAUTION: Plastic biopsy kits can only be disinfected by using a chemically compatible cold-disinfectant. Disinfection by autoclaving, or by using gas or radiation, will cause damage to these parts.

Please refer to the user instructions of the disinfectant for details of proper storage, use, and disposal of the disinfectant.

1. Check the disinfection duration (generally 10 hours) and temperature of the disinfectant.
2. After disinfection, follow the proper post-disinfection procedure for the disinfection method used.
3. Inspect the components for damage such as cracks, rust or breakage. If damage is discovered, contact the Samsung Medison Customer Support Department.

Assembling the Biopsy Kit

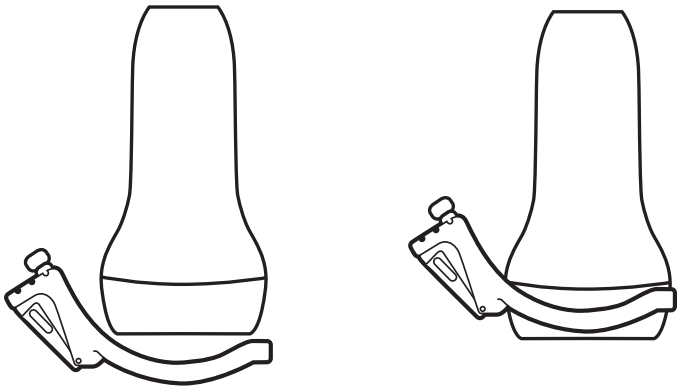
CS1-4 Biopsy Guide

Biopsy Specifications

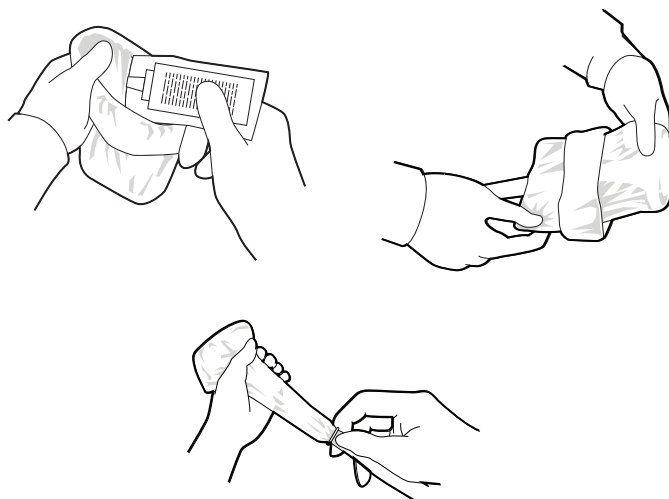
Model name	BP-KIT-051		
Component	Biopsy Bracket	1 EA	
	Needle Guide	5 EA	
Material	Acetal Copolymer		
Available Gauges	8.5F, 14G, 15G, 16G, 17G, 18G, 20G, 21G, 22G, 23G		

Installation

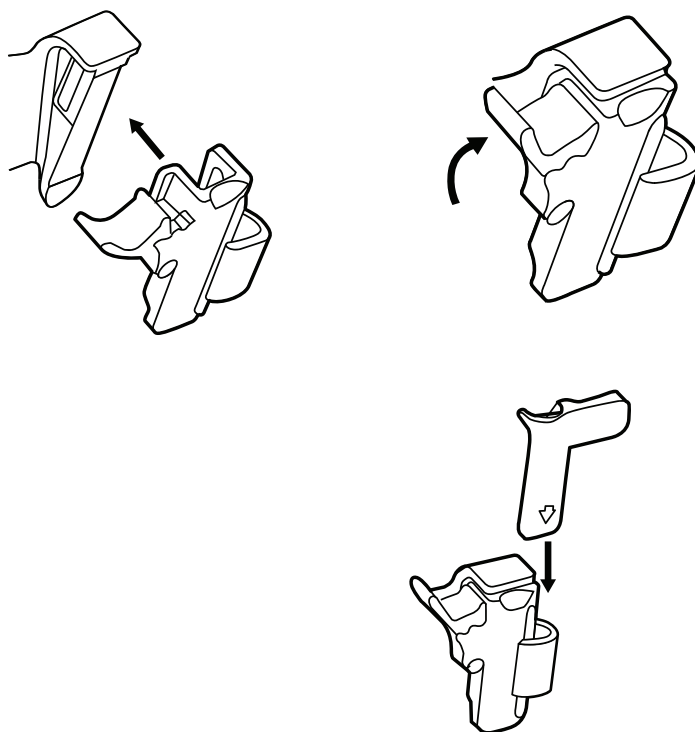
- 1. Mount the adapter onto the probe.



2. Fill the sheath with the ultrasound gel and place the sheath over the probe, all the way down to the Adapter.



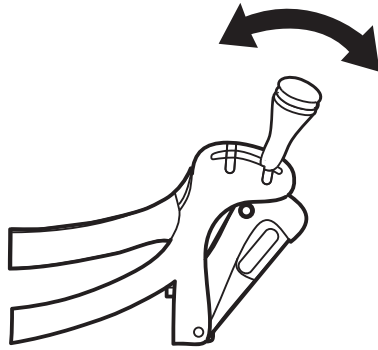
3. Mount the needle guide for the desired gauge onto the adapter.



4. Install the needle into the needle guide for use.

Tips!**Using Multi Angle**

Use the angle adjuster.



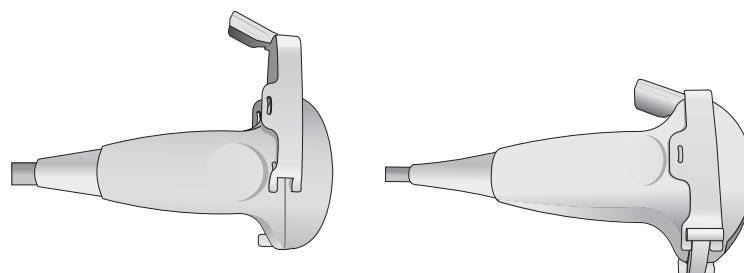
C2-8 Biopsy Guide

■ Biopsy Specifications

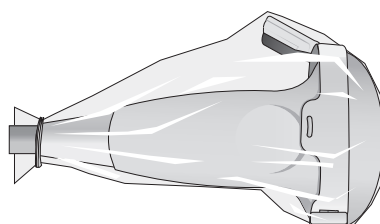
Model name	BP-KIT-035	
Component	Biopsy Bracket Needle Guide	1 EA 24 EA
Material	Acetal Copolymer	
Available Gauges	16G, 18G, 22G	

■ Installation

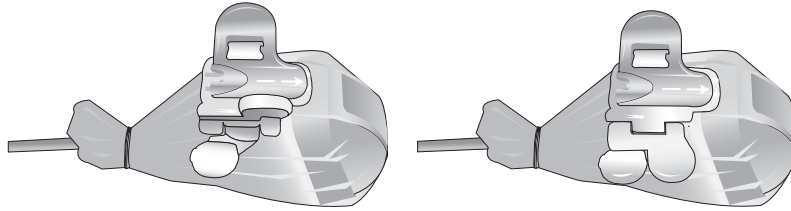
1. Mount the adapter onto the probe.



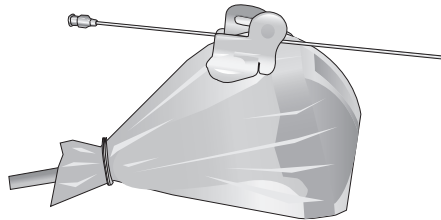
2. Fill the sheath with the ultrasound gel and place the sheath all the way down to the Adapter.



3. Mount the needle guide for the desired gauge onto the adapter.



4. Install the needle into the needle guide for use.



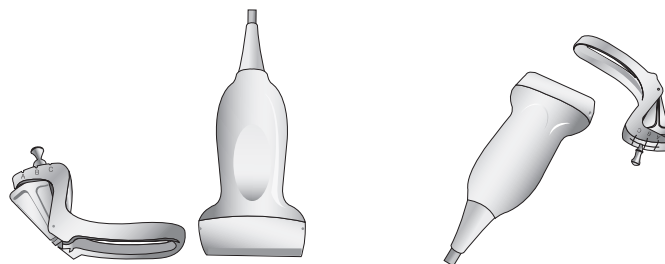
■ L5-13 Biopsy Guide

■ Biopsy Specifications

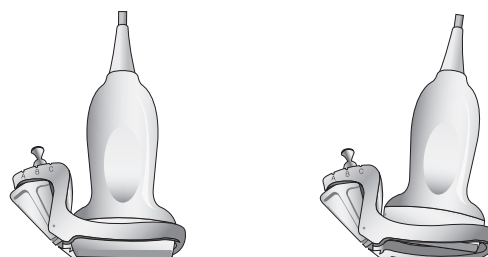
Model name	BP-KIT-012	
Component	Biopsy Adapter	1 EA
	Needle Guide	24 EA
	Clip	2 EA
Available Gauges	14G, 15G, 16G, 17G, 18G, 19G, 20G, 21G, 22G, 23G	

■ Installation

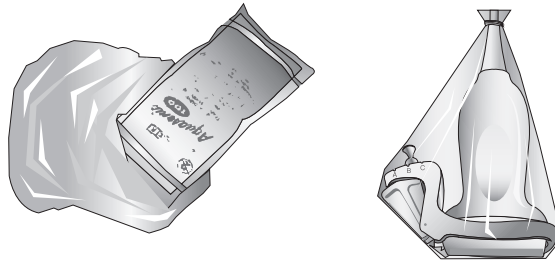
1. Mount the biopsy adapter onto the probe as shown below.



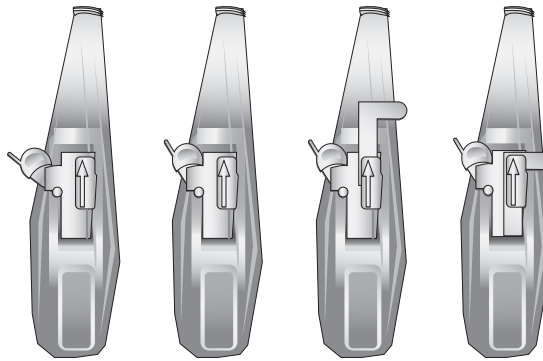
2. Select the angle for installing the needle guide.



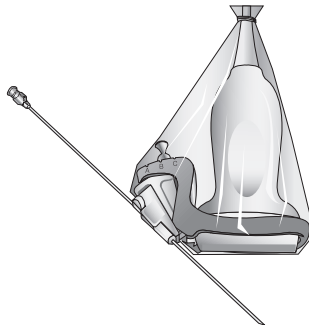
3. Place the probe cover all the way down to the adapter.



4. Install the Needle Guide and Clip.



5. Install the needle into the needle guide for use.



ER4-9, EVN4-9 Biopsy Guide



NOTE:

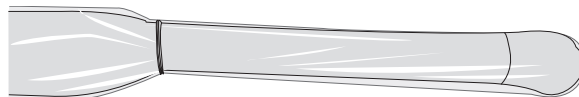
- ▶ When using e-Motion Marker, which is an optional feature for this product, the main body of e-Motion Marker must be completely covered by the sheath.
- ▶ For more information, refer to 'Chapter 9. Image Management', or the installation guide for e-Motion Marker.

Biopsy Specifications

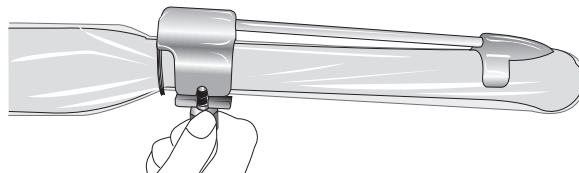
Model name	BP-KIT-024	
Component	Biopsy Adapter Sheath	1 EA 2 EA
Material	Stainless	
Available Gauges	16G	

Installation

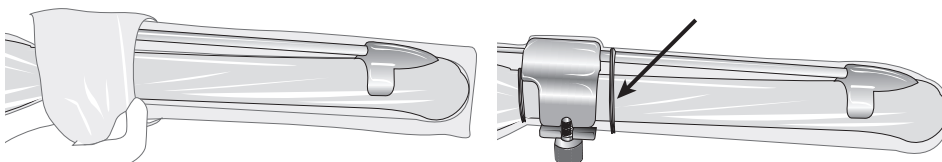
1. Fill the sheath with the ultrasound gel and place the sheath all the way down to the adapter. And then tie with a rubber band.



2. Mount the adapter onto the probe



3. Place the sheath again and tie with the rubber band again. Tie the lower part than 1.



4. Install the needle into the needle guide for use.

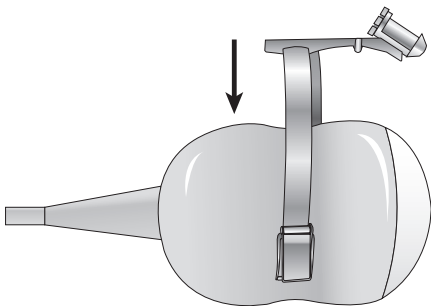
VE4-8 Biopsy Guide

■ Biopsy Specifications

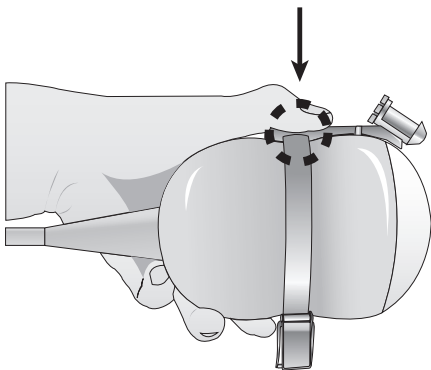
Model name	BP-KIT-028	
Component	Biopsy Adapter	1 EA
Material	Stainless	
Available Gauges	14G, 18G, 21G	

■ Installation

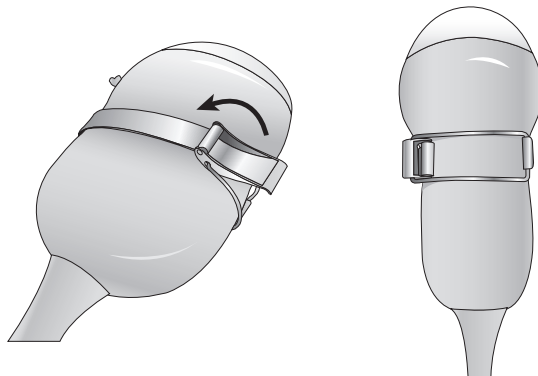
1. Place the biopsy adapter onto the probe and insert the bracket into the groove on the surface of the probe.



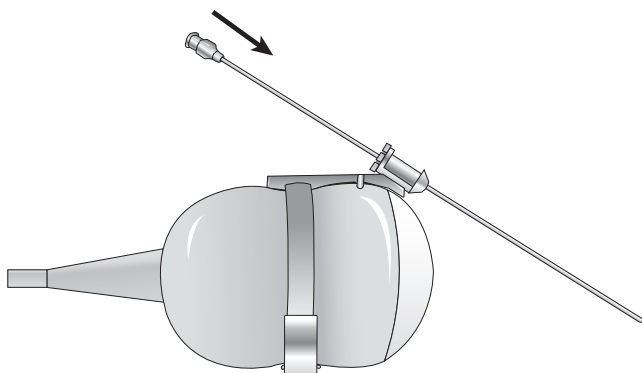
2. Push it forward until the bracket is firmly secured onto the probe.



3. Fix the adapter by locking the clip with the level on the opposite side of needle guide.



4. Install the needle into the needle guide for use.



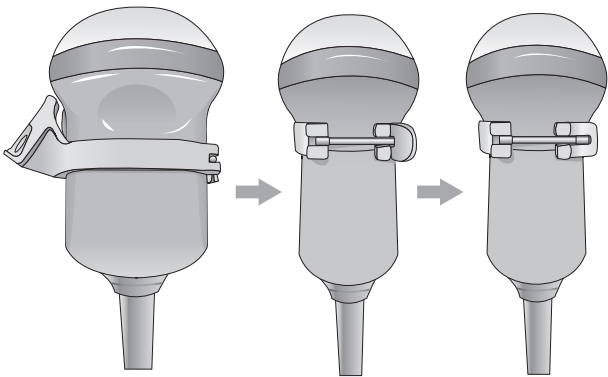
❑ 3D2-6 Biopsy Guide

■ Biopsy Specifications

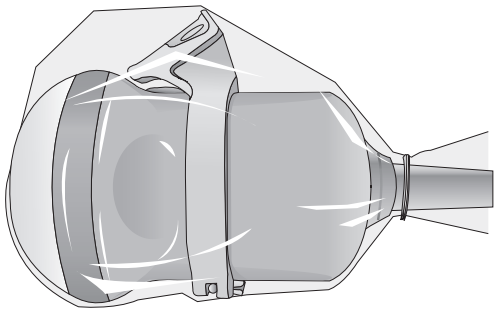
Model name	BP-KIT-033	
Component	Biopsy Adapter Needle Guide	1 EA 1 EA
Material	Ticona-Acetal	
Available Gauges	14G ~ 23G (Except 19G)	

■ Installation

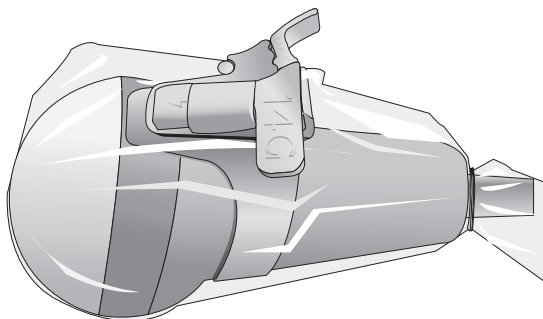
1. Place the biopsy adapter onto the probe.



2. Fill the sheath with ultrasound gel and insert the probe.



3. Mount the needle guide on the adapter.



4. Install the needle into the needle guide for use.

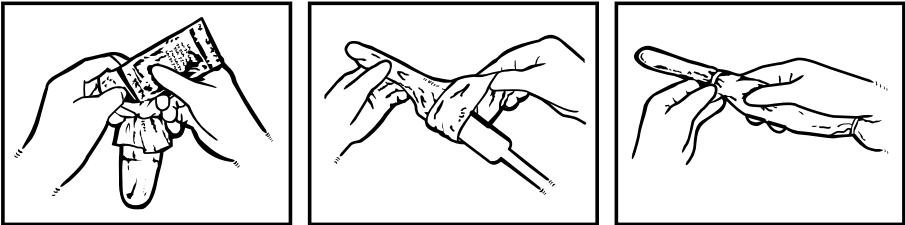
3D4-9 Biopsy Guide

■ Biopsy Specifications

Model name	BP-KIT-027	
Component	Adapter	1 EA
Material	Stainless	
Available Gauges	16~22G	

■ Installation

1. Fill the sheath with ultrasound gel and insert the probe.



2. Mount the adapter on the probe, and then insert the needle.

