

**SAMSUNG**

SAMSUNG MEDISON  
DIAGNOSTIC ULTRASOUND SYSTEM

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# HS50/HS60 User 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.

Subject to the applicable laws of the relevant territory, Samsung Medison reserves the right to accommodate service requests by

- (1) replacing the product presented for repair with a refurbished product of the same model or
- (2) repairing the product with refurbished parts.

The refurbished products and parts shall be subject to the same inspection, quality control procedures as for new products and parts.

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

## SAMSUNG

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SAMSUNG MEDISON  
DIAGNOSTIC ULTRASOUND SYSTEM

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Version 1.00

# HS50/HS60

## User Manual

English



## **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 systems contain Samsung Medison 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 or CF Applied Part
- ▶ 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/A1:2012**]
- ▶ 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 60601-1-6:2010**]
- ▶ 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 1-1: General Requirements for Safety - Collateral Standard: Safety Requirement for Medical Electrical Systems [**IEC 60601-1-1:2000**]
- ▶ Medical Electrical Equipment, Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Test [**IEC 60601-1-2:2001, A1:2004**]
- ▶ Medical Electrical Equipment, Part 1-4: General Requirements for Safety - Collateral Standard: Programmable Electrical Medical Systems [**IEC 60601-1-4:1996, A1:1999**]

- ▶ Medical Electrical Equipment, Part 2-37: Particular Requirements for Safety - Ultrasonic Medical Diagnostic and Monitoring Equipment [**IEC 60601-2-37:2001 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 [**UL 60601-1:2003**]
- ▶ Medical Electrical Equipment, Part 1: General Requirements for Basic Safety and Essential Performance [**CAN/CSA-C22.2 No. 60601-1:14**]
- ▶ Medical Electrical Equipment, Part 1: General Requirements for Basic Safety and Essential Performance [**ANSI/AAMI ES60601-1:2005/(R)2012, AND C1:2009 AND A2:2010(R)2012**]
- ▶ Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing within a risk management process [**ISO 10993-1:2009**]
- ▶ Standard Means for the Reporting of the Acoustic Output of Medical Diagnostic Ultrasonic Equipment [**IEC 61157:2007**]

## ■ Declarations



Nemko-CCL mark with the indicators “C” and “US” means that the product is certified for both the U.S. and Canadian markets, to the applicable U.S. and Canadian standards.



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 for Korean Good Manufacturing Practice quality system regulation.

## ⚠️ Precautions for Use

You should be familiar with all of these areas before attempting to use this manual or your ultrasound system.

- ▶ Please keep this user guide close to the product as a reference when using the system.
- ▶ For safe use of this product, you should read 'Chapter 1. Safety' and 'Chapter 4. Maintenance' in this manual, prior to starting to use this system.
- ▶ This manual does not include diagnosis results or opinions. Also, check the measurement reference for each application's result measurement before making the final diagnosis.
- ▶ This product is an ultrasound scanner and cannot be used from a user's PC. We are not responsible for errors that occur when the system software is run on a user's PC.
- ▶ Only medical doctors or persons supervised by medical doctors should use this system. Persons who are not qualified must not operate this product.
- ▶ The manufacturer is not responsible for any damage to this product caused by carelessness and/or neglect by the user.
- ▶ Please note that orders are based on the individually agreed specifications and may not contain all features listed in the user manual.
- ▶ It might be possible that some features, options or probes are NOT available in some countries.
- ▶ All references to standards / regulations and their revisions are valid for the time of publication of the user manual.
- ▶ The figures in the user manual for illustrational purposes only and may be different from what you see on the screen or device.
- ▶ Information contained in this user manual is subject to change without prior notice.
- ▶ Products that are not manufactured by Samsung Medison are marked with the trademark of their respective copyright holders.
- ▶ The headings below describe vitally important precautions necessary to prevent hazards.



**DANGER:** Describes precautions necessary to prevent user hazards of great urgency. Ignoring a DANGER warning will risk life-threatening injury.



**WARNING:** Used to indicate the presence of a hazard that can cause serious personal injury, or substantial property damage.



**CAUTION:** Indicates the presence of a hazard that can cause equipment damage.



**NOTE:** A piece of information useful for installing, operating and maintaining a system. Not related to any hazard.

## Revision History

The revision history of this manual is as follows.

VERSION	DATE	NOTE
v1.00.06-00	2017.04.14	Initial Release

### Product Upgrade and Manual Update

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

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

### If You Need Assistance

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



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### \*\*Reference Manual

Samsung Medison is providing an additional HS50/HS60 Reference Manual (English version).



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## :: Purpose of Use

Ultrasound diagnostic system and probes were designed for obtaining ultrasound images and analyzing human blood.

The clinical applications include: Fetal/Obstetrics, Abdominal, Gynecology, Pediatric, Small Organ, Neonatal Cephalic, Adult Cephalic, Trans-rectal, Trans-vaginal, Muscular-Skeletal (Conventional, Superficial), Urology, Cardiac Adult, Cardiac Pediatric and Peripheral vessel.



**NOTE:** For detailed information on applications and presets, please refer to 'Chapter 2. Introduction' and 'Chapter 5. Probes' in this user manual.

## Contraindications

This product must not be used for ophthalmological applications, or any other use that involves the ultrasound beam passing 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.



### 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
	WARNING: The accompanying information must be followed to prevent serious accidents and/or damage to property.		Data Input/Output port
	CAUTION: The accompanying information helps to prevent minor accidents and/or damage to property.		Input port
	Refer to the user manual.		Output port
	Follow the user manual.		Print remote output
	CAUTION: Risk of electric shock		Foot Switch Port
	Type BF applied part (Classification based on degree of protection against electric hazard)		ECG port
	Defibrillation-proof type CF applied part (Classification based on degree of protection against electric hazard)		USB port
	Power On/Off		Network port

Symbols	Description	Symbols	Description
	Power On	IPX 1	Protected against vertically falling water drops
	Power Off	IPX 7	Protected against the effects of temporary immersion in water
	Power On for part of the product	IPX 8	Protected against the effects of continuous immersion in water
	Power Off for part of the product		CAUTION: Electrostatic sensitive devices (ESD)
	Alternating current voltage source		Do not sit on the product.
	Direct current voltage source		Do not push the product.
	Dangerous voltage (Indicates dangerous voltages over 1000V AC or 1500V DC)		Do not lean against the product.
	Protective earth (ground)		Be mindful of the space. Do not place a finger, and or any part of your body in the space.
	Equipotentiality		DANGER: Do not place your fingers, hands, or any other part of your body in this space.
	Data output port	 kg	Do not place objects on the monitor that are heavier than the weight specified by the symbol.
	Data input port		Do not place heavy objects on the monitor while the monitor mount is folded.
	Microphone Port		Do not push down on the monitor while the monitor mount is folded.
	Probe port		

## Symbols

Symbols	Description	Symbols	Description
	Authorized Representative In The European Community		Manufacturer

## Labels

Phrases containing the words 'warning' and/or 'caution' are displayed on the product's surface in order to protect it.



## ⚡ Electrical Safety

This equipment is categorized as a Class I device with Type BF or Type CF (ECG) applied parts.

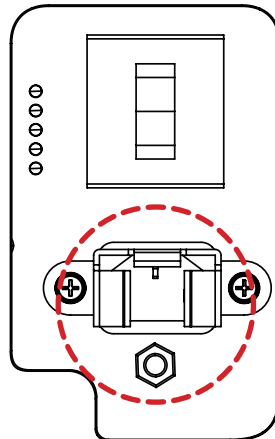


### CAUTION:

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

## Prevention of Electric Shocks

In a hospital environment, hazardous current can form due to potential differences between exposed conductive parts and connected devices. The solution to the problem is consistent equipotential bonding. Medical equipment is connected with connecting leads made up of sockets which are angled to the equipotential bonding network in medical rooms.



[Figure 1.1 Equipotential Bonding]

Additional equipment connected to medical electrical equipment must comply with the respective IEC standards (e.g. IEC 60950/EN 60950 for data processing equipment, IEC 60601-1/EN 60601-1 for medical devices). Furthermore, all configurations shall comply with the requirements for medical electrical systems (see IEC 60601-1-1/EN 60601-1-1). Anybody connecting additional equipment to signal input and output ports of medical electrical equipment should make sure that the equipment complies with IEC 60601-1-1/EN 60601-1-1.

**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 (N<sub>2</sub>O) 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 together with HF surgical equipment. HF surgical equipment may be damaged, which may result in fire.
- ▶ 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.
- ▶ Make sure that the inside of the system is not exposed to or flooded with liquids. In such cases, fire, electric shock, injury, or damage to the product may occur.
- ▶ 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.

## ECG-Related Information

**WARNING:**

- ▶ This device is not intended to provide a primary ECG monitoring function, and therefore does not have means of indicating an inoperative electrocardiograph.
- ▶ Do not use ECG electrodes with HF surgical equipment. HF surgical equipment may be damaged, which may result in fire.
- ▶ Do not use ECG electrodes during cardiac pacemaker procedures or any procedures that involve other types of electrical stimulators.
- ▶ Do not use ECG leads and electrodes in an operating room.

## ESD

Electrostatic discharge (ESD), commonly referred to as a static shock, is a naturally occurring phenomenon. ESD is most prevalent during conditions of low humidity, which can be caused by heating or air conditioning. 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

Testing of the EMC (Electromagnetic Compatibility) of this system has been performed according to the international standard for EMC with medical devices (IEC 60601-1-2). This IEC standard was adopted in Europe as the European norm (EN 60601-1-2).

### 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 A	The Ultrasound System is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emission IEC 61000-3-2	Class A	
Flicker Emission IEC 61000-3-3	Complies	

## Approved Cables, Probes and Peripherals for EMC

### Cables

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	2.99m
Audio R.L	Shielded	Normal
Parallel	Shielded	Normal
HDMI	Shielded	Normal
MIC	Unshielded	Any
ECG 3-lead	Shielded	Normal

### Probes

The image probe used with this product may affect its emission. The probe listed in 'Chapter 5. Probes' when used with this product, have been tested to comply with the group1 Class A emission as required by International Standard CISPR 11.

### Peripherals

Peripherals used with this product may affect its emissions.




**CAUTION:** When connecting other customer-supplied accessories to the system, it is the user's responsibility to ensure the electromagnetic compatibility of the system.



**WARNING:** The use of cables, probes, and peripherals other than those specified may result in increased emission or decreased Immunity of the Ultrasound System.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic discharge (ESD)  IEC 61000-4-2	±6KV Contact  ±8KV Air	±6KV Contact  ±8KV Air	Floors should be wood, concrete or ceramic tile.  If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst  IEC 61000-4-4	±2KV for power supply lines ±1KV for input/output lines	±2KV for power supply lines ±1KV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge  IEC 61000-4-5	±1KV differential mode  ±2KV common mode	±1KV differential mode  ±2KV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines  IEC 61000-4-11	<5% $U_T$ 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.
<b>NOTE:</b> $U_T$ is the AC 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	3V	<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><b>Recommended Separation Distance</b></p> $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P} \quad 80\text{MHz to } 800\text{MHz}$ $d = 2.3\sqrt{P} \quad 800\text{MHz to } 2.5\text{GHz}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	<p>Where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,<sup>a</sup> should be less than the compliance level in each frequency range.<sup>b</sup></p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p><b>NOTE 1:</b> At 80MHz and 800MHz, the higher frequency range applies.</p> <p><b>NOTE 2:</b> These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
<p><sup>a</sup> 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><sup>b</sup> Over the frequency range 150kHz to 80MHz, field strengths should be less than 3V/m.</p>			



## ❑ Recommended Distance Between Wireless Communication Device and this Product

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 $d = 1.2\sqrt{P}$	80MHz to 800MHz $d = 1.2\sqrt{P}$	800MHz to 2.5GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance  $d$  in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where  $p$  is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

**NOTE 1:** At 80MHz and 800MHz, the separation distance for the higher frequency range applies.

**NOTE 2:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

## ❑ Electromagnetic Environment – Guidance

It is recommended to use ultrasound systems in shielded locations offering RF shielding effectiveness, with shielded cables. 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 <sup>1</sup>	RF <sup>2</sup>	Power Line <sup>3</sup>
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.
<ol style="list-style-type: none"> <li>ESD caused by discharging of electric charge build-up on insulated surfaces or persons.</li> <li>RF energy from RF transmitting equipment such as portable phones, hand-held radios, wireless devices, commercial radio and TV, and so on.</li> <li>Conducted interference on powerlines or connected cables caused by other equipment, such as switching power supplies, electrical controls, and natural phenomena such as lightning.</li> </ol>			

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:** Special caution should be taken during movement. 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

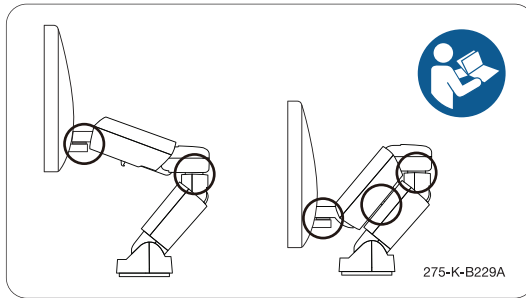
**CAUTION:**

- ▶ 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 service life 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 1.2 Safety Note for Monitor]

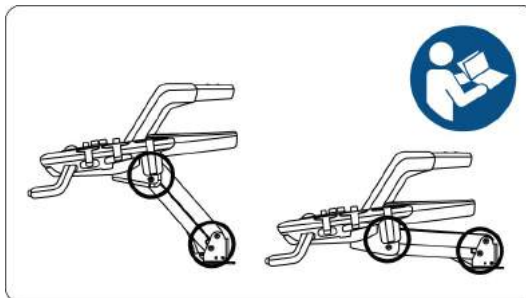
### Caution for Using Control Panel



**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 1.3 Safety Note for Control Panel]

# :: Biological Safety

For safety instructions concerning probes and biopsies, refer to “Chapter 5. Probes”.

**WARNING:**

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

## ALARA Principle

Guidance for the use of diagnostic ultrasound is defined by the “**As Low As Reasonably Achievable**” (ALARA) principle. The decision as to what is reasonable has been left to the judgment and insight of qualified personnel. No set of rules can be formulated that would be sufficiently complete to dictate the correct response to 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.

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 its applications, have resulted in the need for increased and improved information to guide the user. The output indices are designed to provide that important information.

There are a number of variables, which affect the way in which the output display indices can be used to implement the ALARA principle. These variables include mass, body size, location of the bone relative to the focal point, attenuation in the body, and ultrasound exposure time. Exposure time is an especially useful variable, because the user controls it. The ability to limit the index values over time 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, concentrate the 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 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 biological effect is actually occurring, it 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 and can be divided into three categories: direct, indirect, and receiver control.

## ■ Direct Controls

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

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

## ■ Indirect Controls

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



The choice of imaging mode determines the nature of the ultrasound beam. 2D mode is a scanning mode, Doppler is a stationary or unscanned mode. A stationary ultrasound beam concentrates energy on a single location. A moving or scanned ultrasound beam disperses the energy over a wide area and the beam is only concentrated on a given area for a fraction of the time necessary in unscanned mode.

The 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 of 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 intensity to scan at an increased 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 (TIs), bone (Tlb) and cranial bone (Tlc). One of these three thermal indices will be displayed at all times. The thermal index to be displayed is determined by the system preset or user choice, depending upon the application.

The mechanical index is continuously displayed over the range of 0.0 to 1.9, in increments of 0.1. The thermal index consists of the three indices, and only one of these is displayed all the time. Each diagnostic probe application has a default selection. The Tlb or TIs is continuously displayed over its 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 applied automatically by the ultrasound system when the power is turned on, new patient data is entered into the system database, or a change of application takes place.

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

Appropriate index for the application: TIs is used for imaging soft tissue, and Tlb 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, may cause the potential for local zone heating to be lower than the thermal index indicates.

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

Always limit ultrasound exposure time. Do not rush the 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 biological effects 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 bioeffect 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 of potential temperature increase occurring on 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 (Tib) 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 month old fetus. The cranial bone thermal index (Tic) informs the user about the potential heating of bone at or near the surface, for example, the cranial bone. The soft tissue thermal index (Tis) informs the user about the potential for heating within soft homogeneous tissue. Tic is displayed when you select a trans-cranial application.

You can select the TI to display at Setup > Imaging > Application/Preset > Thermal Index Type.

## ■ 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 manual's Acoustic Output Tables. These accuracy estimates are based on the variability ranges of probes and systems, inherent acoustic output modeling errors, and the 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 derated 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.

A 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 are also a contributor to variability. There are inherent uncertainties in the algorithms used for estimating acoustic output values over the range of possible system operating conditions and pulse voltages. Inaccuracies in laboratory measurements are related to differences in hydrophone calibration and performance, positioning, alignment and digitization tolerances, and variability among test operators.

The conservative assumptions of the output estimation algorithms of linear propagation, at all depths, through a 0.3dB/cm-MHz attenuated medium are not taken into account in the 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 the 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 – Controls 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 total TI is the sum of TIs of the individual modes. Each mode is a vital 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 the resolution. This action may change the 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 automatically changing the frame rate or focal depth. Lower frame rates decrease the TI. The MI displayed will correspond to the focal zone with the largest peak intensity.

### ■ Focus

In general, 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. More time is required for the scanning of 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 the 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 the 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 an ancillary element. 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.

## ❑ Doppler, CW, M Mode, and Color Imaging Controls

When a new imaging mode is selected, both the TI and the MI will change to their 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 derated intensity. If a mode is turned off and then reselected, the system will return to the previously selected settings.

### ■ Probe

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

### ■ Depth

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

### ■ Application

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

## Related Guidance Documents

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

- ▶ Medical Ultrasound Safety (AIUM, 2014).
- ▶ 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 (Bioeffect Considerations for the Safety of Diagnostic Ultrasound, *J Ultrasound Med.*, Sept. 1988: Vol.7, No.9 Supplement), sometimes referred to as the Stowe Report, which reviewed available data on possible effects of ultrasound exposure. Another report, "Bioeffects and Safety of Diagnostic Ultrasound", dated January 28, 1993, provides more up to date information.

In addition, periodically updated reports on biological effects, results, and guidelines on safe usage have been published by groups such as the 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*, Derated, 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:

$$In\ Situ = Water [e^{-(0.23\ a\ l\ f^2)}]$$

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 is commonly reported using this formula:

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

Since this value is not the true *In situ* intensity, the term “derated” is used.

The maximum derated and maximum water values do not always occur under the same operating conditions. Therefore, the reported maximum water and derated values may not be related to the *In Situ* (derated) formula. For example, a multi-zone array transducer has the greatest water value intensities at its deepest zone. The same transducer may have its largest derated intensity at 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 <sup>2</sup> )
$d_{eq}$ 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 <sup>2</sup> )
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)
$I_{pa,\alpha}$ at max. MI	The average attenuated pulse strength at the location where Mechanical Index (MI) is maximal (unit: W/cm <sup>2</sup> )
$I_{ta,\alpha}(z)$	Attenuated average strength over time at a specific focal length ( $z$ ) (unit: mW/cm <sup>2</sup> )

MI	MECHANICAL INDEX, a variable representing potential cavitations within the human body (unit: N/A)
P	OUTPUT POWER, the average power over time of an ultrasonic transducer's emissions into a free field through a specified medium 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)
prr	PULSE REPETITION RATE, the inverse number of the time interval between two contiguous acoustic pulses (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 (in the 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. the 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)
$z_{at\_max\_I_{pi,\alpha}}$	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 the 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 $1\text{ cm}^2$ 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
$I_{pi,ra}$ (attenuated pulse intensity integral)	3.2%	+21% to -24%
P (acoustic power)	6.2%	±19%
$P_{ra}$ (attenuated rarefaction pressure)	5.4%	±15%
$f_{awf}$ (acoustic working frequency)	< 1%	±4.5%

### Systematic Uncertainties

For the pulse intensity integral, derated rarefaction pressure  $P_r$ , center frequency, and pulse duration, the analysis includes considerations of the effects on accuracy of:

Hydrophone calibration drift or errors.

Hydrophone/Amp frequency response.

Spatial averaging.

Alignment errors.

Voltage measurement accuracy, including.

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

The acoustic power is measured using a Radiation Force for systematic uncertainties through the use of calibrated NIST acoustic power sources.

We also refer to a September 1993 analysis conducted by the 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

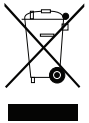
The users of this ultrasound system must familiarize themselves with the ultrasound system to optimize the performance of the device and to detect possible malfunctions. It is recommended that all users receive proper training before using the device. You can receive training on the use of the product from the Samsung Medison service 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 service lives, 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 service engineer or an authorized dealer.

### EU WEEE Directive

**Correct Disposal of This Product  
(Waste Electrical & Electronic Equipment)**

This marking on the product, accessories or literature indicates that the product and its electronic accessories (e.g. charger, headset, USB cable) should not be disposed of with other household waste at the end of their working life. To prevent possible harm to the environment or human health from uncontrolled waste disposal, please separate these items from other types of waste and recycle them responsibly to promote the sustainable reuse of material resources.

Household users should contact either the retailer where they purchased this product, or their local government office, for details of where and how they can take these items for environmentally safe recycling.

Business users should contact their supplier and check the terms and conditions of the purchase contract. This product and its electronic accessories should not be mixed with other commercial wastes for disposal.

## EU REACH Regulation

For information on Samsung's environmental commitments and product specific regulatory obligations e.g. REACH visit:

[Samsung.com/uk/aboutsamsung/samsungelectronics/corporatecitizenship/data\\_corner.html](https://samsung.com/uk/aboutsamsung/samsungelectronics/corporatecitizenship/data_corner.html)

## State of California Proposition 65 Warning (US Only)



**WARNING:** This product contains chemicals known to the State of California to cause cancer, birth defects or other reproductive harm.







# Introduction

- ▣ ***Product Specifications***..... 2-3
  
- ▣ ***Product Configuration*** ..... 2-7
  - Monitor .....2-9
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  - Console .....2-18
  - Peripheral Devices .....2-21
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## :: Product Specifications

<b>Physical Dimensions</b>	Height: 1,344mm (with Monitor) Width: 529mm Depth: 767mm (with Keyboard) Weight: 79.8kg (without accessories) Weight: Approx. 98kg (with Safe Working Load)
<b>Imaging Modes</b>	2D Mode M Mode Color M Mode Anatomical Mode Color Doppler Mode Pulsed Wave (PW) Spectral Doppler Mode Continuous Wave (CW) Doppler Mode Tissue Doppler Imaging (TDI) Mode Tissue Doppler Wave (TDW) Mode Power Doppler (PD) Mode ElastoScan Mode 3D/4D/XI STIC imaging Mode Dual Mode Quad Mode Combined Mode Simultaneous Mode Zoom Mode
<b>Gray Scale</b>	256 (8 bits)
<b>Focusing</b>	Transmit focusing, maximum of eight points (four points simultaneously selectable) Digital dynamic receive focusing (continuous)

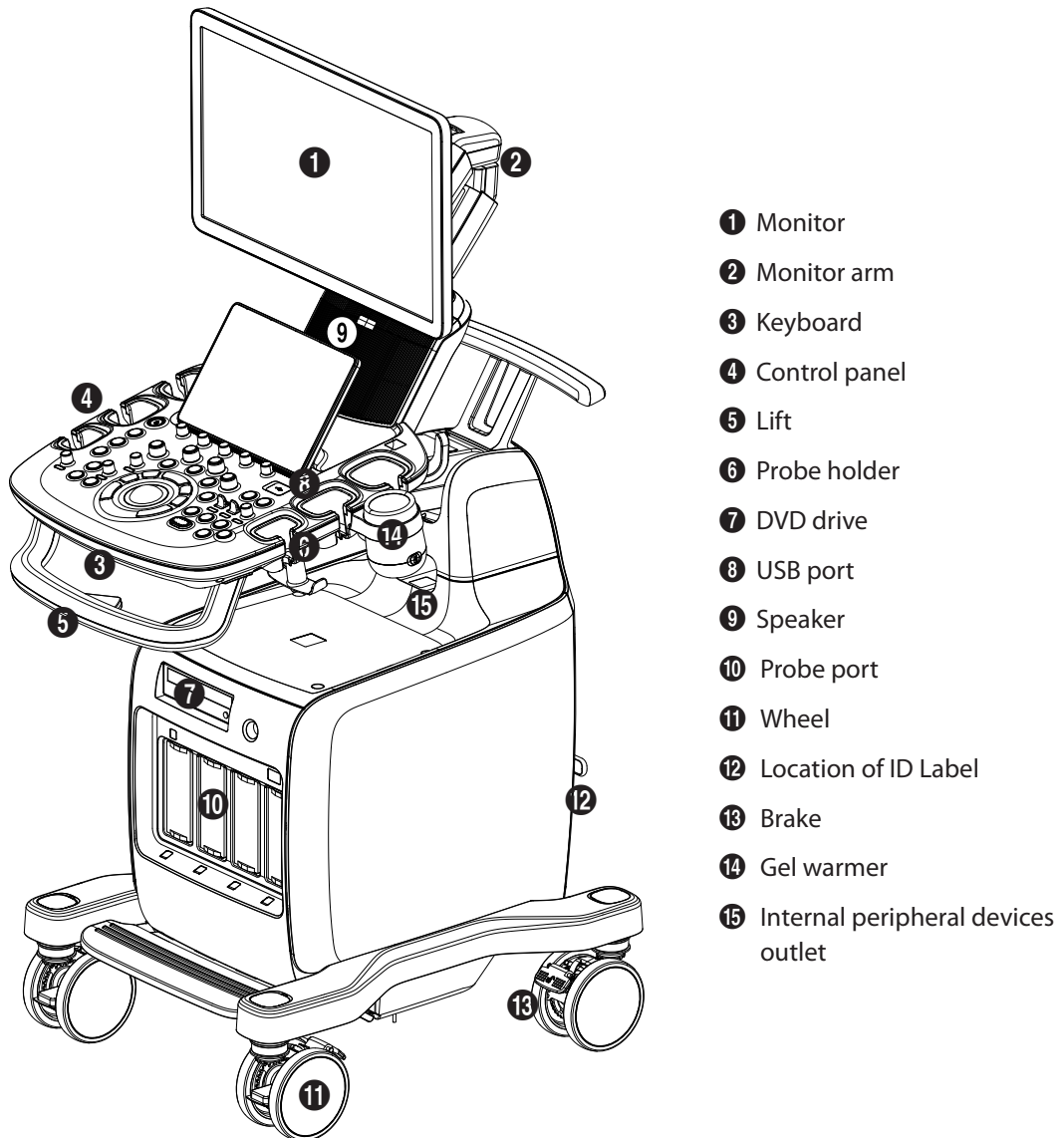
<p><b>Probes</b> (Type BF/IPX7)</p>	<p><b>Linear Array</b> LA3-14AD, LA2-9A, LA3-16AI, LA4-18BD, LA3-16A</p> <p><b>Curved Array</b> CA1-7AD, CA2-9AD, CA2-6BM, CF4-9</p> <p><b>Endo Cavity</b> ER4-9, EA2-11B</p> <p><b>Phased Array</b> PA1-5A, PA3-8B, PE2-4</p> <p><b>3D</b> CV1-8AD, V5-9</p> <p><b>CW</b> CW6.0, DP2B</p> <div style="display: flex; align-items: center;">  <div> <p><b>NOTE:</b></p> <ul style="list-style-type: none"> <li>▶ HS50 does not support LA2-9A and LA3-16AI, EA2-11B, LA4-18BD, PA1-5A.</li> <li>▶ HS60 does not support PE2-4 and ER4-9.</li> <li>▶ Probe CA2-6BM is not supported in Canada.</li> </ul> </div> </div>									
<p><b>Probe Connections</b></p>	<p>3 Probe Connectors, 4 Probe Connectors for option</p> <div style="display: flex; align-items: center;">  <div> <p><b>NOTE:</b></p> <table border="1" data-bbox="636 1150 1255 1304" style="margin-left: 10px;"> <thead> <tr> <th></th> <th>HS50</th> <th>HS60</th> </tr> </thead> <tbody> <tr> <td>3 PORT</td> <td style="text-align: center;">○</td> <td style="text-align: center;">×</td> </tr> <tr> <td>4 PORT</td> <td style="text-align: center;">○ (Option)</td> <td style="text-align: center;">○</td> </tr> </tbody> </table> </div> </div> <p>CW Probe Connector</p>		HS50	HS60	3 PORT	○	×	4 PORT	○ (Option)	○
	HS50	HS60								
3 PORT	○	×								
4 PORT	○ (Option)	○								
<p><b>Monitor</b></p>	<p><b>Main Monitor</b> Number of Pixel: 1,920 x 1,080 21.5 inch LCD Monitor (LED Backlight unit, hereafter referred to as “LCD monitor”)</p> <p><b>Touch Screen Monitor</b> Number of Pixel: 1,280 x 800 10.1 inch LCD Monitor (LED Backlight unit, hereafter referred to as “LCD monitor”)</p>									
<p><b>ECG</b></p>	<p>USB Type (Type CF)</p>									

<b>Rear Panel Input/Output Connections</b>	<p>Audio Output Port (Right/Left)</p> <p>VGA monitor</p> <p>LAN</p> <p>USB Port</p> <p>HDMI output</p>
<b>Image Storage</b>	<p>Maximum 45,000 frames for Cine memory</p> <p>Maximum 14,000 Lines for Loop memory</p> <p>Image filing system</p>
<b>Application</b>	<p>Obstetrics, Gynecology, Urology, Abdomen, Cardiac, Vascular, Small Parts, TCD, MSK, Pediatric</p>
<b>Electrical Parameters</b>	<p>100-240VAC, 800VA, 50/60Hz</p>
<b>Measurement Packages</b>	<p>Abdomen, Obstetrics, Gynecology, MSK, Pediatric, Small Parts, Urology, Vascular, Cardiac, Fetal Heart</p> <p>* Refer to the 'Chapter 8. Measurements and Calculations' for additional information.</p>
<b>Signal Processing (Pre-Processing)</b>	<p>Acoustic Power Control</p> <p>Dynamic Aperture Control</p> <p>Dynamic Apodization Control</p> <p>Dynamic LPF Control</p>
<b>Signal Processing (Post-Processing)</b>	<p>Digital TGC Control</p> <p>Slider TGC Control</p> <p>Mode-Independent Gain Control</p> <p>Black Hole/Noise Spike Filtering</p> <p>1D Lateral/Axial Filtering</p> <p>2D Edge/Blurring Filtering</p> <p>Frame average</p> <p>M/D Mode Sweep Speed Control</p> <p>Zoom</p> <p>Image View Area Control</p> <p>Image Orientation (left/right and up/down)</p>
<b>Measurement</b>	<p>Trackball operation of multiple cursors</p> <ul style="list-style-type: none"> <li>▶ 2D mode: Linear measurements and area measurements using elliptical approximation or trace</li> <li>▶ M mode: Continuous readout of distance, time, and slope rate</li> <li>▶ Doppler mode: Velocity and trace</li> </ul>

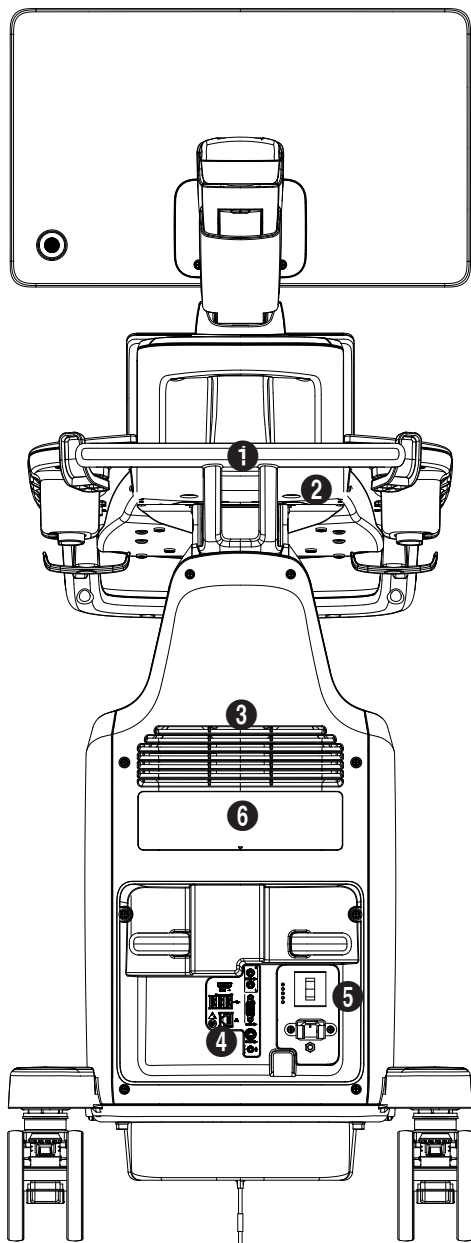
<p><b>Auxiliary</b></p>	<p>DVD Multi-Drive                  Digital B/W Video Printer                  Digital Color Video Printer                  USB Printer                  DVD Recorder                  Foot switch (IPX8)                  USB Flash Memory Media                  USB HDD                  USB ECG                  Monitor</p>
<p><b>User Interface</b></p>	<p>English, German, French, Spanish, Italian, Portuguese</p>
<p><b>Pressure Limits</b></p>	<p>Operating: 700 – 1060hPa                  Storage: 700 – 1060hPa</p>
<p><b>Humidity Limits</b></p>	<p>Operating: 30 – 75%                  Storage &amp; Shipping: 20 – 90%</p>
<p><b>Temperature Limits</b></p>	<p>Operating: 10 – 35°C                  Storage &amp; Shipping: -25 – 60°C</p>

## :: Product Configuration

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



[Figure 2.1 Front of the Product]



- ❶ Handle
- ❷ Storage compartments
- ❸ Ventilation
- ❹ Rear panel
- ❺ Power connection part
- ❻ ID label

[Figure 2.2 Back of the Product]



## 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.



[Figure 2.3 Monitor Display]

#### 1 Title Area

Displays patient information, hospital name, application, frame rate, depth, probe information, acoustic output information, and the current date and time.

#### 2 Image Area

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

#### 3 Thumbnail Area

Images saved by pressing the preset **Store** button are shown in the thumbnails. When you save Single screens, up to 4 images are shown in a list; for Quad screens, up to 12 images are shown. Click it with the pointer to enlarge the preview image.

#### 4 User Information and Status Information Area

Information that is useful to the user, such as current system status, image information, selectable items, etc., is displayed.

5 User Key (User Defined Key) Area

Settings for User Defined Keys, including the positions of **Set** and **Exit** buttons, are displayed. You can change the setting of each button in Setup > Customize > Buttons.



**NOTE:** For information on User Key Setup, please refer to 'Chapter 3. Utilities.'



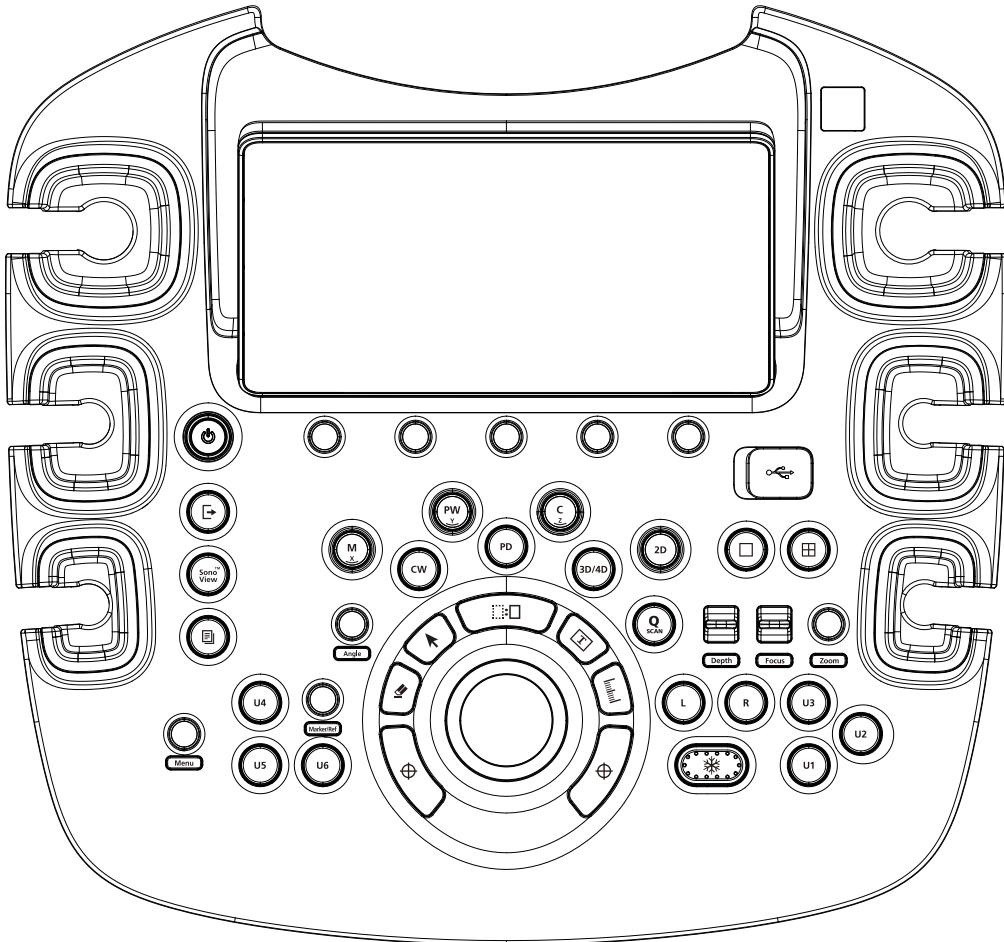
**Principles of Operation of the Diagnostic Ultrasound System**

Medical ultrasound images are created by digital memory and computer when they convert the high-frequency wave signals that are transmitted and received by the probe.

As ultrasound waves propagate through the human body, they generate reflected signals whenever they encounter a change in density. For example, reflected signals are generated when signals pass from fatty tissues to muscle tissues. Reflected signals return to the probe, where they are converted into electronic signals. The reflected signals are amplified and processed by analog and digital circuits that have filters for various frequencies and response time options. Then they are again converted into high-frequency electronic signals, and saved as a series of digital image signals. The monitor displays the image signals stored on the storage device in real time. The entire process of transmitting, receiving, and processing signals is controlled by the computer.

## Control Panel

The system can be controlled by using the control panel.
















[Figure 2.4 Control Panel]




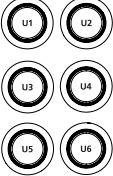








The control panel consists of a keyboard, soft menus, buttons, dials, dial-buttons, a slider, and a trackball.







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.

 <b>On/Off</b>	Button	Turns the system on/off.
 <b>End Exam</b>	Button	Finishes the exam of the currently selected patient and resets the related data.
 <b>SonoView</b>	Button	Displays the screen for viewing and managing stored images.
 <b>Report</b>	Button	Displays the Report screen that shows the measurement results of the current application and other information.
 <b>Menu</b>	Dial-button	When you press the dial-button, the menu items that are available in the current scan mode are shown on screen. Rotating the <b>Menu</b> dial-button to the right selects the menu one row above the current menu selected, and rotating it to the left selects the menu one row below.
 <b>Marker/Ref</b>	Dial-button	<ul style="list-style-type: none"> <li>▶ Marker: Allows the user to enter a BodyMarker over an image.</li> <li>▶ Ref: Moves the reference slice horizontally in 3D View.</li> </ul>
 <b>Angle</b>	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.
	Button	In this mode, only the image is displayed on the screen.
	Button	Compares four independent images.
	Button	Compares two independent images. The active image mode is on the left.
	Button	Compares two independent images. The active image mode is on the right.
 <b>Depth</b>	Switch	Adjusts the scanning depth of the image.
 <b>Focus</b>	Switch	Moves the focus to the target area for observation.

	Dial-button	<p>Makes the Zoom Box appear. In order to close the Zoom mode, press the <b>Exit</b> button.</p>
	Button	<p>Press this button to turn the Quick Scan function on. The 'Q scan' mark will appear at the top of an image. It can be used in applications of all probes.</p>
	Button	<p>Pauses/resumes scanning.</p>
	Button	<p>Stands for User Key; functions can be assigned to these buttons as desired. The function for each button can be assigned in Setup &gt; Customize &gt; Buttons &gt; User Key.</p>
	Dial-button	<p>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.</p>
	Dial-button	<p>Press this 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.</p>
	Dial-button	<p>Press this 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.</p>
	Button	<p>Press this button to start/stop Power Doppler mode.</p>
	Button	<p>Press this button to start/stop CW Spectral Doppler mode. Available only with the phased array probe.</p>
	Dial-button	<p>Press this button to start 2D mode. Rotate this dial-button to adjust Gain.</p>
	Button	<p>Press this button to turn 3D/4D Mode on/off.</p>
	Button	<p><b>Set or Exit</b> function may be assigned to this button. The function for each button can be assigned in Setup &gt; Customize &gt; Set/Exit Key.</p> <ul style="list-style-type: none"> <li>▶ Set: Select an item or value using the trackball. Also used to change the function of the trackball.</li> <li>▶ Exit: Exits the function currently being used and returns to the previous state.</li> </ul>

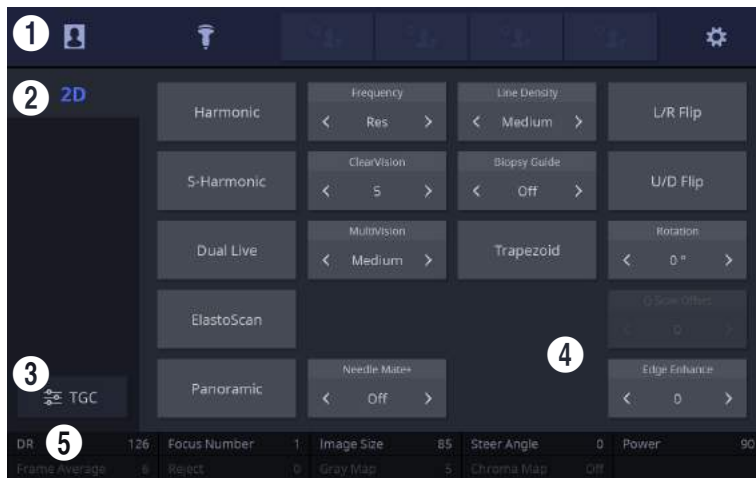
 <b>Clear</b>	Button	Deletes text, Arrow, BodyMarker, measurement results, etc. displayed on an image.
 <b>Pointer</b>	Button	When this is pressed, an arrow marker appears to point to parts of the displayed image.
 <b>Change</b>	Button	Changes the current trackball function.
 <b>T</b>	Button	Allows the user to place text on an image.
 <b>Calculator</b>	Button	Starts measurements by application.
 <b>Trackball</b>	Trackball	Moves the cursor on the screen. Also scrolls through Cine images.



## 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 Layout



[Figure 2.6 Touch Screen Display]

- 1 These buttons are always displayed on the touch screen. Buttons that are in use are shown in blue and buttons that cannot be used are deactivated.

Patient	The <i>Patient Information</i> screen will appear, where you can select a Patient ID in the list or enter new patient information.
Probe	It displays the <i>Probe Selection</i> screen where you can select and modify the probe and application.
Quick Preset 1–4	It shows up to 4 Preset buttons configured at Setup.
Setup	The general system settings that do not have a direct bearing on imaging are explained below.



**NOTE:** For further details about setting up Quick Preset, please refer to 'Setup > System > Quick Preset' in 'Chapter 3. Utilities'.



- ② Displays the mode that is currently used.
- ③ This is the TGC area. Adjust TGC Slide when TGC Curve is activated on the touch screen. Move the slider to the right to increase Gain and brighten the image. TGC stands for Time Gain Compensation.



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

- ④ **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 blue. To change the values in the menu, use the ◀ and ▶ buttons.
- ⑤ **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.



**Tips!**

**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.

## 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

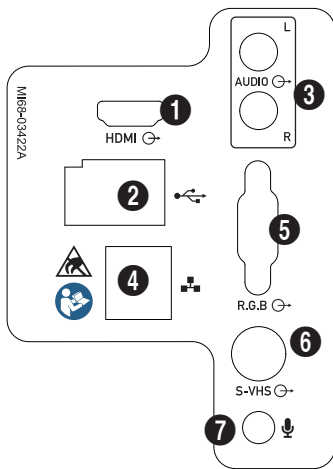
Press the lever on the handle of the control panel and move it carefully up or down.

## 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.

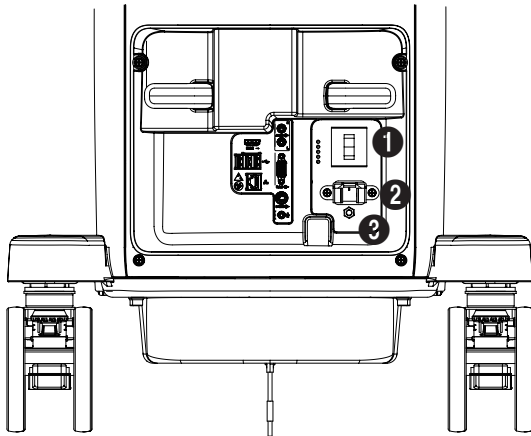


[Figure 2.7 Rear Panel]

- 1** HDMI port (Output): Outputs digital signals to the monitor. (Input: Not supported.)
- 2** USB port: Used to connect to peripheral USB devices.
- 3** Audio Port (Output): Outputs audio signal. (Input: Not supported.)
- 4** Network port: Connect to a network. You can transfer patient information to another server via DICOM network.
- 5** R.G.B Port (Output): Provides analog signal output to be displayed on the monitor.
- 6** S-VHS Port (Output): Provides an S-VHS connection for a VCR.
- 7** Microphone port (Input): Connects a microphone.

## ❑ Power Connection Part

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



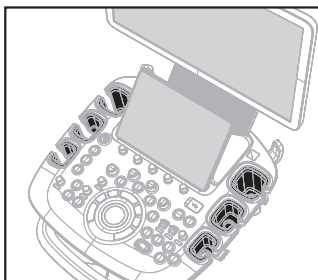
- ❶ Power switch/breaker: Turns on the power of the product, and cuts off power if overcurrent or overvoltage occurs.
- ❷ Power inlet: Accepts the power cord, which connects to an external power supply.
- ❸ Equipotential Terminal: This should be connected to the equipotential connection part in the exam room.

[Figure 2.8 Power Connection Part]

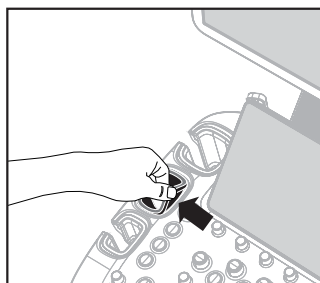
## Probe Holder

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

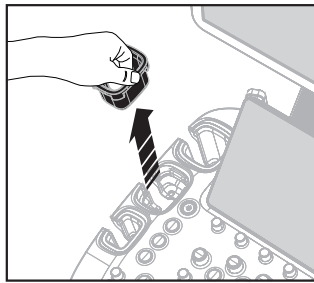
The holder can be separated for easy cleaning.



The six probe holders on the control panel can be attached and removed.



Hold the marked area at the top of the holder and pull it in the direction shown by the arrow.



Pull the holder up to detach it.

[Figure 2.9 Removing the Probe Holder]



### Hockey Stick Probe Holder

Insert the Hockey stick probe holder into the probe holder to mount. It is provided as an option.

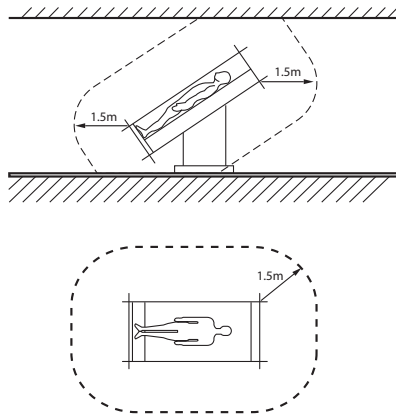
## Peripheral Devices

Peripheral devices can be connected to their corresponding ports on the left/right or rear sides of the console, as needed.



### CAUTION:

- ▶ Do not install peripheral devices that are not listed in this user manual in the patient environment. If you install an unlisted device in the patient environment, it may cause an electrical hazard.
- ▶ Do not connect additional external peripheral devices to the auxiliary socket outlet. Doing so may decrease safety level.



[Figure 2.10 Patient Environment]



**NOTE:** Refer to the user 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

### ■ Solid State Device

SSD 512G

## 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:** When using a peripheral device via a USB port, always turn the power off before connecting/disconnecting the device. Connection/disconnection of USB devices while the power is on may lead to malfunction of the system and the USB devices.



The console's USB ports are located on the rear panels of both the control panel and the console. We recommend that you connect USB storage devices (flash memory media, etc.) to the ports on the control panel, and other USB peripheral devices to the rear panel for convenience.

The following products are recommended:

### ■ Digital Video Printer

- ▶ Black and White: Sony UP-D897 (UP-897MD, UP-X898MD, UP-D898MD), Mitsubishi P95DE (P95DW, P95D, 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 driver compatible with the English version of Microsoft Windows 7. 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

### ▶ 3 Pedals HID Type

To configure the foot switch function, go to Setup > Customize > Buttons > Foot Switch. You can select **Exit, Freeze, U1, U2, U3, U4, U5, U6, Update, Single, or Quad.**

## ■ Misc.

### Flash Memory Media



#### **NOTE:**

- ▶ The system cannot recognize USB 1.1 flash memory. Remove the flash memory from the console and equip again with an appropriate device.
- ▶ Regarding file formats that are not ordinarily saved: Please check first to see if it is possible to save the file format on a desktop PC before trying to save the file on flash memory.
- ▶ Do not use flash memory media which contain anti-virus programs or are defective. Otherwise, the product may fail to work properly.

## Probes

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



**NOTE:** For information on probes, refer to 'Chapter 5. Probes' and the Reference Manual.

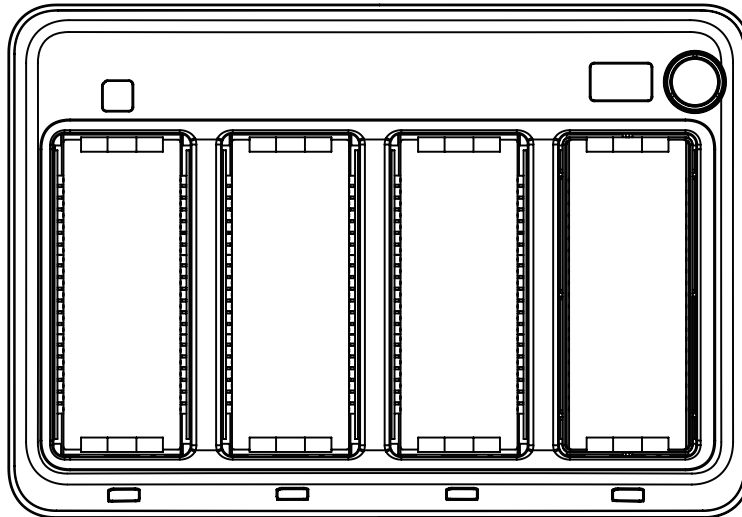
### Connecting Probes

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 (options inclusive) (five including CW) probes 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 2.11 Probe Connector]

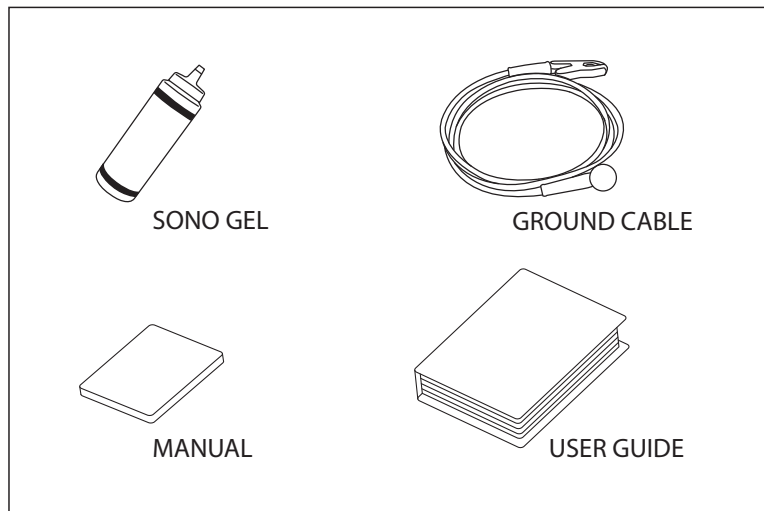


## Accessories

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



**NOTE:** Accessories can be different according to the country.



[Figure 2.12 Accessories]

## Optional Functions

HS50 and HS60 products have the following options based on the version:

Option	HS50	HS60
4D	O	O
3D XI	O	O
DICOM	O	O
Ez Exam+	O	O
MultiVision	O	Basic option
5D NT	O	O
CW Function	O	O
Cardiac Measurement	O	O
Strain+	X	O
Auto IMT+	O	O
ElastoScan	O	O
E-Strain	X	O
Panoramic	O	O
XI STIC	O	O
SEE Stream (RU region only)	O	O
Needle Mate+	O	O
CEUS+	X	O
Realistic Vue	O	O
HDVI	X	O
Mobile Export	O	O
5D Follicle	O	O

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

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Strain+ .....	3-81
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## ECG

If an ECG is installed, the **ECG** tab will be displayed on the touch screen. In a Multi Image Mode such as Dual or Quad, ECG Cine can be used for each image.



**NOTE:** You can set each Preset to show or hide the ECG on the screen by going to Setup > Application/Preset > Preset Setting.

### Starting and Terminating an ECG

Tap the **ECG** button on the touch screen menu to turn the function on or off.

### ECG Setup

#### ■ Sweep Speed

Tap the **Sweep Speed** button in the touch screen menu to select the ECG display speed. You can select 15mm/s, 29mm/s, 44mm/s, 59mm/s, 88mm/s, or 117mm/s.

#### ■ Invert

Tap the **Invert** button on the touch screen menu to turn ECG Invert on or off.

#### ■ Gain

Adjust the amplitude of the ECG. Rotate the Soft Menu dial-button **1** to adjust the gain between 0-100.

#### ■ Position

Rotating the Soft Menu dial-button **2** changes the display position of the ECG signal. You may select a position between 0-10; selecting a higher value will position the ECG higher on the screen.

#### ■ Clip

Rotate the Soft Menu dial-button **3** to select the interval for saving the clip. You can select either Time or Beat.

### ■ Trigger

Tap the **Trigger** button on the touch screen menu to set up Trigger. You can rotate the Soft Menu dial-button **4** to select a number of ECG Triggers between 1 and 7.

### ■ Trig Delay

Select the time delay between the R-wave and the frame containing the trigger, which will be applied to the Trigger function. Rotate the dial-button **4** to select a value between 0 and 3,000msec.

### ■ Dual Trigger

Tap the **Dual Trigger** button on the touch screen menu to turn Dual Trigger on or off.

### ■ Dual Trig Delay

Select the time delay between the frame containing the first trigger and the frame containing the second trigger, which will be applied to the Dual Trigger function. Rotate the dial-button **4** to select a value between 6 and 3,000 msec.




**CAUTION:**

- ▶ If the ECG is less than 30 Hz, the Heart Rate (HR) might not be displayed.
- ▶ In CW Mode, when the ECG is active, the error ratio of the Heart Rate (HR) should be within 2%.

## ⚙️ System Settings

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

1. Tap  button on the touch screen or press **Setup** button on the keyboard.
2. *Setup* screen will appear on the monitor and the touch screen. Select a tab that contains items you want to specify.

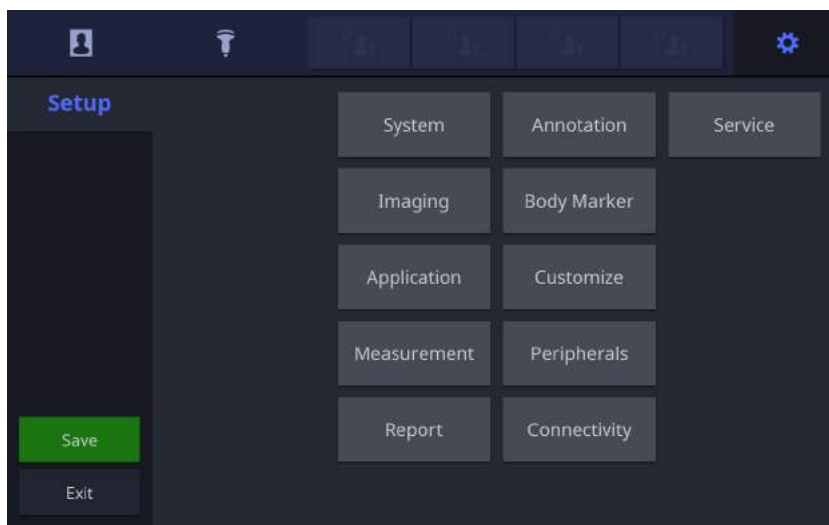
### Tips!

#### Selecting a Tab

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

- ▶ Use the trackball and the **Set** button to select a tab.
- ▶ Tap the corresponding button on the touch screen.

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



[Figure 3.1 Setup – Touch Screen]

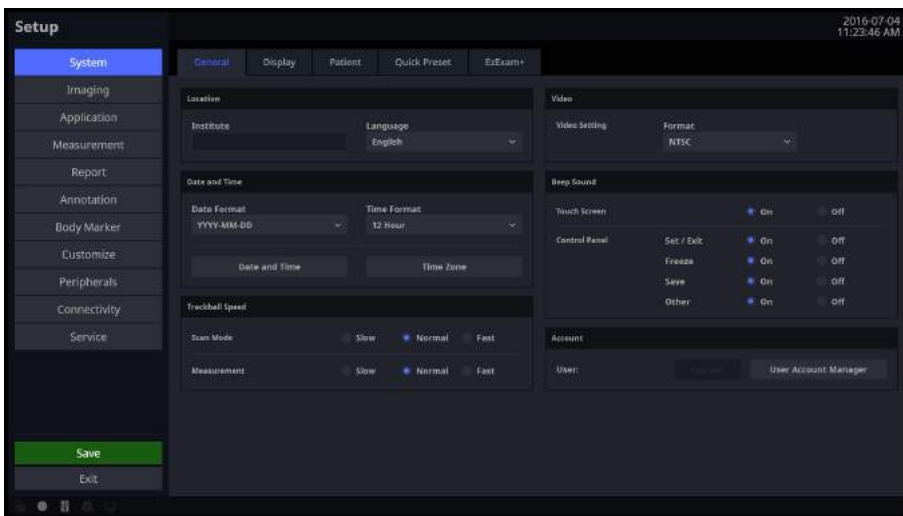
## General System Settings

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

From this tab, you can configure the general system settings.

## General

In the *Setup* screen, select **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. Special characters can be entered.

#### Language

Select the system language.

(Supported languages: English, German, French, Spanish, Italian, Portuguese)



## Date and Time

Set the date and time for use in the system.



### CAUTION:

- ▶ Before starting diagnosis, please confirm the time, date and time zone and modify the settings if necessary.
- ▶ Make sure to set the date and time to the time zone in which the system is installed. If it is not set, the date and time can be automatically synchronized to the time zone of the country of the manufacturer.



### 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.
- ▶ When the system time and date are changed, the change is not reflected in the time and date indicated in previous diagnosis results.

### ■ Date Format

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

### ■ Time Format

Specify the time format. Press the combo button to select the preferred display format (12 Hour or 24 Hour).

### ■ Date and Time

Select settings for date and time. When you press this button, the *Date and Time* screen appears.

1. Set the date and time by using the trackball and the **Set** button on the control panel.
2. Press **Save** to apply the settings. Tap **Cancel** or press **Exit** button on the control panel to cancel.

### ■ Time Zone

Specify the local time zone where the system is used. When you press this button, the *Time Zone Settings* screen appears.

1. Press **Time Zone**.
2. Specify the time zone by using the trackball and the **Set** button for the combo button.
3. Press **OK** to apply the settings. Tap **Cancel** to cancel.

## ❏ Trackball Speed

### ■ Scan Mode

Specify the trackball speed in Scanning Mode as Slow, Normal, or Fast.

### ■ Measurement

Used to specify the trackball's speed during measurement. Select Slow, Normal, or Fast.

Slower speeds allow for more precise measurements.

## ❏ Video

### ■ Format

Choose between NTSC or PAL.

## ❏ Beep Sound

### ■ Touch Screen

Set the sound level when using the touch screen. Turn it on or off by using the trackball.

### ■ Control Panel

Set the sound level of sound when using buttons and dial-buttons in the control panel. You can turn it on or off by using the trackball.

In particular, for **Set/Exit**, **Freeze**, **Save**, and **Other** buttons and dial-buttons, you can turn them on or off.

## Account

Register a user ID and password.

### ■ User Log-in

Set the user account (log-in) function. If the user log-in is set to on, it can be used for the following areas:

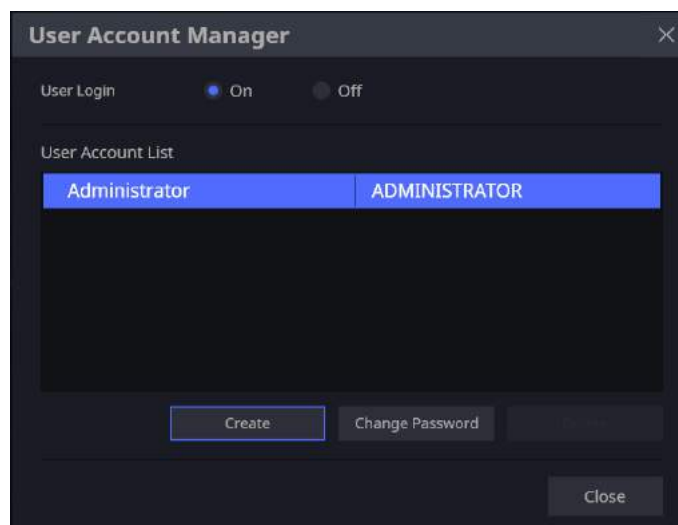
Screen Saver

- ▶ Accessing SonoView/Patient
- ▶ Patient *Search* Window

### ■ User Account Manager

This is the exclusive administrator function for approval and management of accounts. The *Account List* window will be enabled.

- ▶ Create: Fill out the User ID, Password, and Name fields. Then click the **OK** button to create a new ID.
- ▶ Change Password: Change password.
- ▶ Delete: Delete the selected ID.
- ▶ Close: Close Settings.



[Figure 3.3 Setup – User Account Manager]

## ■ Log-in

You can set a User Account ID after logging in to the Admin account. Please contact the service engineer to learn how to reset user account information including the Admin account.



**NOTE:**

- ▶ The Admin account can be configured when you run 'User Account Manager' at Setup for the first time.
- ▶ The Admin account cannot be deleted.
- ▶ Once the user account function is activated, you cannot load exams without logging in.
- ▶ The password must be 8 to 16 characters and composed of at least three of the following:
  - English alphabet upper case
  - English alphabet lower case
  - Numbers
  - Special characters

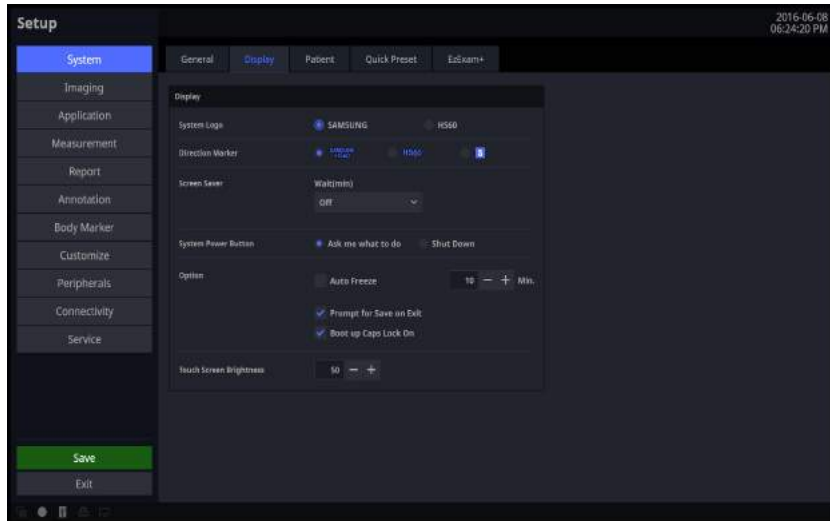
## ■ Log-out

Close the Admin account.

## Display

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

Configure the settings for displaying images.



[Figure 3.4 Setup – System – Display]

## Display

### ■ System Logo

Choose one of SAMSUNG or HS50/HS60.

### ■ Direction Marker

Set the Direction Marker. Among SAMSUNG HS60, HS60, and S Marker, select a desirable shape.

### ■ Screen Saver

Select the wait time (in minutes) for the screen saver. Use the trackball to set it off or 5, 10, 30 or 60 minutes.

### ■ System Power Button

- ▶ Ask me what to do: Set a message to recheck the Off status when it is shut down.
- ▶ Shut Down: The power will turn off.

### ■ **Option**

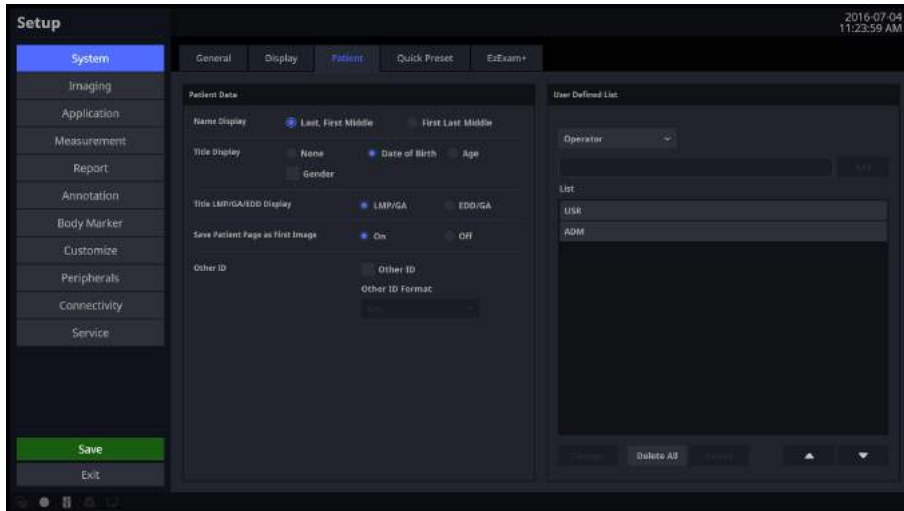
- ▶ Auto Freeze: Automatically switch to freeze state. Set the freeze time between 0 and 60 minutes.
- ▶ Prompt for Save on Exit: Use the checkbox to select whether to save or not.
  - Check On: Set a message to recheck whether to save the changes when closing the setup.
  - Check Off: Set it to automatically save changes when closing the setup.
- ▶ Boot up Caps Lock On: When the checkbox is selected, Caps Lock is turned on after completing the system booting.

### ■ **Touch Screen Brightness**

- ▶ By using the trackball, adjust brightness of the touch screen between 0 and 100 in the units of 10.
- ▶ Adjust it by pressing – and + buttons.

## Patient

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



[Figure 3.5 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.

#### ■ Title Display

Show or hide patient information in the Title area of the screen.

- ▶ None: Patient information is not displayed.
- ▶ Date of Birth: Displays the patient's date of birth.
- ▶ Age: Displays the patient's age.
- ▶ Gender: Select this checkbox to display the patient's gender. Note that the patient's gender can only be displayed if their date of birth or age is also displayed.

### ■ Title LMP/GA/EDD Display

- ▶ LMP/GA: The last menstruation date and estimated gestation weeks are shown on the screen.
- ▶ EDD/GA: The expected delivery date and estimated gestation weeks are shown on the screen.

### ■ Save Patient Page as First Image

If On is checked, Patient information is saved as the first image.

### ■ Other ID

When a Patient record is created, a GUI for text input is displayed for you to enter the Other ID.

- ▶ Other ID Format: Any, Numbers, Letters and Numbers, and NHS Numbers are available. Except Any, inputs in each format type can only be entered as text.

## ✚ User Defined List

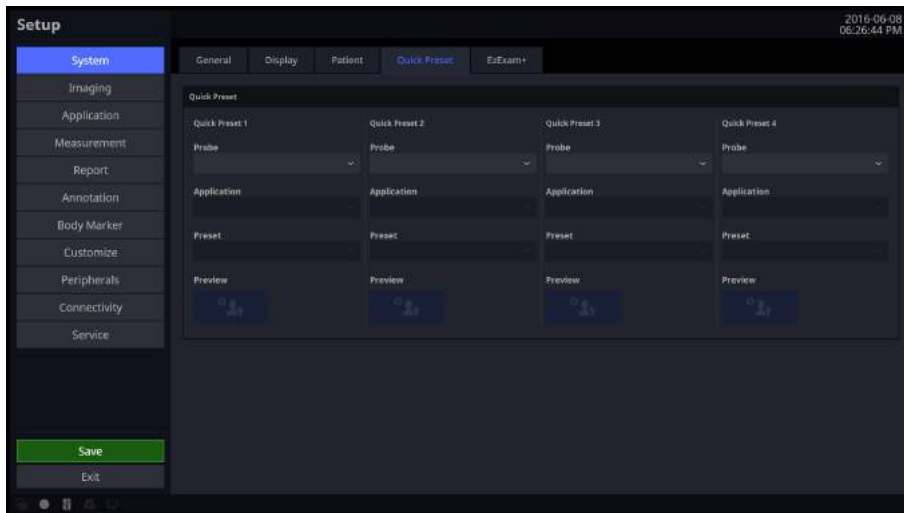
You may enter information related to studies beforehand, so that you can assign the information easily when entering patient information. Use the **Change**, **Delete All**, **Delete**, **Up**, and **Down** buttons to add, edit, or delete information; you may create a list of up to 20 for each item.

- ▶ Operator: You can save the name of the operator who scanned the patient.
- ▶ Diag. Physician: The name of the physician who diagnosed the patient can be saved.
- ▶ Ref. Physician: You can save the name of the referring physician.
- ▶ Indication: You can save information about the patient's medical history.
- ▶ Description: You can save up to 20 diagnostic memos per application.



## Quick Preset

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



[Figure 3.6 Setup – System – Quick Preset]

### Quick Preset

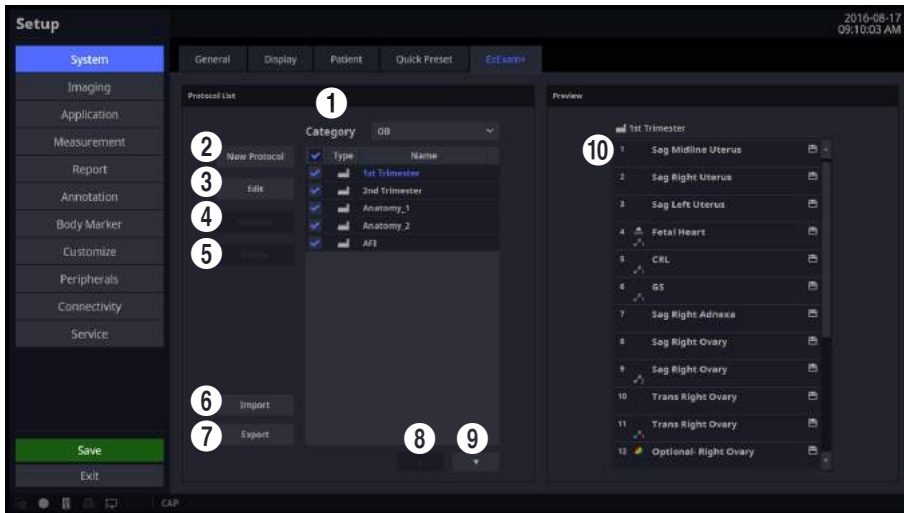
After selecting the Probe, Application, and Preset connected to the port, save them to Quick Preset. Up to 4 sets can be saved. By using Preview, you can preview the saved preset.

- ▶ In the diagnosis mode, the saved Probe and Preset are shown as a button on the touch screen.

## Ez Exam+

In the *Setup* screen, select the **Ez Exam+** tab in the **System** category.

Ez Exam+ is a macro function that saves your frequently used exams as a protocol and runs them together. This feature streamlines the diagnosis process.



[Figure 3.7 Setup – System – Ez Exam+]

## Protocol List

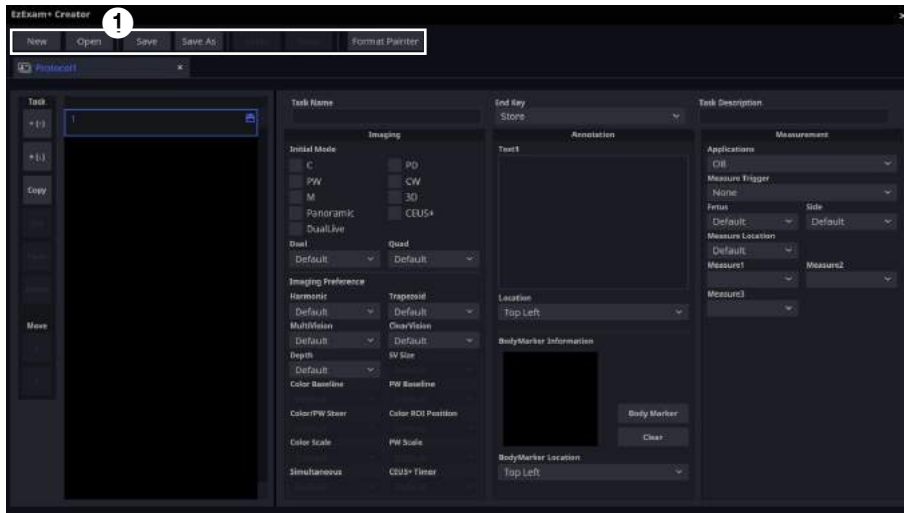
Protocol List: Provides a protocol list for the application. Ez Exam+ in the Default List cannot be deleted or edited and the addition of new Ez Exam+ is not allowed.

- ❶ Category: A list of available applications is shown. If previously configured Ez Exams are available, they will be shown in the Preset Lists when an application is selected. Selection of ABD, CARD, GYN, MSK, OB, PED, SMP, TCD, URO, or VAS is available.
- ❷ New Protocol: When *New Protocol* window appears, enter a name and press **OK**. Tap **Cancel** to cancel.
- ❸ Edit: You can select any protocol in the protocol list.
- ❹ Rename: You can edit the name of any protocol in the protocol list.
- ❺ Delete: Delete a protocol selected from the protocol list.
- ❻ Import: Import the protocol data.
- ❼ Export: Exports the protocol selected from the protocol list.
- ❽ Move Up Button: Moves the protocol selected from the protocol list up one row.
- ❾ Move Down Button: Move the protocol selected from the protocol list down one row.

## Preview

- ⑩ Task List: Provide a task list which belongs to the protocol selected from the protocol list.

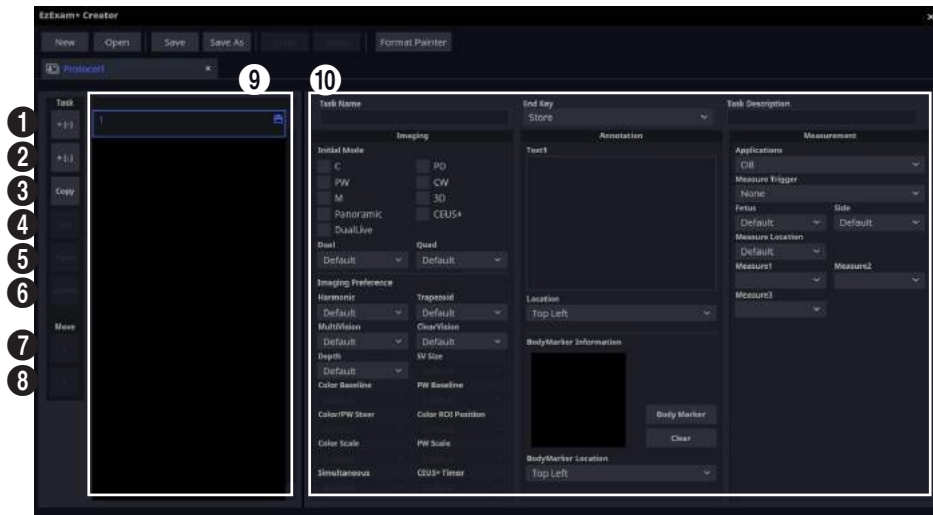
### Ez Exam+ Creator



[Figure 3.8 Setup – System – Ez Exam+ Creator]

#### ① Options in Function Window

- ▶ New: Create a new protocol.
- ▶ Open: Load an existing protocol.
- ▶ Save: Save the current protocol. It is activated at any time even when there is no change of data.
- ▶ Save As: Save the current protocol with a different name.
- ▶ Undo/Redo: Undo the last performed function, or restores the last undone function. (Up to 50 Undo/Redo actions can be done; this function will be inactive if it cannot be performed.)
- ▶ Format Painter: Applies the format settings from one protocol to another.



[Figure 3.9 Setup – System – Ez Exam+ Creator]

- 1 Add Task(↑): Create a new task on the row above the task selected from the task list.
- 2 Add Task(↓): Create a new task on the row below the task selected from the task list.
- 3 Copy: Copies a task selected from the task list.
- 4 Cut: Cuts a task selected from the task list.
- 5 Paste: Pastes a task below the task selected from the task list.
- 6 Delete: Delete a task selected from the task list.
- 7 Move Up: Move a task selected from the task list up one row.
- 8 Move Down: Move a task selected from the task list down one row.
- 9 Task List: Provide the task list which belongs to the protocol.
- 10 Task Parameter: Provide a parameter which belongs to the protocol selected from the protocol list.

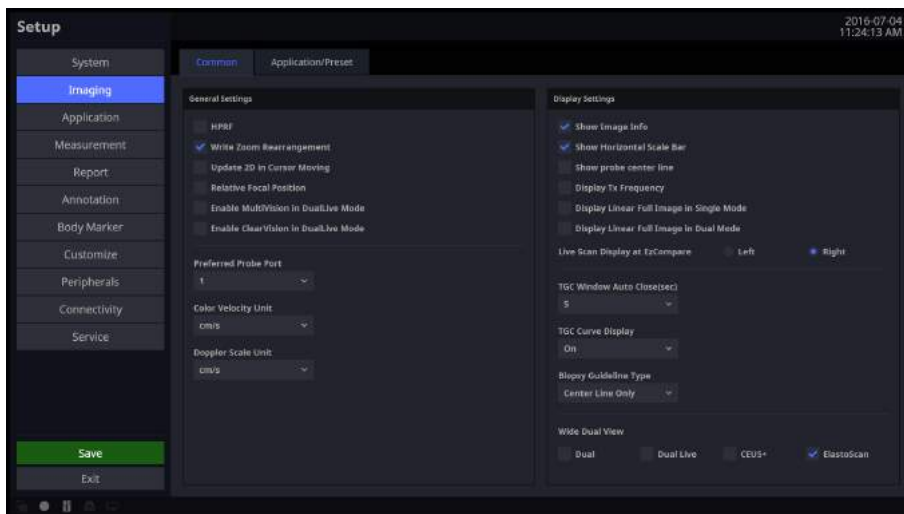
## Imaging

In the *Setup* screen, select the **Imaging** tab. Or tap **Imaging** on the touch screen. Configure the settings for displaying images.

## Common

Common settings apply to all applications.

You can select multiple items. Use the trackball and **Set** button to select items and set the checkbox.



[Figure 3.10 Setup – Imaging – Common]

## General Setting

### ■ HPRF

In PW Spectral Doppler Mode, this detects blood flow 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.

■ **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.

■ **Display Setting**

■ **Show Image Info**

Show or hide the image information. If the image information intrudes too much on the screen, When it is turned off, it hides the image information.

■ **Show Horizontal Scale Bar**

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

■ **Show Probe Center Line**

Select whether or not to display the Center Line of the probe.

■ **Display Tx Frequency**

Specify how to display the Tx Frequency for each probe. If checked, the current state will be indicated in MHz; if unchecked, the state will be indicated as PEN, GEN, or RES.

■ **Display Linear Full Image in Single Mode**

Show the full image of the Linear (including virtual convex) probe in Single Mode. When the sides of an ultrasound image are not visible at a low depth, use this function to view the entire image.

■ **Display Linear Full Image in Dual Mode**

Show the full image of the Linear (including virtual convex) probe in Dual (or Dual Live) Mode. When the sides of an ultrasound image are not visible at a low depth, use this function to view the entire image.

■ **Live Scan Display at EzCompare**

When EzCompare is executed, you can locate the live images to the left or right.

### ■ **TGC window Auto Close (sec)**

Specify how much time must elapse before the TGC Control Window on the touch screen automatically closes because of a lack of user input. It can be set at 5, 10, 15, or 20 seconds. If Off is checked, it does not automatically close: you must press **Close** button.

### ■ **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).

### ■ **Biopsy Guideline Type**

Select the type of Biopsy Guide Line displayed. Select one from Center Line Only, Outer Line Only, or Both.

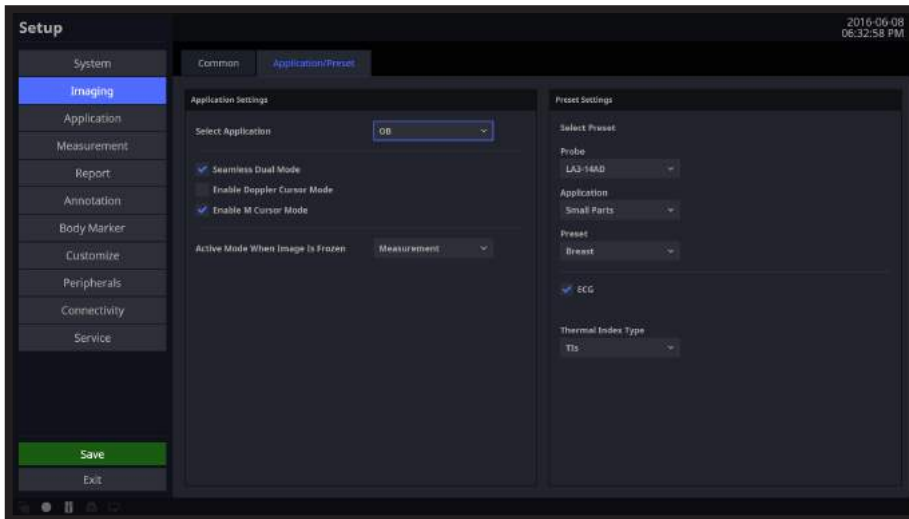
### ■ **Wide Dual View**

Wide screen is provided. Select one from Dual, Dual Live, CEUS+, or ElastoScan.

## Application/Preset

These settings specifically apply to the selected application.

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



[Figure 3.11 Setup – Imaging – Application/Preset]

### Application Setting

#### Select Application

Set up the measurement application.

#### Seamless Dual Mode

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

When checked, no space will be shown between the left and right images in the Dual Mode, while when unchecked, a space will be shown between the left and right images.

#### 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 which mode will activate upon freezing an image.

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

## ■ **Preset Setting**

### ■ **Select Preset**

Check the Probe, Application, and Preset.

### ■ **ECG**

Enable or disable ECG for each Preset.

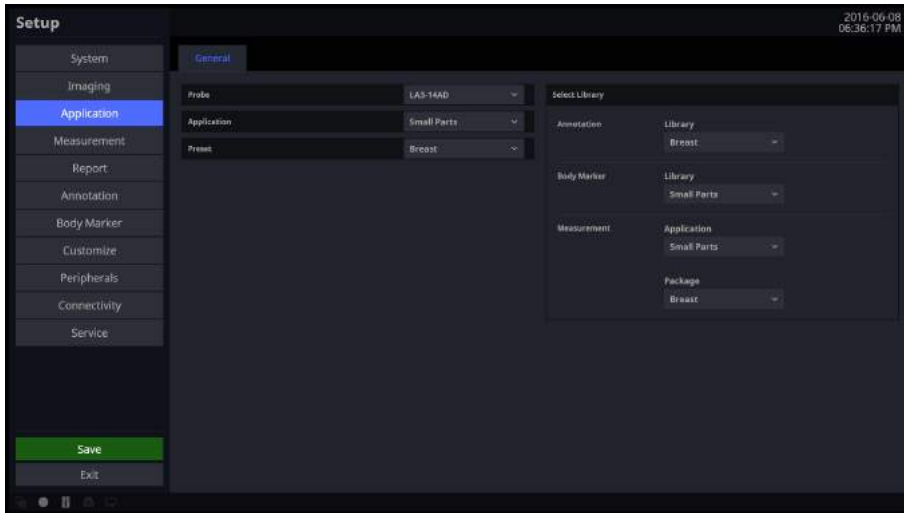
### ■ **Thermal Index Type**

Set the TIs shown on the screen from among TIs (Soft tissue thermal Index), TIb (Bone thermal index), TIc (Cranial bone thermal index). You can specify indices by Preset.

## Application

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

### General



[Figure 3.12 Setup – Application – General]

#### ❏ Probe

Select a probe.

#### ❏ Application

Select an application.

#### ❏ Preset

Select the Preset that is supported by the selected application.

## **Select Library**

### ■ **Annotation**

Setup a text library.

### ■ **BodyMarker**

Setup a BodyMarker library.

### ■ **Measurement**

- ▶ Application: Setup the measurement application.
- ▶ Package: Setup a package for the measurement application.

## Measurement Settings

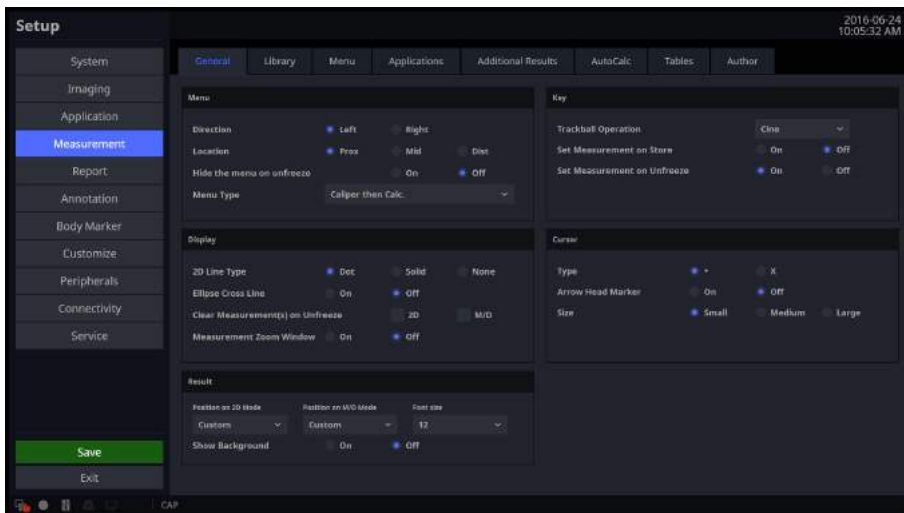
Specify various setup options for measurements. The setup can be modified depending on your specific needs or preferences.

1. Press **Setup** on the touch screen or keyboard. When the *Setup* screen appears, select the **Measurement** tab.
2. When the *Measurement* screen appears, select the tab that contains the items you wish to configure.
3. Specify the settings for each item.
4. Press the **Save** button to save the settings and finish. 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

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

You can specify basic measurement options.



[Figure 3.13 Setup – Measurement – General]

## Menu

### ■ Directions

Select the Direction Type to be applied to the measurement target in the initial system status. The options are Left and Right.

### ■ Location

Select the Location Type to be applied to the measurement target in the initial system status. The options are Prox, Mid, and Dist.

### ■ Hide the menu on Unfreeze

Hide or show the Measurement menu on the screen after taking measurements. Show the Scan Mode (On) or hide the Measurement menu (Off).

### ■ Menu Type

- ▶ Caliper then Calc: Each press of the **Calculator** button changes the mode in the order of Caliper and Calc.
- ▶ Calc. then Caliper: Each press of the **Calculator** button changes the mode in the order of Calc. and Caliper.
- ▶ Caliper Only: Each press of the **Calculator** button changes the mode to Caliper.
- ▶ Calc. Only: Each press of the **Calculator** button changes the mode to Calc.



When Caliper Only or Calc. Only type is selected, pressing the Measurement Key on the control panel during measurement serves as Exit.

## 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) to use for measurement in 2D Mode.

### ■ 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

Show or hide measurement results on the screen when switching to Scan Mode after taking measurements. Select this checkbox to show measurement results in 2D or M/D Mode.

### ■ Zoom Window

Generate an enlarged image centered around the marker. You can select On or Off.

## Result

Select how measurement results are displayed.

### ■ Position On 2D Mode

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-hand corner of the screen.
- ▶ Custom: Measurement results are displayed in a location selected by the user.

### ■ Position On M/D Mode

Move the measurement results.

- ▶ Left-Top: Move the measurement results towards the top left-hand 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.

### ■ Font Size

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

### ■ Show Background

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

## ■ Key

### ■ Trackball Operation

Set the motion of the trackball when using Caliper or Measure.

- ▶ Marker: Stand-by and ready to measure; display the basic marker on the measurement screen.
- ▶ Cine: Ready to select a Cine frame by using the trackball.

### ■ Set Measurement on Store

Turn the function on or off 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 completes measurements when the image is unfreezed by using Freeze Key while a measurement is being taken.

## **Cursor**

### ■ **Cursor Type**

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

### ■ **Arrow Head Marker**

Show or hide the Head Marker when measuring a small area.

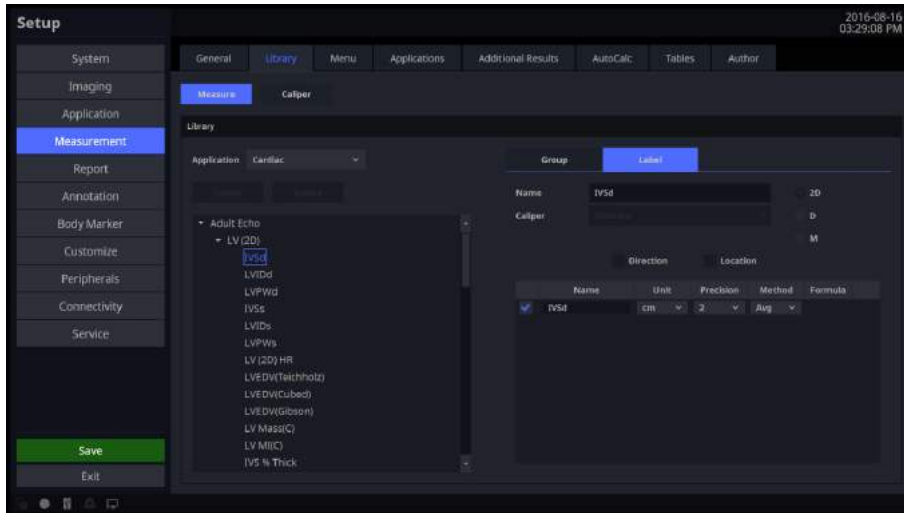
### ■ **Size**

Select the size of the default caliper cursor displayed on the screen. Select Small, Medium, or Large.



## Library

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



[Figure 3.14 Setup – Measurement – Library]

## Measure

Library in the Measure category is shown.

### ■ Application

Select an application.

### ■ Create

Create a USERGROUP other than default group. A USERLABEL can be created within a created group.



**NOTE:** 'User Label' can be edited.

### ■ Delete

A newly generated 'Label' can be deleted.

## Caliper

Specify whether additional information will be shown along with the basic measurement values when basic measurements are taken by pressing the control panel's **Caliper** button. If this option is selected, the additional information will be saved as an output along with the measurement results.

Setting 'Application' to General will change the items in 'D Trace'. Setting 'Application' to Cardiac will change the items in 'D Trace' and 'D Velocity'.



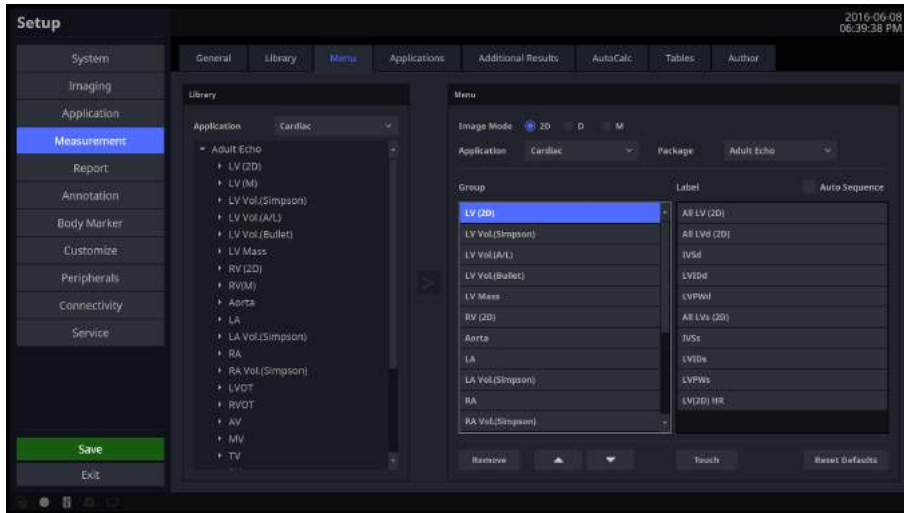
**NOTE:** 'Cardiac' setting is activated when the probe setting is Cardiac.

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

- ▶ 2D Mode: Distance, Trace, Trace Length, Ellipse, Open Spline, Closed Spline, Distance Stenosis, Trace Length Stenosis, Open Spline Stenosis, Ellipse Stenosis, Trace Stenosis, Closed Spline Stenosis, Ellipse Trace Stenosis, 2 Lines Angle, 3 Point Angle, 1 Dist Volume, 2 Dist Volume, 3 Dist Volume, Ellipse Volume, Ellipse + Dist Vol, Disk Volume
- ▶ D Mode: Velocity, Velocity (Cardiac), Accel, Time(D), HR(D), RI, Auto Trace, Limited Trace, Manual Trace, Auto Trace (Cardiac), Limited Trace (Cardiac), Manual Trace (Cardiac), Dist Volume Flow, Trace Length Volume Flow, Open Spline Volume Flow, Ellipse Volume Flow, Trace Volume Flow, Closed Spline Volume Flow, S/D Ratio, D/S Ratio, Velocity(F), Velocity(F) (Cardiac), Auto Trace(F), Limited Trace(F), Manual Trace(F), Auto Trace(F) (Cardiac), Limited Trace(F) (Cardiac), Manual Trace(F) (Cardiac), Dist Volume Flow(F), Trace Length Volume Flow(F), Open Spline Volume Flow(F), Ellipse Volume Flow(F), Trace Volume Flow(F), Closed Spline Volume Flow(F), S/D Ratio(F), D/S Ratio(F)
- ▶ M Mode: Distance, Slope, Time(M), HR(M)

## Menu

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



[Figure 3.15 Setup – Measurement – Menu]

## Library

Measurement items provided for each application are shown in a list.

## Menu

### ■ Package

Select the Packages that are supported by each application.

### ■ Image Mode

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

### ■ 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.

### ■ Label View

Label 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.

### ■ Auto Sequence

It is activated when the Auto Sequence box is checked. It supports a function to execute all items in a group in sequential order. It also supports the sequential measurement function for measuring AFI and Volume in OB.

### ■ Up, Down

Adjust the order of the groups or items in Label View.

### ■ Remove

Delete a group or item selected in Group View or Item View.

### ■ Touch

A Group or an Item can be placed on the touch screen or shown in the Group View or Item View.

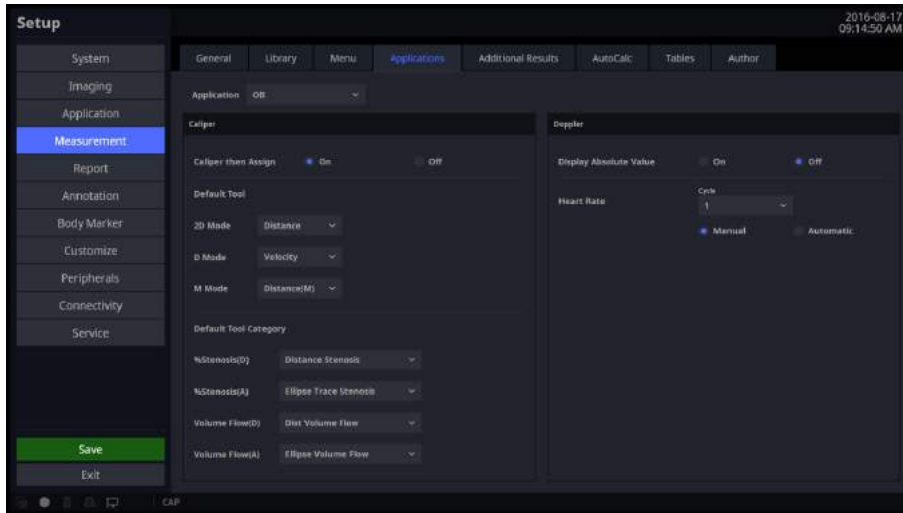
- ▶ Click the touch button to display a dialog box that shows the touch button.
- ▶ Clear All: Delete all groups and items.
- ▶ Add Page: Add a page.
- ▶ Remove Page: Delete a page.
- ▶ Click the touch button to display the groups and items that may be assigned to the button.
- ▶ Select Empty in the groups and items shown to delete the groups and items currently assigned to the touch button.
- ▶ Deleted groups and items from the Touch will be removed from the Group View or Item View when closing the dialogue box by clicking the **Save** button.

### ■ Reset Defaults

Press the **Reset Defaults** button and then select **OK** to go to the initial state.

## Applications

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



[Figure 3.16 Setup – Measurement – Applications]

## Caliper

### ■ Caliper then Assign

After taking a Basic Measurement, the measurement result may be set as a Label. Enable or disable this by choosing On or Off.

### ■ Default Tool

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

- ▶ 2D Mode: Distance, Trace, Trace Length, Ellipse, Open Spline, Closed Spline, %Stenosis(D), %Stenosis(A), 2 Lines Angle, 3 Points Angle, 1 Dist Volume, 2 Dist Volume, 3 Dist Volume, Ellipse Volume, Ellipse Dist Vol, Disk Volume
- ▶ D Mode: Velocity, Accel, Time(D), HR(D), RI, Limited Trace, Manual Trace, Volume Flow(D), Volume Flow(A), S/D Ratio, D/S Ratio
- ▶ M Mode: Distance, Slope, Time(M), HR(M)

### ■ **Default Tool Category**

Select the default tool for each measurement category.

- ▶ %Stenosis(D): Distance Stenosis, Trace Length Stenosis, Open Spline Stenosis
- ▶ %Stenosis(A): Ellipse Trace Stenosis, Ellipse Stenosis, Trace Stenosis, Closed Spline Stenosis, Ellipse Trace Stenosis
- ▶ Volume Flow(D): Dist Volume Flow, Trace Length Volume Flow, Open Spline Volume Flow
- ▶ Volume Flow(A): Ellipse Volume Flow, Trace Volume Flow, Closed Spline Volume Flow

## ❏ **Doppler**

### ■ **Display Absolute Value**

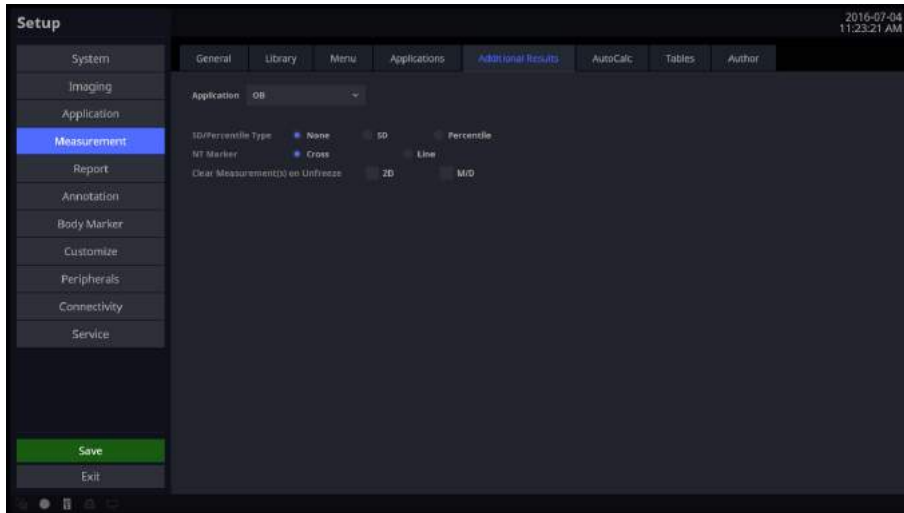
The doppler measurement is displayed as an absolute value.

### ■ **Heart Rate**

- ▶ Cycle: Select the number of heart rate (HR) cycles.
- ▶ Manual: Enter the heart rate manually when conducting a measurement.
- ▶ Automatic: Heart rate is entered automatically by the ECG while conducting a measurement.

## Additional Results

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



[Figure 3.17 Setup – Measurement – Additional Results]

## Application

Select an application.

### ■ Cardiac

- ▶ RAP default value: Configure the default value of RAP. You may select 0, 5, 10, 15, 20, or 25mmHg.
- ▶ LV Volume Method: Specify how the volume of the left ventricle is measured. Select Teichholz, Gibson, or Cubed. For more information on calculation formulae, please refer to the reference manual.
- ▶ LV Study On Straight Line: The measurement direction can be set for each LV measurement. If it is On, the initial measurement direction is fixed. If it is Off, measurement can be conducted in any desirable direction.

## ■ OB

- ▶ SD/Percentile Type: Select None, SD, or Percentile.
- ▶ NT Marker: Select the indicator symbol for measuring NT. You can select either Cross or Line type.
- ▶ Clear Measurement(s) on Unfreeze: You can set whether to delete the results at Unfreeze. Select either of 2D or M/D or both of them.
  - 2D: Set whether to delete the values shown in the 2D image.
  - M/D: Set whether to delete the values shown in the Trace image.

## ■ Vascular

ICA/CCA Ratio: Select a measurement item to use to calculate the ICA/CCA ratio.

You can select Max, Prox, Mid, or Dist as PS and ED for ICA and CCA, individually.



**NOTE:** You may select this when the application is OB, GYN, Vascular, or Cardiac.

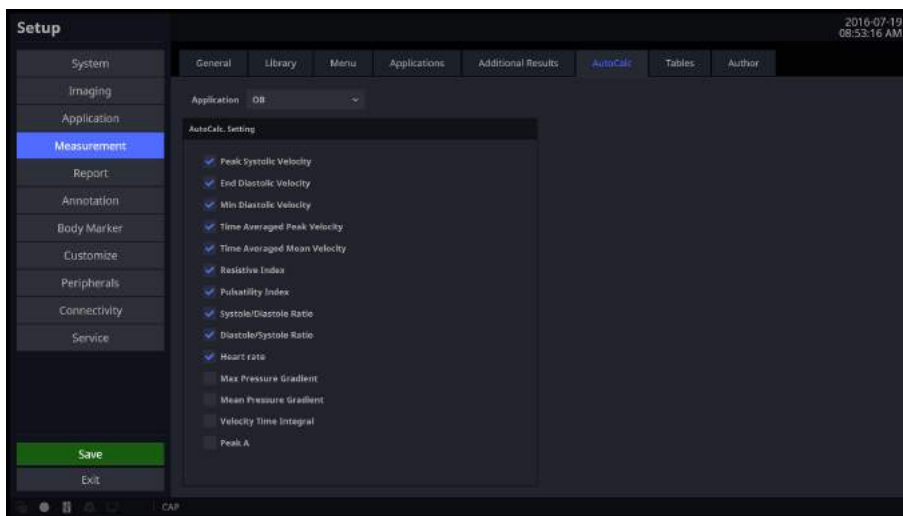


## AutoCalc.

In the *Setup* screen, select the **AutoCalc.** tab in the **Measurement** category. AutoCalc. is a Spectral Doppler Mode feature that automatically performs specific calculations based on measured values.



**NOTE:** The specified items will only appear on the screen when the **AutoCalc.** button on the touch screen is tapped in Power Doppler Mode.



[Figure 3.18 Setup – Measurement – AutoCalc.]

### ❏ AutoCalc. Setting

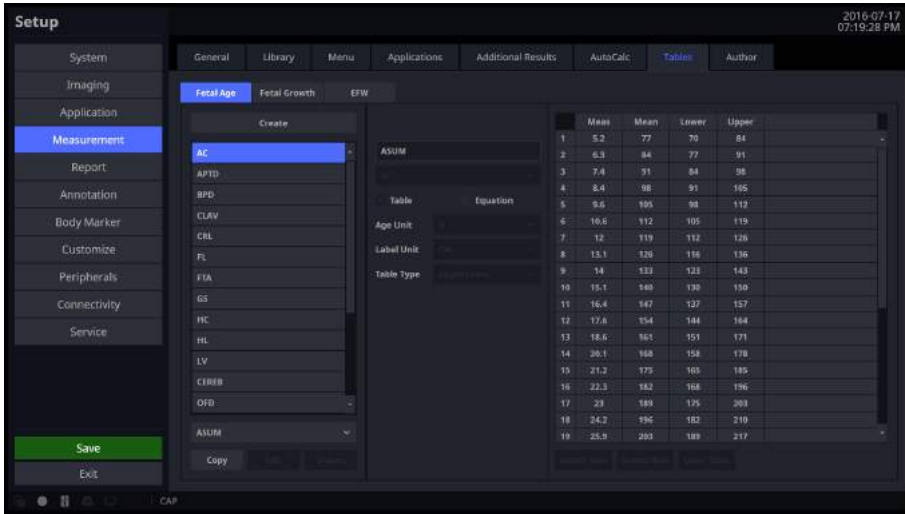
Add and remove automatic calculations by using the check boxes.

When the Peak Systolic Velocity and End Diastolic Velocity values are 0, not all results for the items will be displayed on the screen. In addition, the resulting value for Time Averaged Mean Velocity is displayed only when Mean Trace is turned on.

## Tables

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

View and edit the Tables and Equations to be used in each measurement item of OB.



[Figure 3.19 Setup – Measurement – Tables]

### ■ 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 copied into the combo box and the first Author’s data will be displayed on screen.

### ■ Select Author

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

### ■ Create

Create new Author data.

### ■ Copy

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

### ■ Edit

Modify the currently selected Author data.

### ■ Delete

Delete the currently selected Author data.



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

### ■ Author Name

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



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

### ■ Author Data Label

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

### ■ Author Data Type

Represents the currently selected Author data type.



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

### ■ Age Unit

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

### ■ Valid GA Range

Indicates 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**

Indicates the Label unit for the currently selected Author data. The 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**

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

■ **SD Type**

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

■ **EFW Unit**

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

■ **Equation**

Indicates 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**

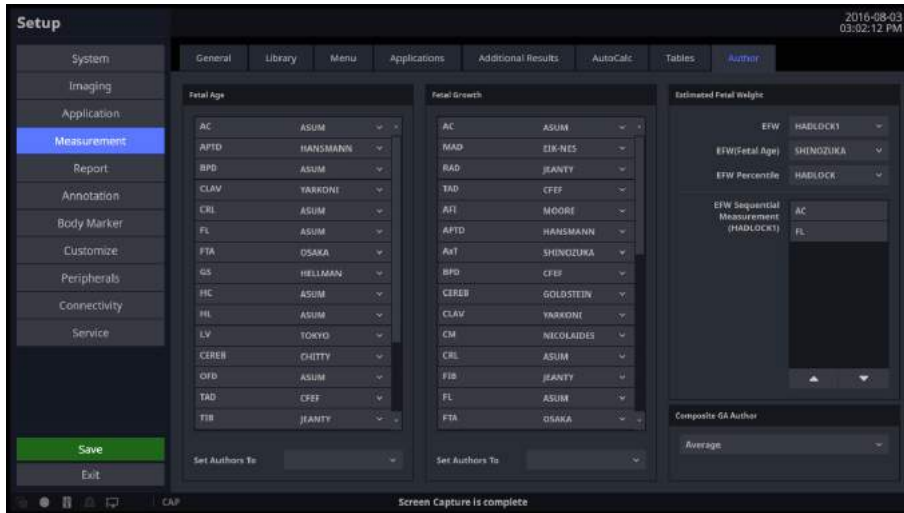
Indicates the table for the currently selected Author data. The table may be changed using the **Insert Row**, **Delete Row**, and **Clear Table** buttons when creating new Author data.



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

## Author

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



[Figure 3.20 Setup – Measurement – Author]

### ❏ 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

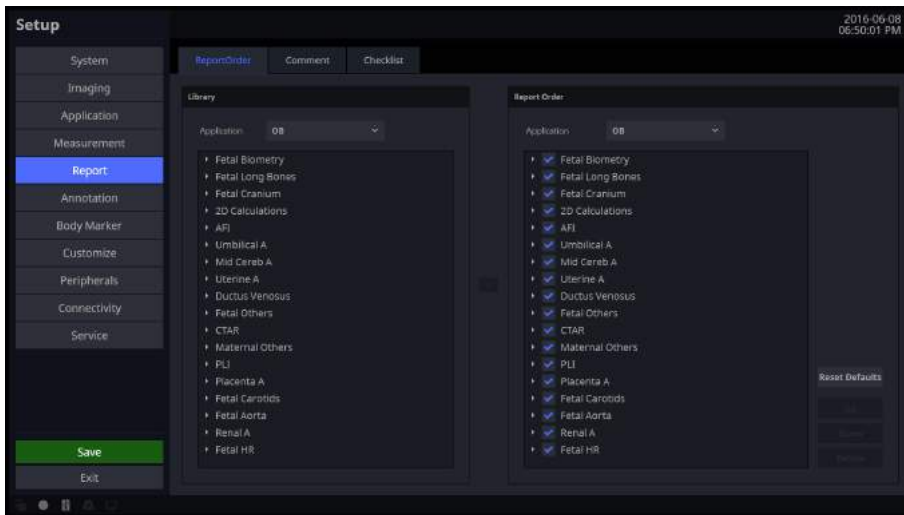
Specify the Author to use for Composite GA.

#### ■ Set Authors To

This enables the user to set all applicable measurement values at a time as selected in the applicable list box.

## Report

In the *Setup* screen, select the **Report** tab. Or tap **Report** on the touch screen. Here you can set items related to the measurement report.



[Figure 3.21 Setup – Report – Report Order]

## Report Order

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

### Library

Application ComboBox: It provides a list of labels for each application.

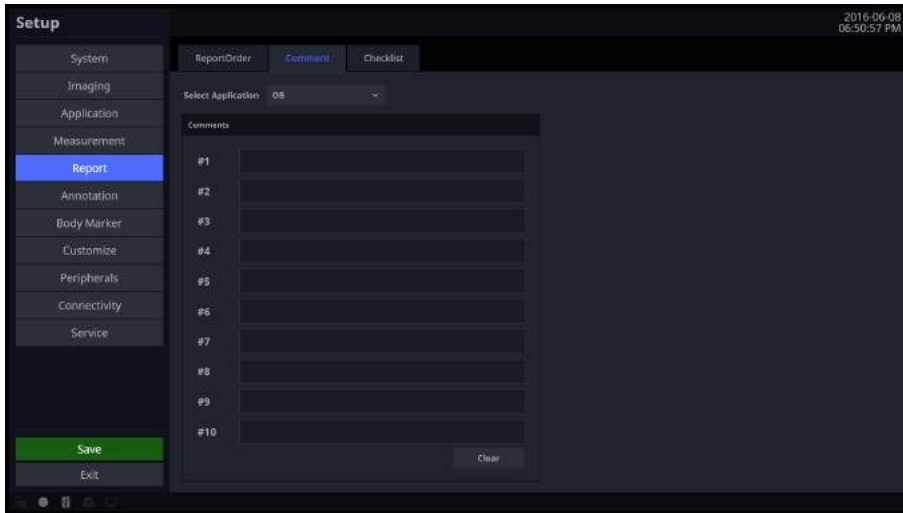
### Report Order

You can add items from the library to the Report Order list.

- ▶ Reset Defaults: Restores the default settings for Report Order.
- ▶ Up/Down: Change the order (up/down) of the selected items in Report Order.
- ▶ Delete: Removes the items from the library when they've been moved by the user. (Original items in the Application cannot be deleted.)

## Comment

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



[Figure 3.22 Setup – Report – Comments]

### ❏ Select Application

Display all diagnostic measurement information and select the measurement information to show in Report.

### ❏ Comments

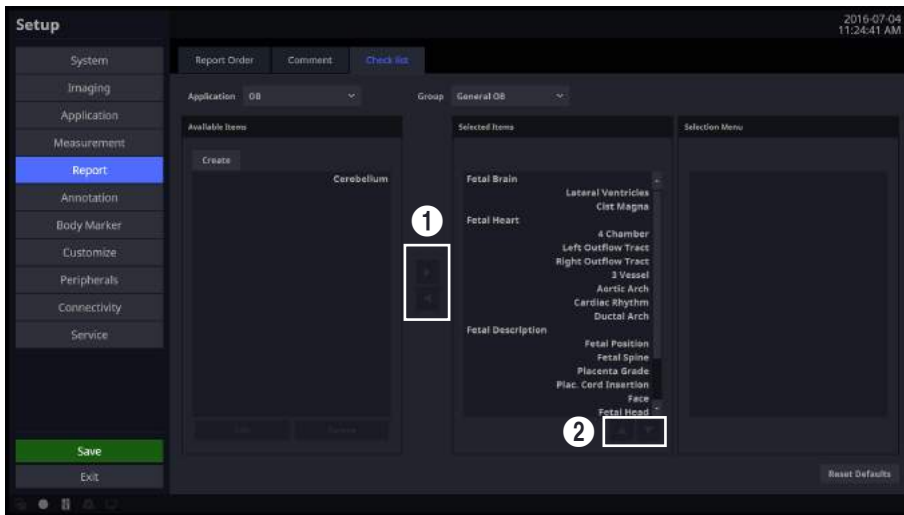
The user can enter comments manually.

#### ■ Clear

Delete saved comments. When executing Unfreeze, any annotation is deleted.

## Checklist

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



[Figure 3.23 Setup – Report – Checklist]

### ■ Application

Select an available application. Preset items exist for this application, but for other applications, only user-added items are available.

### ■ Create

Create a user item. Enter a name and category, then tap the **OK** button to create, or tap the **Cancel** button to reset all values to the defaults.

### ■ 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 a list of the lower-tier items belonging to an item you have selected that has been added to the Anatomy page.

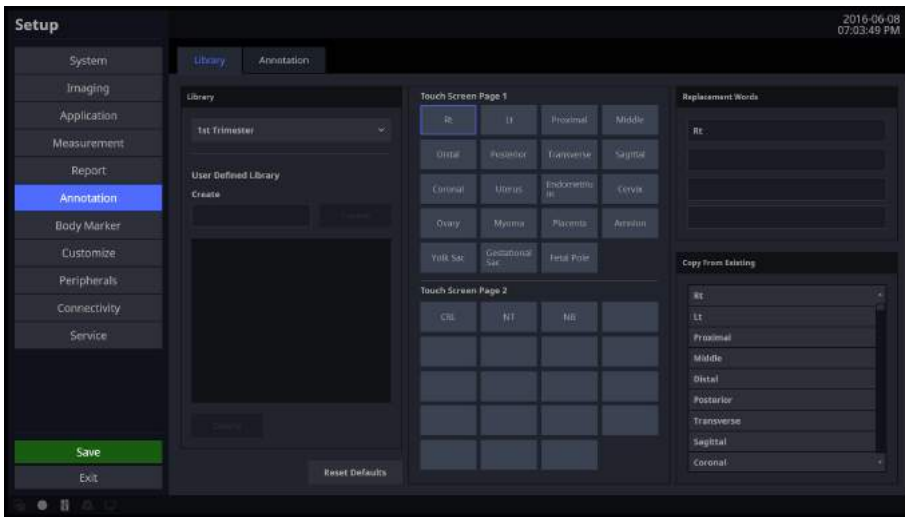
- ▶ Edit: Items added by the user can be edited.
- ▶ Delete: Items added by the user can be deleted.
- ▶ Users can tap the **1** button in the Figure 3.23 to add or remove a selected item.
- ▶ User can tap the **2** button in the Figure 3.23 to change the order of the selected items.

## Annotation

In the *Setup* screen, select **Annotation**. Or tap **Annotation** on the touch screen. Set up 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 3.24 Setup – Annotation – Library]

### Library

Select an application type.

### User Defined Library

The user can enter or delete text.

#### Create

Create text.

- **Delete**

Delete text.

- **Reset Defaults**

Revert to default settings.

- **Touch Screen Page1**

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

- **Touch Screen Page2**

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

- **Replacement Words**

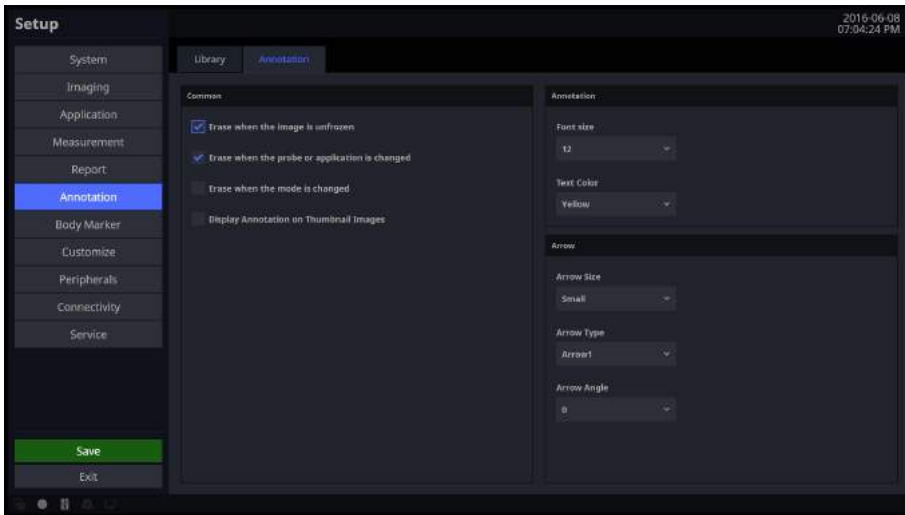
Select and edit the text you wish to modify and then save it by tapping the **Save** button. Up to four different preset text entries can be added for one text button.

- **Copy From Existing**

Select and set up items provided by the system.

## Annotation

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



[Figure 3.25 Setup – Annotation – Annotation]

### Common

#### ■ Erase When the Image is Unfrozen

When executing Unfreeze, the annotation is deleted.

#### ■ Erase When the probe or application is changed

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

#### ■ Erase When the mode is changed

Select whether or not to erase annotations when the diagnosis mode is changed.

#### ■ Display Annotation on Thumbnail Images

Select whether or not to display annotations on thumbnail images.

## Annotation

### ■ 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.

## BodyMarker

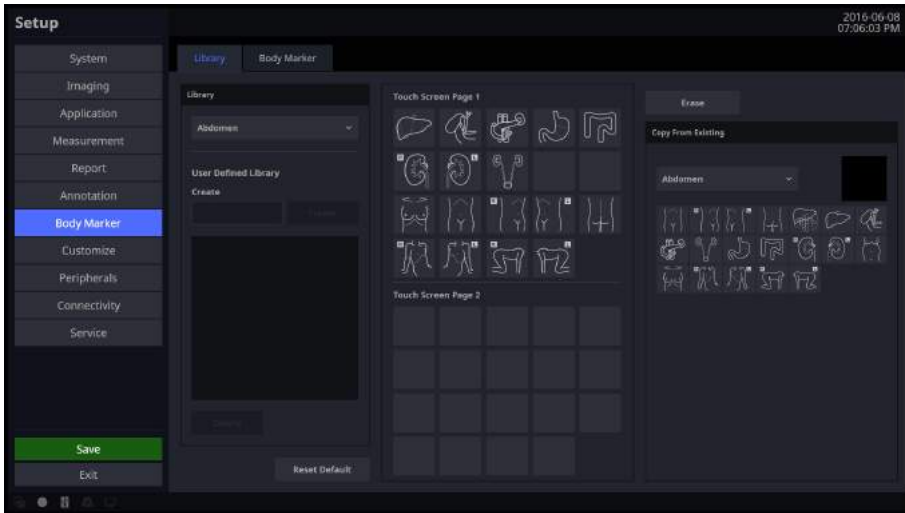
In the *Setup* screen, select the **BodyMarker** tab. Or tap **BodyMarker** on the touch screen.

### Library

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

You can create, edit, or delete a library in the BodyMarker category.

1. On Touch Screen Page 1 or Touch Screen Page 2, use the trackball to select the location you want; the touch button will be selected.
2. In Copy From Existing, select the BodyMarker you want; the new BodyMarker will be created at the location marked in blue.
3. On Touch Screen Page 1 or Touch Screen Page 2, use the trackball to select a BodyMarker to display it in blue; tap **Erase** to delete the BodyMarker.



[Figure 3.26 Setup – BodyMarker – Library]

## **Library**

Select an application.

## **User Defined Library**

The user can create or delete a Library.

### ■ **Create**

Create a new Library.

### ■ **Delete**

Delete a BodyMarker.

### ■ **Reset Defaluts**

Revert to default settings.

## **Touch Screen Page1**

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

## **Touch Screen Page2**

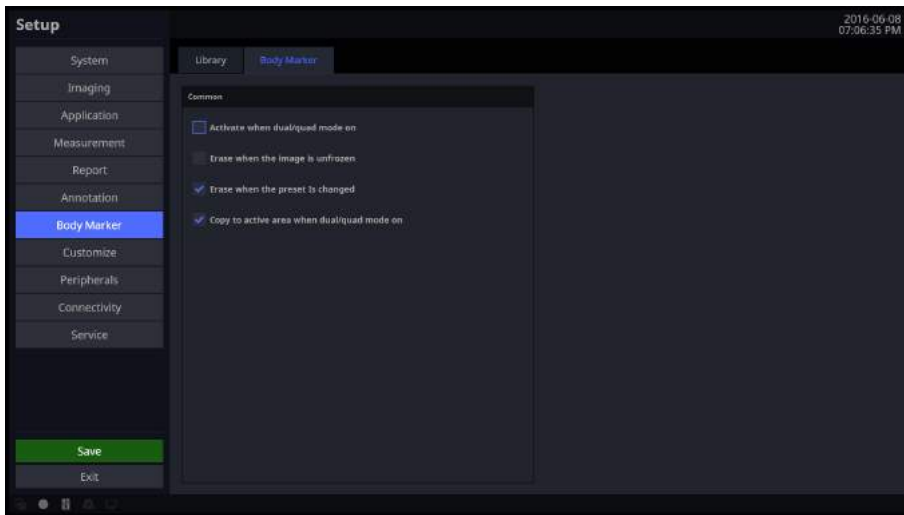
Specify the items that will be displayed on the second page of the touch screen.

## **Copy From Existing**

Select and set up the BodyMarker provided by the system.

## BodyMarker

In the *Setup* screen, select the **BodyMarker** tab in the **BodyMarker** category.



[Figure 3.27 Setup – BodyMarker – BodyMarker]

### Common

#### ■ Activate when dual/quad mode on

Show or hide BodyMarker when Dual or Quad Mode is active.

#### ■ Erase when the image is unfrozen

Choose whether or not pressing the **Freeze** button on the control panel to switch to Scan Mode automatically deletes the BodyMarker.

#### ■ 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

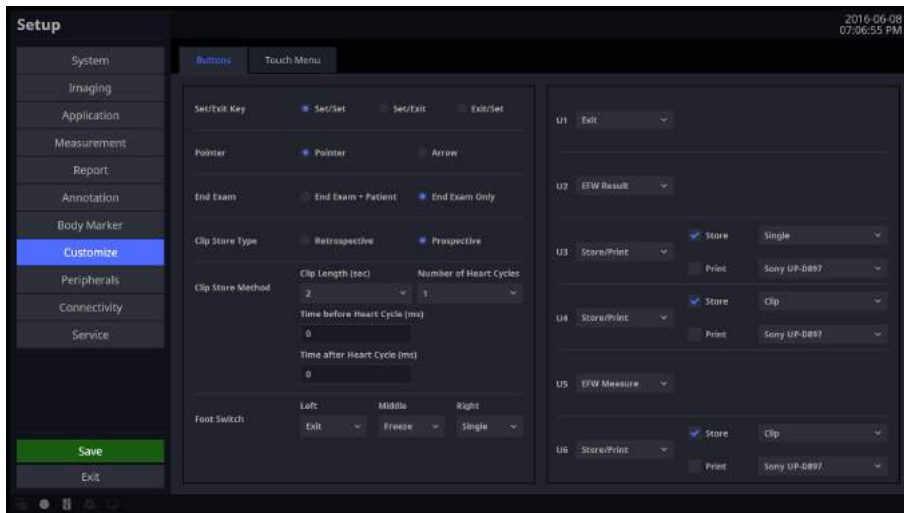
Select whether or not to copy the BodyMarker to the active area when Dual or Quad Mode is activated.



## Customize

### Buttons

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



[Figure 3.28 Setup – Customize – Buttons]

### ■ Set/Exit Key

Select the functions to assign to the buttons on the left and right sides of the trackball on the control panel.

#### ■ Set/Set

Both the left and the right buttons are set to the **Set** function.

#### ■ 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**.

## ❏ Pointer

Select Pointer or Arrow.

## ❏ End Exam

### ■ End Exam + Patient

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

### ■ End Exam Only

Pressing the **End Exam** button on the control panel closes the exam and switches the screen to *B mode Scan* screen.

## ❏ Clip Store Type

### ■ Retrospective

When saving images, images before pressing the save button are saved.

### ■ Prospective

When saving images, images after pressing the save button are saved.

## ❏ Clip Store Method

### ■ Clip Length (sec)

Specify the length of the image to save. Select one of 2, 4, 6, 8, 10, 20, 30, 60, 120, 240, and 360 seconds.

### ■ Number of heart cycles

Specify the number of Heart Cycles to be included in the image.

### ■ Time before heart cycle (ms)

Specify the time to be included before a Heart Cycle begins from 1 to 10 hours.

### ■ Time after heart cycle (ms)

Specify the time to be included before a Heart Cycle completes.

### ■ Foot Switch

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

- ▶ Exit, Freeze, U1, U2, U3, U4, U5, U6, Update, Single, and Quad.

### ■ User Key

Assign functions to the **U1**, **U2**, **U3**, **U4**, **U5**, and **U6** buttons on the control panel.

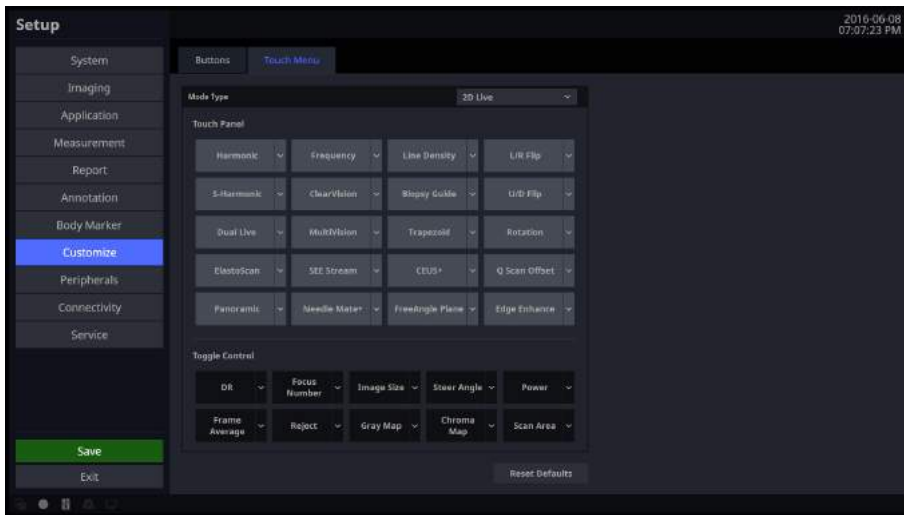
The functions you can assign are as follows:

U1, U2, U3, U4, U5, U6		
Patient	Quad	Arrow
Exit	Dual Live	Pointer
TGC	Biopsy	Probe Change
Q scan	Simultaneous	TDI
Harmonic	EFW Measure	TDW
Single	EFW Result	Store/Print

- ▶ When Store/Print is set, additional functions for Store (Single, Clip), and Print can be set.

## Touch Menu

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



[Figure 3.29 Setup – Customize – Touch Menu]

### Mode Type

2D Live, 2D Freeze, C/PD Live, C/PD Freeze, PW Live, PW Freeze, CW Live, CW Freeze, M Live, M Freeze, ECG Live, ECG Freeze, Panoramic Ready, Panoramic Review, ElastoScan Live, ElastoScan Freeze, Strain+ Ready, CEUS+ Live, CEUS+ Freeze, and Lithotripsy functions can be set.

\* SEE Stream Live and SEE Stream Freeze are only available in Russia.

### 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 Defaults

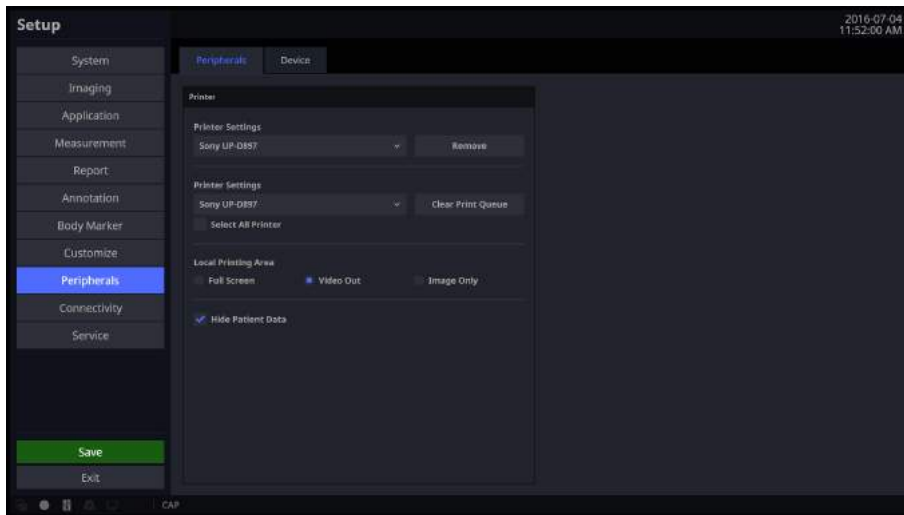
Revert to default settings.

## Peripherals

In the *Setup* screen, select the **Peripherals** tab. 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 3.30 Setup – Peripherals – Peripherals]

## Printer

### ■ Printer Settings

Select the printer to use by using the combo button. To remove a printer that is no longer used, select the printer and press the **Remove** button.

### ■ Clear Printer Queue

Choose whether or not to cancel a printer job while an image is being printed. Use the combo button to select a printer that is printing an image. Press the **Clear Print Queue** button to cancel the print job.

#### ▶ Select All Printers

Select this checkbox to cancel all print jobs for the connected printer.



**NOTE:** A print job can be canceled only if the image data to print has not been completely sent to the printer.

### ■ Local Printing Area

Select the area that will be printed.

- ▶ Full Screen: Prints everything shown on the monitor screen.
- ▶ Video Out: Prints only a certain area of the screen, including the Image area.
- ▶ Image Only: Print out the image area only.

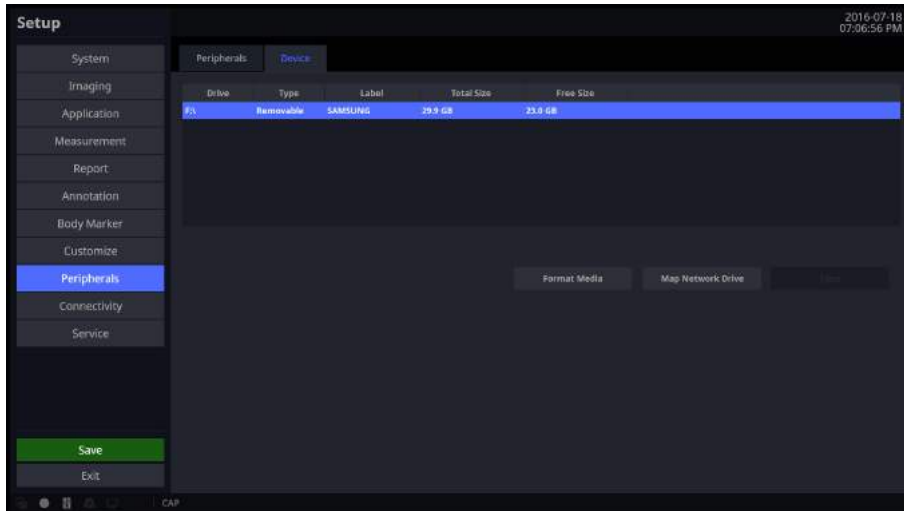
### ■ Hide Patient Data

Select whether or not to display the patient information.

## Device

In 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 3.31 Setup – Peripherals – Device]

## Map Network Drive

Connect to a network.

1. Press **Map Network Drive** button.
2. Select a Drive Name.
3. Enter a Network Folder path.
4. Enter User ID and password and then press the **Connect** button.
5. Select a Drive Name and press the **Disconnect** button to close it.

## Connectivity

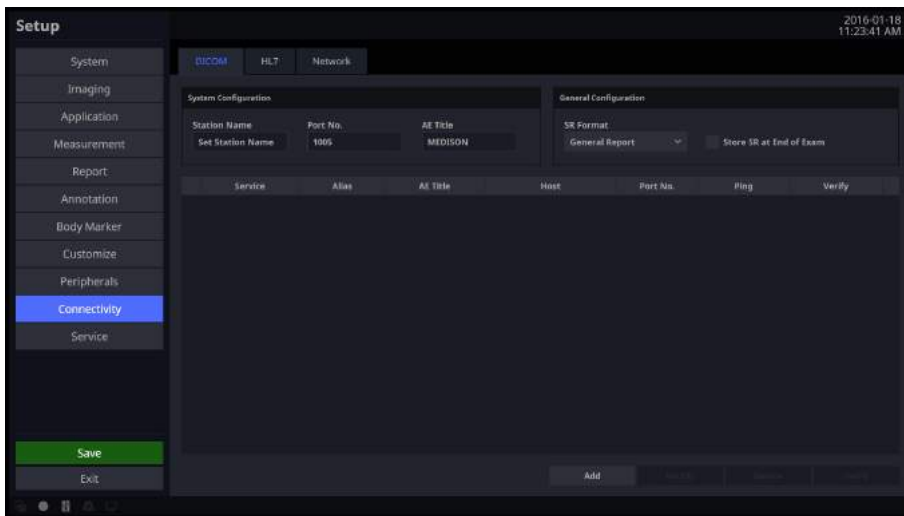
Tap Connectivity on the touch screen. You can perform DICOM administration tasks or manage DICOM server settings and network information for your system.

### DICOM

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



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



[Figure 3.32 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 the '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.

### ■ Port No.

Enter the port number of the server being used.

### ■ AE Title

Enter the name of the DICOM AE (Application Entity). Used for identifying the equipment that uses DICOM on the network.

## General Configuration

### ■ SR Format

Select a format to be used to save SR among General Report and Viewpoint.

### ■ Store SR at End of Exam

Select whether or not to store the SR at the end of the exam. When you select this checkbox, the 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. Tap **Cancel** to cancel.

### ■ DICOM Services

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

### ■ 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.

### ■ Host

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

### ■ Port No.

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

### ■ Connect Timeout

The connection will time out if there is no response from the DICOM server 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**

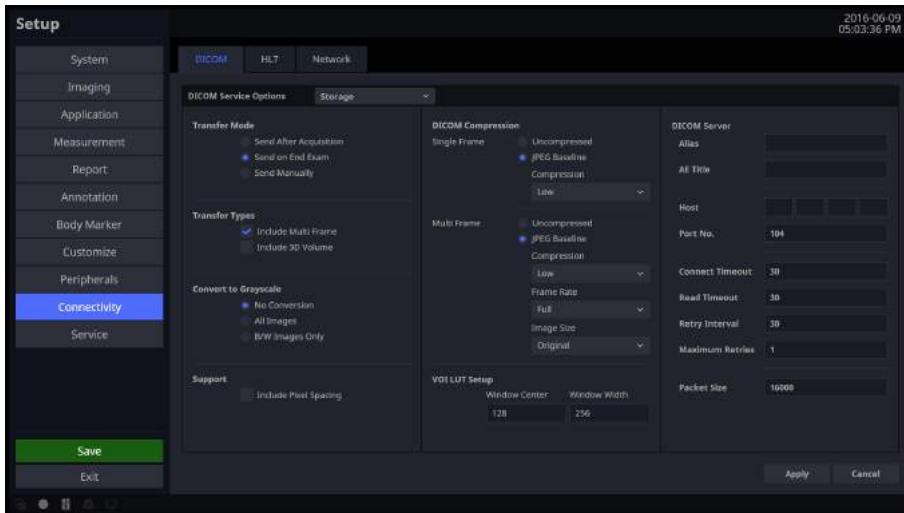
Specify how many times a failed transmission will be retried.

■ **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 3.33 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 or not 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 you want 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 Image 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 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 the JPEG Baseline is selected, you need to select Low, Medium, or High. 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, or 20 as the frame rate for Multi Frame.

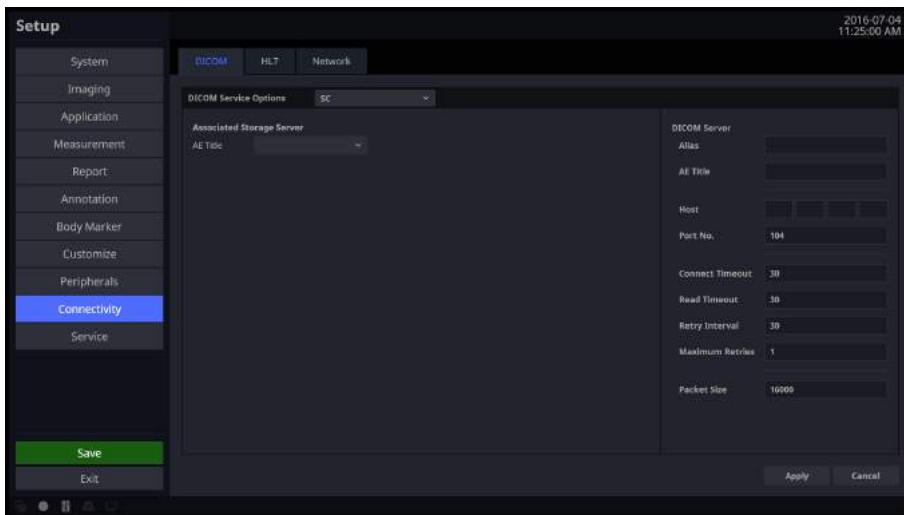
### ■ VOI LUT Setup

Configure the 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 will get 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 contrast of the image displayed by the storage service. Values set to higher than 256 will result in lower contrast. Note that this function is available only when it is supported by the storage service.

## SC Server Information

Select 'SC' (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.



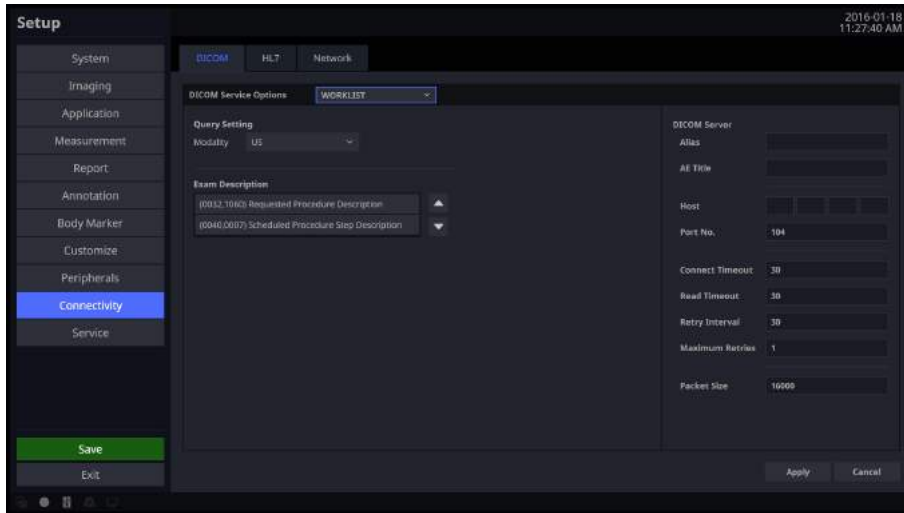
[Figure 3.34 DICOM Service Options – SC]

### ■ Associated Storage Server

Select an Image Storage server to connect to.

## WORKLIST Server Information

Select WORKLIST as the **DICOM Service Options** item. Set Modality Worklist service by using DICOM.



[Figure 3.35 DICOM Service Options – WORKLIST]

### ■ Query Setting

Select the type of Modality to retrieve when updating the worklist.

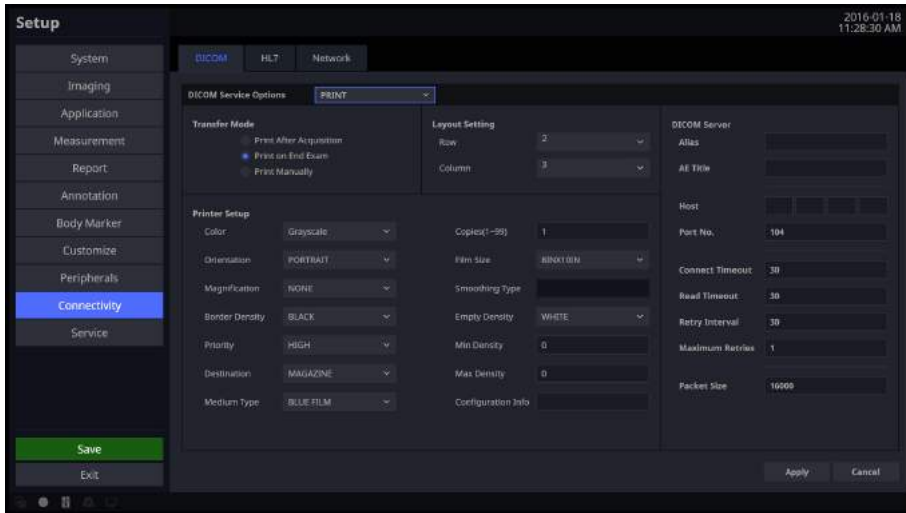
- ▶ Modality: Select either ultrasound images (US) or all images (All).



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 3.36 DICOM Configuration – PRINT]



**NOTE:**

- ▶ You can only configure printers connected to the DICOM network.
- ▶ Depending on the printer, some of the following functions may not be available. Before configuring a printer, please refer to the printer’s user manual, or the 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 Setting

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

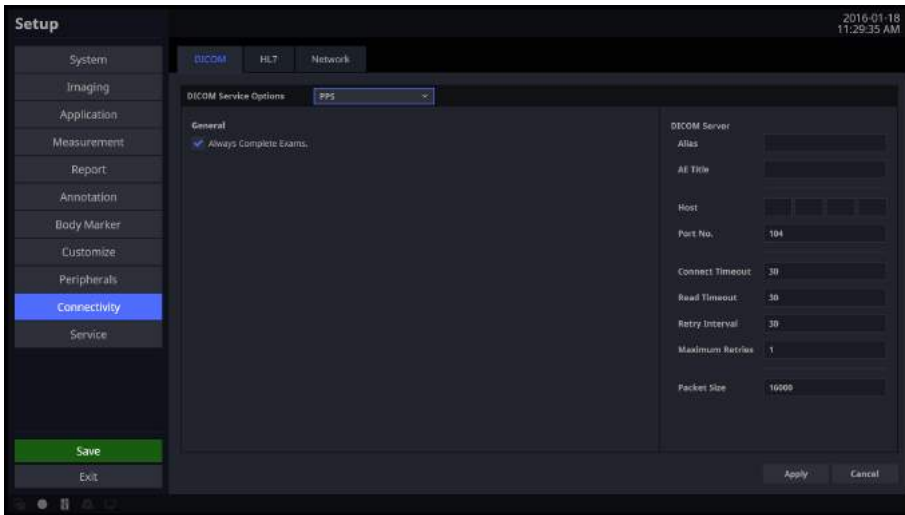


## ■ Printer Setup

- ▶ Color: Specify whether to use colors. Select Grayscale or RGB.
- ▶ Orientation: Specify the paper orientation. Select either Landscape or Portrait.
- ▶ Magnification: Specify the interpolation when resizing an image to print. Select from Replicate, Bilinear, Cubic, or None.
- ▶ Border Density: Specify the border color of the image to be printed. Select Black or White.
- ▶ Priority: Specify a priority for the print command. Select High, Med, or Low.
- ▶ 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, or Mammo Blue Film.
- ▶ Copies (1–99): Enter the number of copies to print, using a value between 1 and 99.
- ▶ Film Size: Select a paper size from 8×10 inches, 8.5×11 inches, 10×12 inches, 10×14 inches, 11×14 inches, 11×17 inches, 14×14 inches, 14×17 inches, 24×24 cm, 24×30 cm, A4, or A3.
- ▶ Smoothing Type: This option is available only when Magnification is set to CUBIC. Enter the value for the printer which is specified in the DICOM Conformance Statement.
- ▶ Empty Density: Specify the background color of an image to print. 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.

## PPS Server Information

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



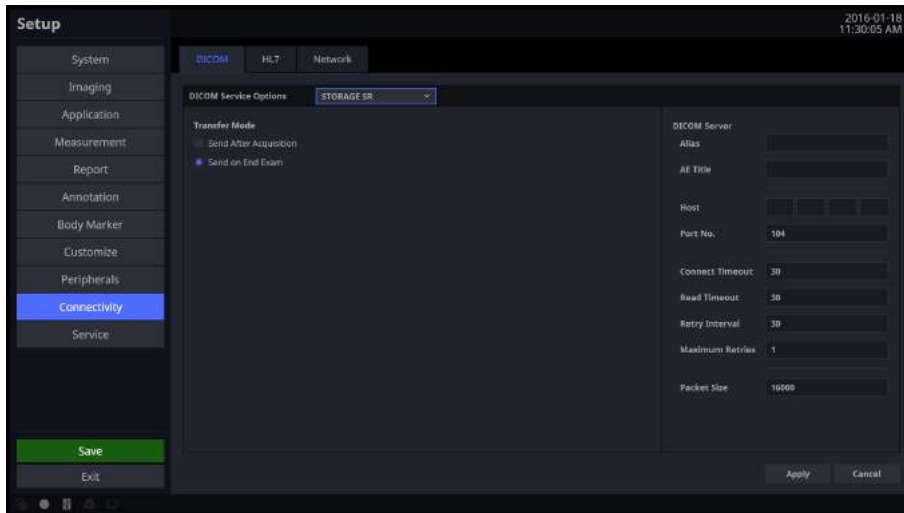
[Figure 3.37 DICOM Service Options – PPS]

### ■ Always complete exams

When you check this checkbox, exams are always reported in their final state. If you press the **End Exam** button without selecting a checkbox, the cancellation message that was selected after you selected the cancellation message for End Exam 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.



[Figure 3.38 DICOM Service Options – STORAGE SR]

### ■ 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.

## QR Server Information

Select 'QR' as the **DICOM Service Options** item. The configuration options are the same as those for the storage server.

### ❏ Modifying DICOM Information

Select a service and click **Modify** on the screen. The information on the selected service will appear. After changing the information, click **Apply** to save the changes. Tap **Cancel** to cancel.

### ❏ Deleting DICOM Services

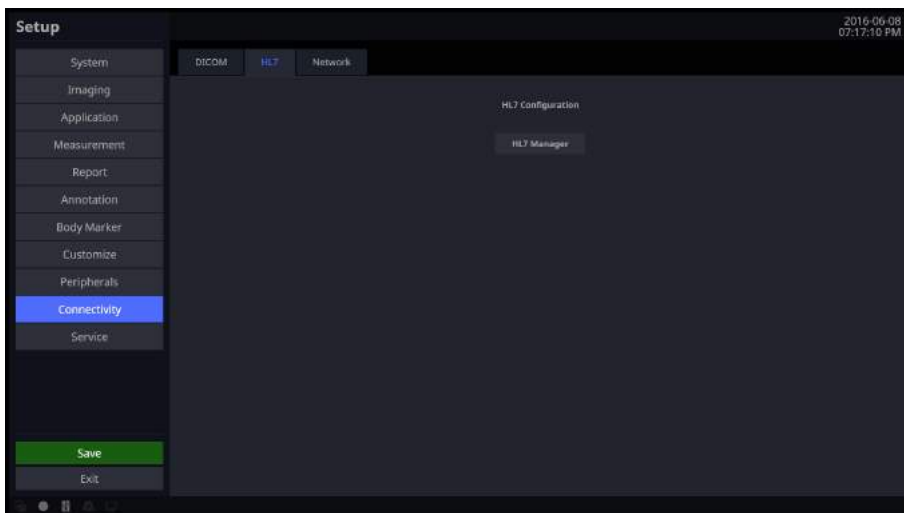
Select a service and click **Delete** on the screen.

### ❏ 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 Verify. If the result is Success, the connection is normal.

## HL7

Include the Measurement Data PDF in the HL7 Message and send it to the HL7 Repository server. Select the HL7 tab and click the HL7 Manager button on the screen.

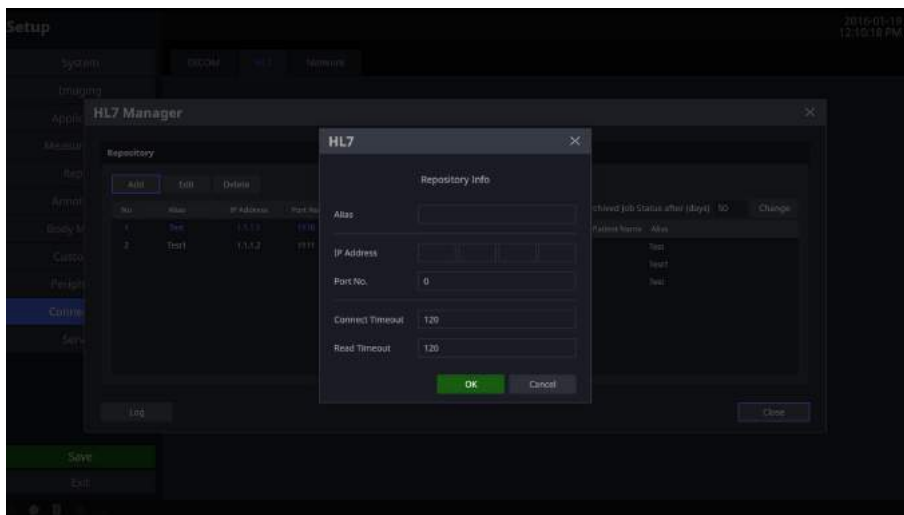


[Figure 3.39 DICOM HL7 – HL7 Manager]

## ■ Repository

Register, edit, and delete a report repository server to send reports to.

- ▶ Add Repository: Add a repository to send an HL7 message.
  - Alias: Refers to a name of the HL7 repository server to send an HL7 message to.
  - IP Address: Enter an IP address for the HL7 repository server.
  - Port No: Enter the port number of the HL7 repository server. (a value between 0 and 65535)
  - Connect Timeout: Select a time for transfer standby in seconds. (a value between 120 and 300)
  - Read Timeout: Set the standby time for transmission in seconds. (a value between 120 and 300)



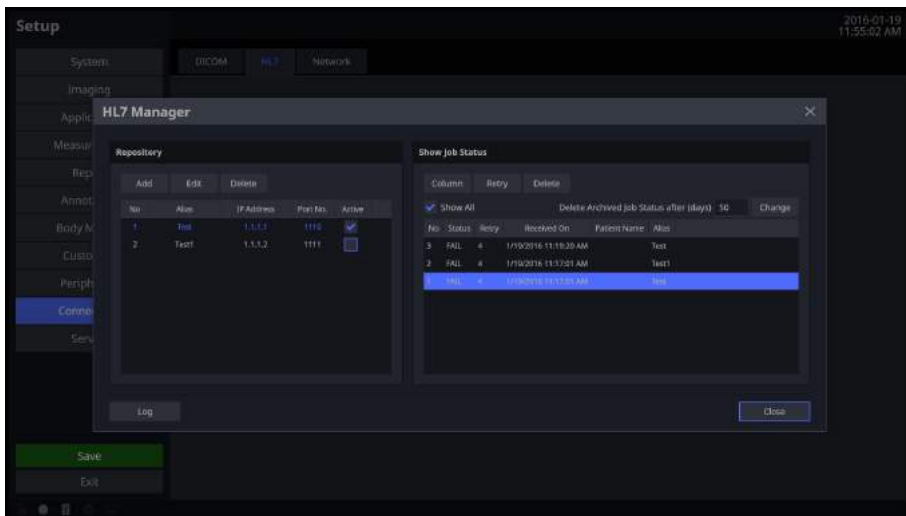
[Figure 3.40 DICOM HL7 – HL7 Manager]

- ▶ Edit Repository: Edit the repository server information.
- ▶ Delete Repository: Delete the repository server information.
- ▶ Active/Inactive Repository: Select whether or not to use the repository server by selecting the Active checkbox for the registered repository.

■ **Show Job Status**

Shows the information regarding the transfer of the HL7 report into an HL7 message.

- ▶ Columns: The user can select columns to check.
- ▶ Retry: The user can select and retry the failed jobs.
- ▶ Delete: The user can delete a job, whether the status is 'SUCCESS' or 'FAIL'.
- ▶ Show All: Shows all jobs.
- ▶ Delete Archived Job Status after(days): Delete archived jobs for the selected dates.



[Figure 3.41 DICOM HL7 – HL7 Manager]

## ■ HL7 Export

If there is an Active repository server registered to the HL7 Manager, the user can export the report by selecting the **HL7** button after taking at least one measurement on the *Report* screen. (However, patient information must exist and a warning message asking for a valid patient ID will appear if the information has not been entered.)

The screenshot shows the 'Report' screen with the following sections:

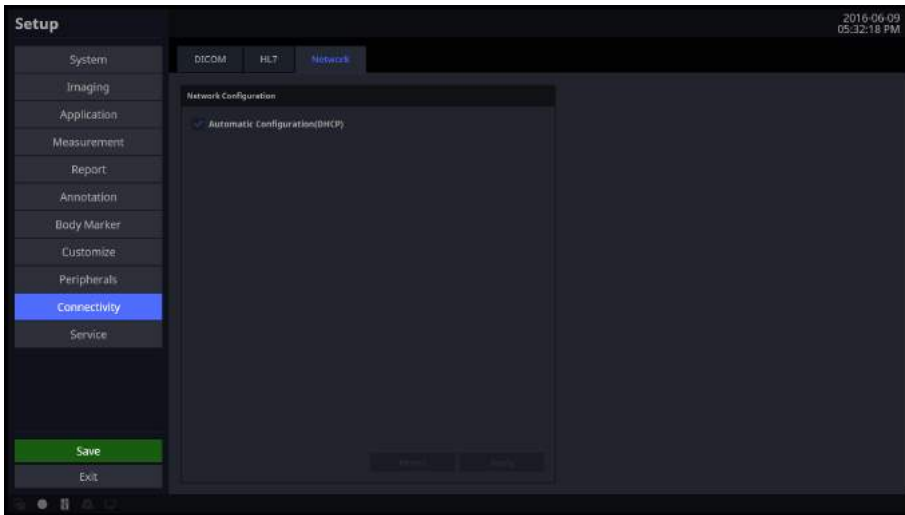
- Header:** Patient ID (20160305-053929PM), Name, Date of Birth (Age), Gender, Indication, Diag. Physician, Ref. Physician, Operator.
- OB (Fetus A):** LMP, Crown-Rump GA, Average GA (GA), 10w GA, EDG (LMP), EDG (GA), 2017-01-04, Gravida, Para, Ectopic, Alberta, EFW1, HVD, CVT, ACFL, BW g ±14 g, Date PRNG, WILLIAMS.
- Fetal Biometry:** Table with columns for measurement (CC, VC, CRL, BPD, FL, AC), units (mm, cm), and last measurement date.
- Z/B Calculations:** FLIAC, FLIAPD, and their respective percentages.
- Gynecology:** LMP, Gravida, Para, Ectopic, Alberta.
- Uterus:** Table with columns for Length, Fetal Weight, and other parameters.

Left sidebar buttons: Preview, Worksheet, OB Graph, Description, Image, Comment, Store SR, HL7, Print, Export, Exit.

[Figure 3.42 Report – HL7 Export]

## Network

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 3.43 Setup – Connectivity – Network]

### ❏ Network Configuration

Set up the network information for the current equipment.

#### ■ Automatic Configuration (DHCP)

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

#### ■ Static Configuration

If the checkbox is empty (Automatic Configuration), you can enter a static IP address. Specify the IP Address, Subnet Mask, Gateway, and DNS information.

#### ■ Revert

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

#### ■ Apply

Use the information entered currently to set up the IP.



## Service

**NOTE:**

- ▶ Users should not attempt to perform anything on their own. They must contact the customer service department of Samsung Medison who can perform this service for them.
- ▶ Restore saved basic patient information and images or changes to the software.
- ▶ Enable or disable optional software or hardware.
  - Option: Show the types of optional software that can be installed on the product.
  - Status: Show the current status of optional software. Registered means that the software can be used until the date specified by the Expiration Date is reached. Unregistered means that the software cannot be used now.
- ▶ Displays the software version of the product.
- ▶ It provides the built-in self test function.

## Help

Press the **Help** button on the keyboard. The electronic manual will appear on the monitor screen. When pressing the button again, it disappears.



**NOTE:** *Help* screen does not provide **Return** key.

## :: Strain+ Image (Optional)

Strain+ Image visualizes the movement of the myocardial muscle to help to diagnose myocardial infarction or disease.



**NOTE:**

- ▶ Strain+ is an option of this product.
- ▶ This function is only available in the HS60 product.C



**NOTE:** The Strain+ Image function can only be used when the following conditions are met:

- ▶ Application: Cardiac
- ▶ Diagnosis Mode: 2D (Freeze state)
- ▶ ECG: On; two or more ECG trigger points; ECG HR: 30–240 Range

### ■ Select an Image

Select an image to analyze, using the trackball and the control panel’s **Set** button.



Select an image by referring to the following:

- ▶ Select an image that shows the entire wall of the heart.
- ▶ We recommend that there should be an R-Peak before/after the selected image, and there should be more than 70 Cine frames between the previous R-Peak and the last image.



-----R----- R-----Selected image-----

[Figure 3.44 R-Peaks]

### ■ Quantification

You may select Strain+ or Auto EF.



**NOTE:** When the image selection is not appropriate, it does not go to *Quantification* screen.

## Strain+

Tap **Strain+** button on the touch screen. It goes to *Strain+* screen.

Strain+ is executed in the following order:

Select an image → Set up the contour line → Calculate Strain data → Analyze the result

### Select an Image

Select the image and chamber information.

The *Strain+* screen is composed as follows:

1. Thumbnail list: Saved images will be displayed as thumbnails.
2. Image Area: The images selected from the Thumbnail list are displayed.
3. Operation Guide: Instructions for using the Strain+ function are displayed on the screen. Select **Show/Hide** to enable or disable the function.

#### ■ Select Images

You need to select three images. Use the trackball and the **Set** button on the control panel to double-click the image you wish to use. Alternatively, select an image and then click the pointer on the desired location in the image area.



**NOTE:** If one or more conditions for using the Strain+ Image function (Cardiac, 2D Mode, ECG On) are not met, the missing criteria will be displayed in red at the top left corner of the image.

#### ■ Selecting Cine Position

Set up the Cine for each image displayed in the image area.

#### ■ Selecting Chamber Information

Use the combo box buttons at the top left corner of each image. Set to 2ch, 3ch, 4ch, Apex short, Mid short, or Basal short.



**NOTE:**

- ▶ To use Multi-Analysis, you must select 2ch, 3ch, or 4ch.
- ▶ If there is previously saved Strain+ data, it will be set up automatically.

### ■ Moving to the Next Step

Tap the **Next** button on the touch screen.



**NOTE:** If chamber information has not been selected (Not Assigned), tapping the **Next** button will not take you to the next step.

### ■ Strain+ Close

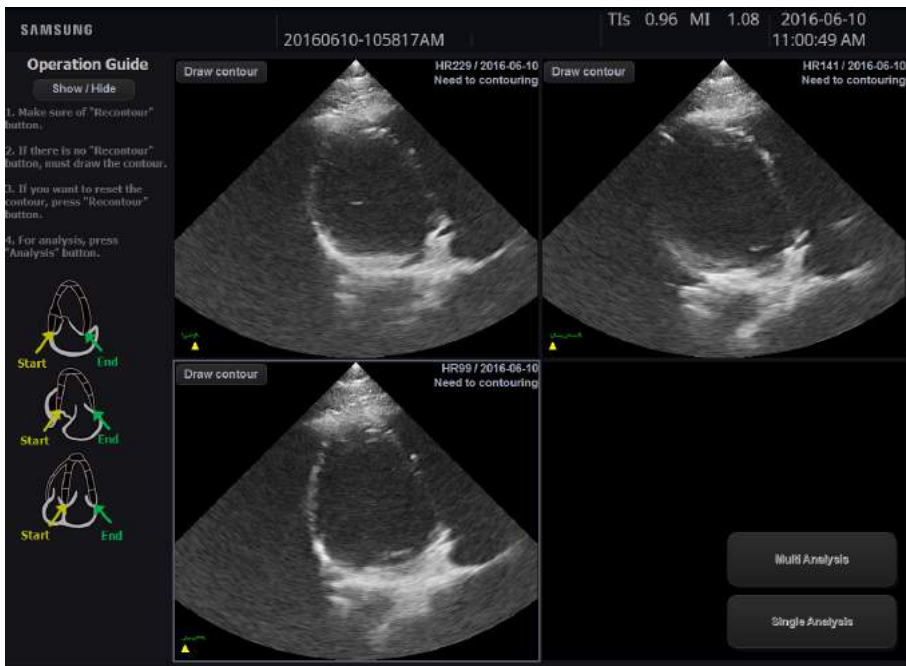
Tap the **Close** button on the touch screen.

## ▣ Contour Line Setup and Calculations

Tap the **Next** button on the *Strain+* screen. The screen will switch to the *Contour Setup* screen.

In the *Contour Setup* screen, a contour line will be drawn on the image and the calculations based on it will be carried out. When an image is selected, it will be surrounded by green borders if the image contains Strain+ data, or by gray borders if it does not.

The Operation Guide will be displayed on the left-hand side of the screen. Click **Show/Hide** to show or hide the guide.

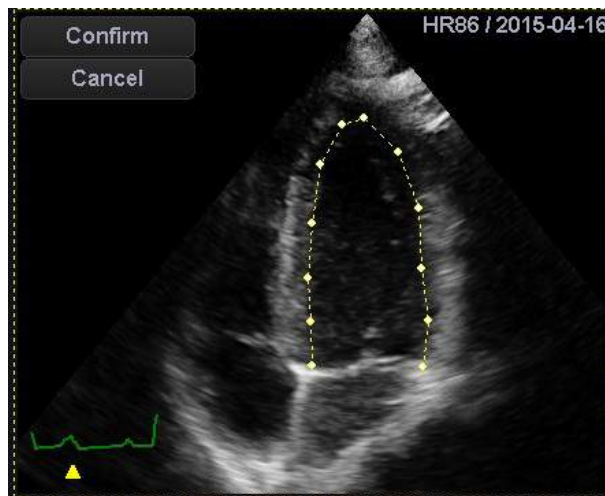


[Figure 3.45 Contour Setup Screen]

### ■ Step 1: Draw and Generate an Endocardial Contour Line

Use the **Draw contour** or **Recontour** button at the top left-hand corner of each image. The image will be surrounded by a yellow dotted border while a contour line is being drawn.

- ▶ **Draw contour:** This will be displayed on images that do not contain Strain data. Click this button, and then use the trackball and the **Set** button on the control panel to specify the point at which to draw a contour line.
- ▶ **Recontour:** This will be displayed on images that contain Strain data. To redraw the contour line, click this button, and then use the trackball and the **Set** button on the control panel to specify the point at which to draw the contour line.
- ▶ While the user is drawing the contour, two buttons, **Confirm** and **Cancel**, will be enabled in the top left-hand corner of each image.
- ▶ After specifying the points of the Endocardial contours, press **Confirm** to generate a contour.

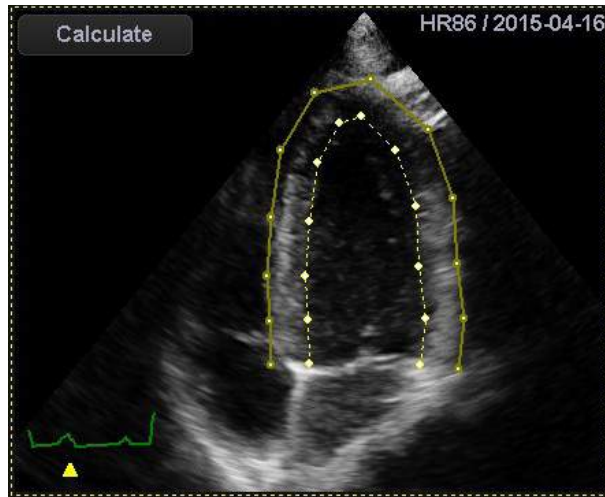


#### NOTE:

- ▶ You must specify five or more points. If fewer than five points have been specified, clicking **Confirm** will display the message 'Abnormal Contour!' and the contour line will be deleted.
- ▶ The method of drawing contour lines differs based on the selected chamber information.

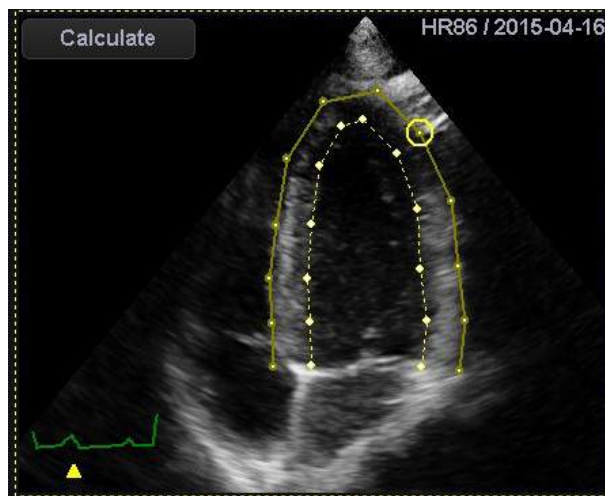
■ **Step 2: Generate or Cancel an Epicardial Contour Line**

The Endocardial contour will be created and the Epicardial line will be displayed 10 mm outside the generated contour line. Tap **Cancel** to cancel and redraw the contour.



■ **Step 3: Modify an Epicardial Contour Line**

Bring the cursor near the point of the Epicardial contour you want to correct. The point will then be surrounded by a yellow border. Press the **Set** button on the control panel and then use the trackball to reposition the point. Press **Set** again to update the Epicardial contour line with the changed point.



#### ■ **Step 4: Calculating Strain Data**

Click **Calculate** displayed on the image. Once the calculations are complete, the image will be surrounded by a sky blue border.

#### ■ **Change Zoom Rate, Contrast, Brightness**

Use the Space bar and Ctrl key on the keyboard to adjust the Zoom Rate, Contrast, and Brightness of the Contour Setup screen.

- ▶ Spacebar: Each time you press the Space bar, the Zoom Rate sequentially changes to 2x, 3x, and 4x.
- ▶ Ctrl + vertical mouse drag: Adjust Contrast
- ▶ Ctrl + horizontal mouse drag: Adjust Brightness

#### ■ **Modifying a Contour**

Bring the cursor near the point you want to correct and the point will be surrounded by yellow borders. Press the **Set** button on the control panel and then use the trackball to reposition the point. Press **Set** again to update the contour line with the changed point.

#### ■ **Calculate Strain+ Data**

Click **Calculate** displayed on the image. Once the calculations are complete, the image will be surrounded by a sky blue border.

## Strain+ Result

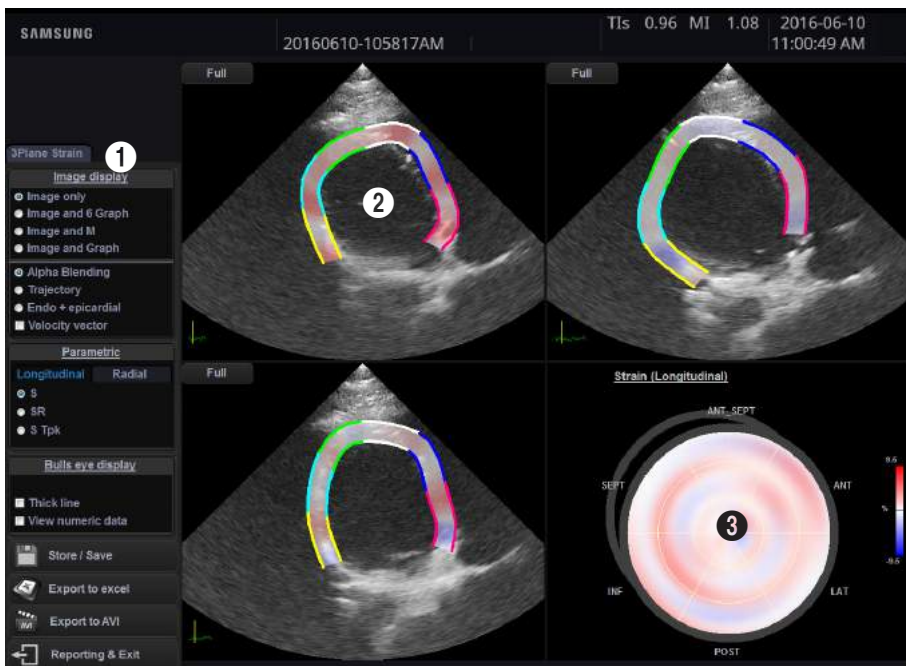
Press **Multi Analysis** or **Single Analysis** on the screen.



**NOTE:** If the image is 2ch, 3ch, or 4ch, the **Multi Analysis** button will be activated. Otherwise, only **Single Analysis** may be used.

The Strain+ result screen is composed as follows:

- ❶ Menu: The on-screen display method, saving, and other items for the data are displayed. For Multi Analysis, 2ch and 4ch Ejection Fraction values are also shown.
- ❷ Image Area: An image with a contour line is displayed.
- ❸ Bull's eye: Information for various slices of the heart (2ch, 3ch, 4ch) is displayed simultaneously. For Single Analysis, only the information for the selected image is displayed.



[Figure 3.46 Strain+ Result Screen]



## ■ Run/Stop

Stop or resume the playback of the image.

### Tips!

#### When Stopped

When stopped, the numeric value will be automatically displayed at the Bull's eye. The numeric value is the numerical Strain+ data based on the color bar. You may select one of the following to review the Strain+ data:

- ▶ Current: The Strain+ data for the current position of the bar is displayed.
- ▶ R-R Interval: The Strain+ data for the R-R interval is displayed.
- ▶ Selected Interval: The Strain+ data for the interval you have selected is displayed.

## ■ Position

Specify the image range to play.

## ■ Image display

Select how to display the image.

- ▶ Image only: Display image only.
- ▶ Image and 6 Graph: Display the image and the segmental graph.
- ▶ Image and M: Display the image and the M Mode.
- ▶ Image and Graph: Display the image and the graph.

### Tips!

#### Image Only

When 'Image only' is selected, pressing the **Full** button at the top left corner of each image will display all graphs and the M mode. Changing the range in M mode will display it in a pink broken line.

To return to 'Image only', press the **3 Plane** button.

### Tips!

#### Image Panning

You can use the trackball to pan the image. Click on the left/right side of the image to pan the image to the left/right side. This is useful when the image is obscured by a graph, etc.

Note that this cannot be used if 'Image only' is selected.

- ▶ Alpha Blending: Displays the movement of the outline.
- ▶ Trajectory: Samples and displays a number of Speckles.
- ▶ Endo + epicardial: Expresses the vector direction, velocity, strain, and movement position of both the endocardium and the epicardium.
- ▶ Velocity vector: Displays the speed on the image.

### ■ Parametric

Select either the **Longitudinal** or the **Radial** tab to configure the settings.

- ▶ S: Denotes Strain.
- ▶ SR: Denotes the Strain Rate.
- ▶ S Tpk: Denotes the Strain Time to Peak.

### ■ Bull's Eye Display

Select how to display the Bull's eye.

- ▶ Thick Line: Select the checkbox to display the border of each segment with a thick line.
- ▶ View numeric data: If the checkbox is selected, numerical data will be displayed at the Bull's eye. When stopped, the numerical data will be always displayed.

### ■ Store/Save

When you press this button, the *Save/Store* screen appears. Save the selected data to the system's hard disk.

- ▶ Strain: Save Strain data only.
- ▶ Screen Capture and AVI: Saves the result along with a captured screen as an AVI file.
- ▶ Strain Data + Screen Capture and AVI: Saves Strain data, the captured screen, and an AVI file.
- ▶ Cancel: Cancels saving.

### ■ Export to Excel

Save the result and the representative image as an Excel file. This is only available if a USB flash memory drive is connected.

### ■ Export to AVI

Save the result as an AVI file. This is only available if a USB flash memory drive is connected.

### ■ Reporting & Exit

The *Confirmation* screen appears. To exit without saving the measurements, press **Close**. To save the measurements and exit, press **Close & Confirmation**. To return to the Strain+ result screen, press **Cancel**.



After finishing reporting in the *Strain+ Analysis* screen, pressing the **Report** button on the control panel opens the Strain Report.

- ▶ The Strain report cannot be edited.

## TMAD

In the Cardiac Preset, execute Freeze and then press the **T-MAD** button. TMAD stands for Tissue Motion Annulus Displacement, which studies the function of the heart by analyzing the displacement of the motion of the annulus.

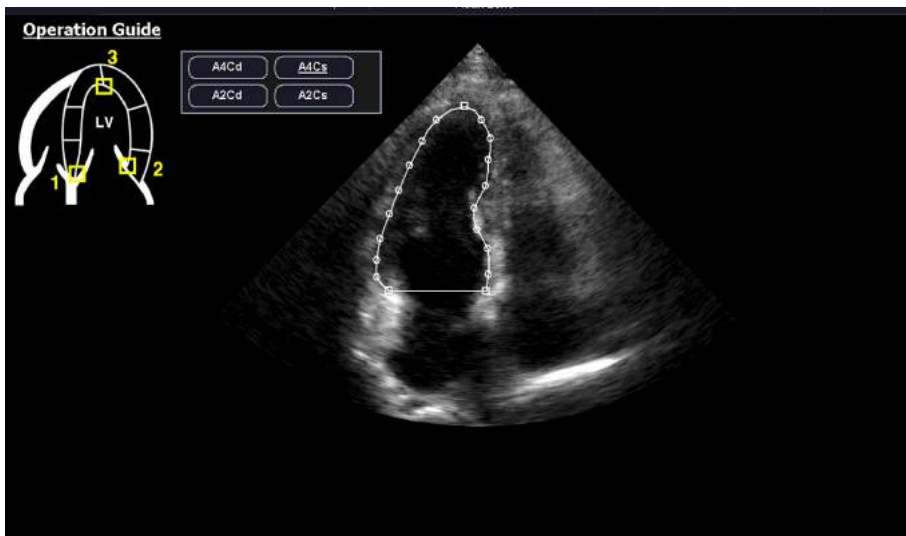


**NOTE:** TMAD function can only be used when the following conditions are met:

- ▶ Application: Cardiac.
- ▶ Diagnosis Mode: 2D (Freeze state)
- ▶ Screen Mode: Single Mode
- ▶ ECG: On

### Setting Up the Points

The Operation Guide will be displayed on the left-hand side of the screen.



[Figure 3.47 Point Setup Screen]

### ■ Designating the Points

These are the names of A4Cd (Apical 4 chamber diastolic), A4Cs (Apical 4 chamber systolic), A2Cd (Apical 2 chamber diastolic), and A2Cs (Apical 2 chamber systolic). The default value at the start is A4Cs. Use the trackball and the **Set** button on the control panel to specify 3 points. First, select a position in the direction of Septal, then a position in the Lateral, and finally one in the Apex. When you designate the points, lines connecting the points will be displayed.

### ■ Repositioning a Point

Place the cursor over a point, and move the trackball while holding down the **Set** button to reposition the point.

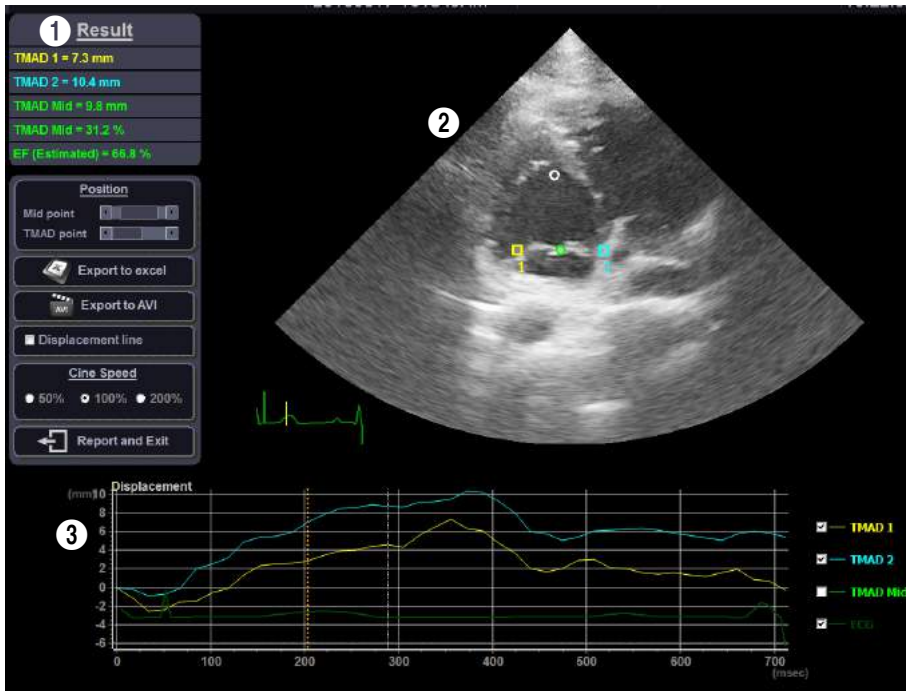
### ■ Viewing TMAD Data

Tap the **Next** button on the touch screen.

### ■ Exit

Tap the **Exit** button on the touch screen.

## TMAD Result



[Figure 3.48 TMAD Result Screen]

TMAD result screen is configured as below:

- ① Measurement result and menu: The result of the measurement as well as the menu for adjusting or saving the Cine are displayed.
- ② Image area: The image with the specified points is displayed.
- ③ Graph: The ECG and the graph of displacement by time are displayed.

### ■ Measurement Result

The displacement and gradient of TMAD points and median are displayed. The color used for displaying the measurement result corresponds to the color of each point in the image.

### ■ Position

Set the positions of the Midpoint and TMAD point.

**■ Export to Excel**

Save the result and the representative image as an Excel file. This is only available if a USB flash memory drive is connected.

**■ Export to AVI**

Save the result as an AVI file. This is only available if a USB flash memory drive is connected.

**■ Displacement Line**

Display the displacement line on the image.

**■ Cine Speed**

Select the playback speed for Cine images.

**■ Reporting and Exit**

Save the measurement result and exit.

**■ ECG Graph**

Display the current position.

**■ Displacement Graph**

Display the displacement by time. The graph line to be studied can be selected from the check box on the right-hand side.

The color used for the graph line corresponds to the color of each point in the image. The vertical dotted line indicates the current position.

**■ Run/Stop**

Stop or resume the playback of the image.

**■ Position**

Specify the image range to play.

## :: EzCompare (Option)

EzCompare is a function that automatically sets and displays the exam list of a previously saved patient and the current scanning images in the same setting values on the screen to help diagnosis.



However, Live scan is available only when the same probe preset is selected as that of the saved image or scan.

- ▶ Tap the **Patient** button on the touch screen. Select an exam list to analyze using the trackball and the **Set** button. (multiple selection of lists allowed)
- ▶ Tap the **EzCompare** button.
- ▶ The saved screen is provided in the Thumbnail field and **Date** tab appears.
- ▶ Double click an image of desirable screen to show the selected exam image in the right or left-hand of the screen and the live scan is shown in the opposite side with the same setting values as that of the exam image.
- ▶ When saved in the *EzCompare* screen, it is saved in the **Current Exam** tab under the thumbnail field.



**NOTE:** Go to Setup > Imaging > Display Settings to designate location of the live image to the left or right.



# Maintenance

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- ▣ ***Product Maintenance*..... 4-4**
  - Cleaning and Disinfecting ..... 4-4
  - Cleaning Air Filters..... 4-7
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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.

- ▶ Optimal conditions for the system are temperatures of 10–35°C and humidity of 30–75%.
- ▶ Avoid excess humidity.
- ▶ Avoid direct sunlight.
- ▶ Avoid places with extreme temperature variations.
- ▶ Avoid heat sources.
- ▶ Avoid dusty and unventilated areas.
- ▶ Avoid places where the system is likely to be exposed to vibration or impacts.
- ▶ Avoid places where the system is likely to be exposed to chemical substances or gases.

## :: 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.

#### ■ Console

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

#### ■ Cleaning Monitor

Gently wipe the LCD surface with a soft, dry cloth.



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

## ■ Touch Screen

Wipe the LCD surface with a soft dry cloth.



**NOTE:** Make sure that the touch screen is not contaminated by an electrically conductive substance. Contamination of the LCD screen by ultrasound gel or other substances may degrade the sensitivity of the touch screen and cause malfunctions. This phenomenon is caused by the contact between the capacitive touch screen and the conductive substance. If the screen is contaminated, clean it with a dry cloth and then reboot the system.

## ■ Trackball



**CAUTION:** While cleaning the trackball, make sure that liquid and other substances do not enter the product.

1. Turn the trackball rim counterclockwise to remove it from the control panel.
2. Wipe the trackball with a soft cloth and turn the trackball rim clockwise to reattach.



[Figure 4.1 Removing the Trackball]



**NOTE:**

- ▶ For information on cleaning and disinfecting the probes, please refer to 'Chapter 5. Probes' in this user manual.
- ▶ This image may differ from the actual system.

## ❏ Disinfection



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

A disinfectant certified by the FDA 510(k) process is recommended. For more information, please refer to the information about detergents, disinfectants, and ultrasound gels in 'Chapter 5. Probes'.

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.

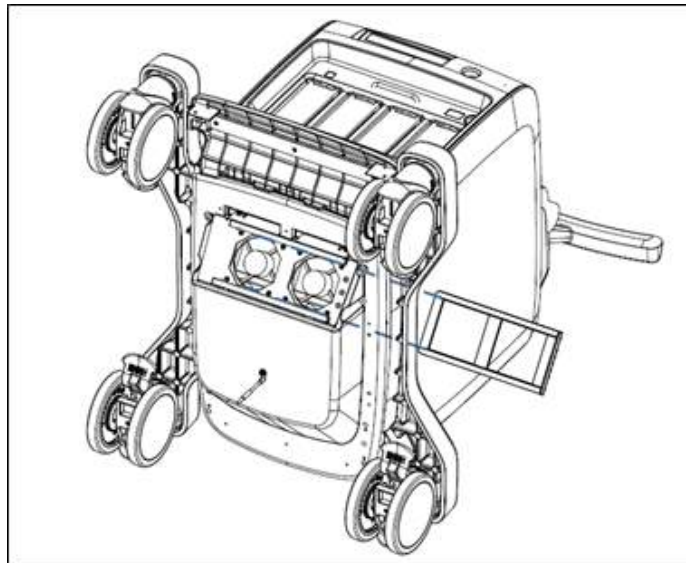
## Cleaning Air Filters

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.



[Figure 4.2 Disconnect Air Filter]

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.

## Electrical Safety Check



**NOTE:** Users may request safety inspections as required, but only trained persons are allowed to perform the safety inspection.

The product's maintenance status may affect the electrical safety of the product. The product should be maintained in an electrical safety state for the safety of the people.

## Accuracy Checks



**NOTE:** In case of doubt in the measurements then an accuracy test can be requested via your local Samsung Medison Service Department.

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.

The equations and table related to measurement accuracy are included in 'Chapter 8. Measurements and Calculations' in this manual.



## :: Data 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 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. Clients cannot back-up the user settings of the product. Please contact the servicing department to attain support for back-up.

### Backing Up Patient Information

The SonoView program can be used to backup 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 Managements'.

### 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 (Windows 7), or you desire to upgrade the operating system, please follow the instructions of the operating system manufacturer.



**NOTE:** This product uses the Windows firewall to prevent any hacker or malicious software from accessing the system through the internet or network.



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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 use a preset that is best suited to the particular organ being scanned.

#### ■ Thermal Index (TI) Table

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 (Tib), and cranial bone (Tic). This product automatically displays an appropriate thermal index for the current probe and application.

Probe types, applications, presets and thermal index available for this product are as follows:

<b>Probe</b>	<b>Application</b>	<b>Preset</b>	<b>Thermal Index</b>
LA3-14AD	Abdomen	Abdomen, Renal, Bowel, Aorta	T1s
	MSK	General, Superficial, Deep, Spine	T1s
	Small Parts	Breast, Thyroid, Testicle	T1s
	Vascular	Carotid, Arterial, Venous	T1s
		TCD	T1c
	OB	1st Trimester	T1s
		2nd Trimester, 3rd Trimester, Fetal Heart	T1b
	GYN	Uterus, Adnexa	T1s
	Pediatric	Ped Abd	T1s
		Ped Hip	T1b
Neo Head		T1c	
LA2-9A	Abdomen	Abdomen, Renal, Bowel, Aorta	T1s
	MSK	General, Superficial, Deep, Spine	T1s
	Small Parts	Breast, Thyroid, Testicle	T1s
	Vascular	Carotid, Arterial, Venous	T1s
		TCD	T1c
	OB	1st Trimester	T1s
		2nd Trimester, 3rd Trimester, Fetal Heart	T1b
	GYN	Uterus, Adnexa	T1s
	Pediatric	Ped Abd	T1s
		Neo Head	T1c
Ped Hip		T1b	

Probe	Application	Preset	Thermal Index
LA3-16AI	Abdomen	Abdomen, Renal, Bowel, Aorta	TIs
	MSK	General, Superficial, Deep	TIs
	Small Parts	Breast, Thyroid, Testicle	TIs
	Vascular	Carotid, Arterial, Venous	TIs
		TCD	TIc
	OB	1st Trimester	TIs
		2nd Trimester, 3rd Trimester, Fetal Heart	TIb
	GYN	Uterus, Adnexa	TIs
	Pediatric	Ped Abd, Ped Hip	TIs
		Neo Head	TIc
Ped Hip		TIb	
LA4-18BD	Abdomen	Abdomen, Renal, Bowel, Aorta	TIs
	MSK	General, Superficial, Deep, Spine	TIs
	Small Parts	Breast, Thyroid, Testicle	TIs
	Vascular	Carotid, Arterial, Venous	TIs
		TCD	TIc
	OB	1st Trimester	TIs
		2nd Trimester, 3rd Trimester, Fetal Heart	TIb
	GYN	Uterus, Adnexa	TIs
	Pediatric	Ped Abd	TIs
		Neo Head	TIc
Ped Hip		TIb	

<b>Probe</b>	<b>Application</b>	<b>Preset</b>	<b>Thermal Index</b>
LA3-16A	Abdomen	Abdomen, Renal, Bowel, Aorta	T1s
	MSK	General, Superficial, Deep, Spine	T1s
	Small Parts	Breast, Thyroid, Testicle	T1s
	Vascular	Carotid, Arterial, Venous	T1s
		TCD	T1c
	OB	1st Trimester	T1s
		2nd Trimester, 3rd Trimester, Fetal Heart	T1b
	GYN	Uterus, Adnexa	T1s
	Pediatric	Ped Abd	T1s
		Neo Head	T1c
Ped Hip		T1b	
CA1-7AD	Abdomen	Abdomen, Renal, Bowel, Aorta	T1s
	MSK	General, Superficial, Deep, Spine	T1s
	OB	1st Trimester	T1s
		2nd Trimester, 3rd Trimester, Fetal Heart, NT	T1b
	GYN	Uterus, Adnexa	T1s
	Pediatric	Ped Abd	T1s
		Neo Head	T1c
		Ped Hip	T1b
	Vascular	Carotid, Arterial, Venous	T1s
		TCD	T1c
Urology	Prostate, Bladder	T1s	



Probe	Application	Preset	Thermal Index
CA2-9AD	Abdomen	Abdomen, Renal, Bowel, Aorta	TIs
	MSK	General, Superficial, Deep, Spine	TIs
	OB	1st Trimester	TIs
		2nd Trimester, 3rd Trimester, Fetal Heart, NT	T1b
	GYN	Uterus, Adnexa	TIs
	Pediatric	Ped Abd	TIs
		Neo Head	T1c
		Ped Hip	T1b
	Vascular	Carotid, Arterial, Venous	TIs
		TCD	T1c
Urology	Prostate, Bladder	TIs	
CA2-6BM	Abdomen	Abdomen, Renal	TIs
CF4-9	Abdomen	Abdomen, Renal, Bowel, Aorta	TIs
	MSK	General, Superficial, Deep, Spine	TIs
	OB	1st Trimester	TIs
		2nd Trimester, 3rd Trimester, Fetal Heart	T1b
	GYN	Uterus, Adnexa	TIs
	Pediatric	Ped Abd	TIs
		Neo Head	T1c
		Ped Hip	T1b
	Vascular	Carotid, Arterial, Venous	TIs
		TCD	T1c
Urology	Prostate, Bladder	TIs	

<b>Probe</b>	<b>Application</b>	<b>Preset</b>	<b>Thermal Index</b>
PA1-5A	Abdomen	Abdomen, Renal, Bowel, Aorta	T1s
	Cardiac	Adult Echo, Ped Echo, Aortic Arch	T1s
	Vascular	Carotid, Arterial, Venous	T1s
		TCD	T1c
	Pediatric	Ped Abd	T1s
PA3-8B	Abdomen	Abdomen, Renal, Bowel, Aorta	T1s
	Cardiac	Adult Echo, Ped Echo, Aortic Arch	T1s
	Vascular	Carotid, Arterial, Venous	T1s
		TCD	T1c
	Pediatric	Ped Abd	T1s
PE2-4	Abdomen	Abdomen, Renal, Bowel, Aorta	T1s
	Cardiac	Adult Echo, Ped Echo, Aortic Arch	T1s
	Vascular	Carotid, Arterial, Venous	T1s
		TCD	T1c
	Pediatric	Ped Abd	T1s
EA2-11B	OB	1st Trimester	T1s
		2nd Trimester, 3rd Trimester, Fetal Heart	T1b
	GYN	Uterus, Adnexa	T1s
	Urology	Prostate, Bladder	T1s
ER4-9	OB	1st Trimester	T1s
		2nd Trimester, 3rd Trimester, Fetal Heart	T1b
	GYN	Uterus, Adnexa	T1s
	Urology	Prostate, Bladder	T1s

Probe	Application	Preset	Thermal Index
CV1-8AD	Abdomen	Abdomen, Renal, Bowel, Aorta	TIs
	MSK	General, Superficial, Deep, Spine	TIs
	OB	1st Trimester	TIs
		2nd Trimester, 3rd Trimester, Fetal Heart, NT	TIb
	GYN	Uterus, Adnexa	TIs
	Pediatric	Ped Abd	TIs
		Neo Head	TIc
		Ped Hip	TIb
	Vascular	Carotid, Arterial, Venous	TIs
		TCD	TIc
Urology	Prostate, Bladder	TIs	
V5-9	OB	1st Trimester	TIs
		2nd Trimester, 3rd Trimester, Fetal Heart	TIb
	GYN	Uterus, Adnexa	TIs
	Urology	Prostate, Bladder	TIs
DP2B	Cardiac	Adult Echo, Ped Echo	TIs
	Vascular	Carotid, Arterial, Venous	TIs
		TCD	TIc
CW6.0	Cardiac	Adult Echo, Ped Echo	TIs
	Vascular	Carotid, Arterial, Venous	TIs
		TCD	TIc

**NOTE:**

- ▶ In addition to the standard presets, users can also create up to five of their own, which can be accessed by selecting User 1-8.
- ▶ For information on the selection and setting of probes, refer to 'Chapter 6. Starting Diagnosis'.
- ▶ The default thermal index may vary, corresponding to the presets.
- ▶ You can change the thermal index in Setup > Imaging > Application/Preset > Preset Settings > Thermal Index Type.



**NOTE:**

- ▶ Probe CA2-6BM is not supported in the USA.
- ▶ The applications and presets of probes below are not supported in the USA.

Probes	Application	Preset
LA3-14AD	Abdomen	Abdomen, Renal, Bowel, Aorta
	Vascular	TCD
	OB	1st Trimester, 2nd Trimester, 3rd Trimester, Fetal Heart
	Pediatric	Neo Head, Ped Abd, Ped Hip
LA2-9A	Vascular	TCD
	OB	1st Trimester, 2nd Trimester, 3rd Trimester, Fetal Heart
	Pediatric	Neo Head, Ped Abd, Ped Hip
LA3-16AI	Abdomen	Abdomen, Renal, Bowel, Aorta
	Small Parts	Breast, Thyroid, Testicle
	Vascular	TCD
	OB	1st Trimester, 2nd Trimester, 3rd Trimester, Fetal Heart
	GYN	Uterus, Adnexa
	Pediatric	Neo Head, Ped Abd, Ped Hip
LA4-18BD	Abdomen	Abdomen, Renal, Bowel, Aorta
	Vascular	TCD
	OB	1st Trimester, 2nd Trimester, 3rd Trimester, Fetal Heart
	GYN	Uterus, Adnexa
	Pediatric	Neo Head, Ped Abd, Ped Hip
LA3-16A	Abdomen	Abdomen, Renal, Bowel, Aorta
	Vascular	TCD
	OB	1st Trimester, 2nd Trimester, 3rd Trimester, Fetal Heart
	Pediatric	Neo Head, Ped Abd, Ped Hip
CA1-7AD	Pediatric	Neo Head, Ped Abd, Ped Hip
	Vascular	Carotid, Arterial, Venous, TCD
	Urology	Prostate, Bladder



Probes	Application	Preset
CA2-9AD	MSK	General, Superficial, Deep, Spine
	Pediatric	Neo Head, Ped Abd, Ped Hip
	Vascular	Carotid, Arterial, Venous, TCD
	Urology	Prostate, Bladder
CF4-9	MSK	General, Superficial, Deep, Spine
	Vascular	TCD
	Urology	Prostate, Bladder
PA1-5A	Vascular	Carotid, Arterial, Venous
	Pediatric	Ped Abd
PA3-8B	Vascular	Carotid, Arterial, Venous
PE2-4	Vascular	Carotid, Arterial, Venous
	Pediatric	Ped Abd
CV1-8AD	MSK	General, Superficial, Deep, Spine
	Pediatric	Neo Head, Ped Abd, Ped Hip
	Vascular	Carotid, Arterial, Venous, TCD
	Urology	Prostate, Bladder



**NOTE:**

- ▶ Probe CA2-6BM is not supported in Canada.
- ▶ The applications and presets of probes below are not supported in Canada.

Probes	Application	Preset
LA3-14AD	Vascular	TCD
LA2-9A	Vascular	TCD
LA3-16AI	Abdomen	Abdomen, Renal, Bowel, Aorta
	OB	1st Trimester, 2nd Trimester, 3rd Trimester, Fetal Heart
	GYN	Uterus, Adnexa
	Vascular	TCD
LA4-18BD	Abdomen	Abdomen, Renal, Bowel, Aorta
	OB	1st Trimester, 2nd Trimester, 3rd Trimester, Fetal Heart
	GYN	Uterus, Adnexa
	Vascular	TCD
LA3-16A	OB	1st Trimester, 2nd Trimester, 3rd Trimester, Fetal Heart
	Pediatric	Neo Head
	Vascular	TCD
CA1-7AD	Pediatric	Neo Head
	Vascular	TCD
CA2-9AD	MSK	General, Superficial, Deep, Spine
	Pediatric	Neo Head
	Vascular	TCD
CF4-9	MSK	General, Superficial, Deep, Spine
	Urology	Prostate, Bladder
	Vascular	TCD
PA3-8B	Vascular	Carotid, Arterial, Venous
PE2-4	Vascular	Carotid, Arterial, Venous
CV1-8AD	Pediatric	Neo Head
	Urology	Prostate, Bladder
	MSK	Superficial

## ■ Function List

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

Probe	Application	Panoramic	ECG	Elasto Scan	Q Scan	CM	TDI	PD	S-Flow
LA3-14AD	Abdomen	O	O	X	O	X	X	O	O
	MSK	O	O	X General (O)	O	X	X	O	O
	Small Parts	O	O	X Breast (O), Thyroid (O)	O	X	X	O	O
	Vascular	O	O	X	O	X	X	O	O
	OB	O	O	X	O	X	X	O	O
	GYN	O	O	X	O	X	X	O	O
	Pediatric	O	O	X	O	X	X	O	O
LA2-9A	Abdomen	O	O	X	O	X	X	O	O
	MSK	O	O	X	O	X	X	O	O
	Small Parts	O	O	X	O	X	X	O	O
	Vascular	O	O	X	O	X	X	O	O
	OB	O	O	X	O	X	X	O	O
	GYN	O	O	X	O	X	X	O	O
	Pediatric	O	O	X	O	X	X	O	O
LA3-16AI	Abdomen	O	O	X	O	X	X	O	O
	MSK	O	O	X	O	X	X	O	O
	Small Parts	O	O	X	O	X	X	O	O
	Vascular	O	O	X	O	X	X	O	O
	OB	O	O	X	O	X	X	O	O
	GYN	O	O	X	O	X	X	O	O
	Pediatric	O	O	X	O	X	X	O	O

Probe	Application	Panoramic	ECG	Elasto Scan	Q Scan	CM	TDI	PD	S-Flow
LA4-18BD	Abdomen	O	O	X	O	X	X	O	O
	MSK	O	O	General (O)	O	X	X	O	O
	Small Parts	O	O	X Breast (O), Thyroid (O)	O	X	X	O	O
	Vascular	O	O	X	O	X	X	O	O
	OB	O	O	X	O	X	X	O	O
	GYN	O	O	X	O	X	X	O	O
	Pediatric	O	O	X	O	X	X	O	O
LA3-16A	Abdomen	O	O	X	O	X	X	O	O
	MSK	O	O	General (O)	O	X	X	O	O
	Small Parts	O	O	X Breast (O), Thyroid (O)	O	X	X	O	O
	Vascular	O	O	X	O	X	X	O	O
	OB	O	O	X	O	X	X	O	O
	GYN	O	O	X	O	X	X	O	O
	Pediatric	O	O	X	O	X	X	O	O
CA1-7AD	Abdomen	O	O	X	O	X	X	O	O
	MSK	O	O	X	O	X	X	O	O
	OB	O	O	X	O	X	X	O	O
	GYN	O	O	X	O	X	X	O	O
	Pediatric	O	O	X	O	X	X	O	O
	Vascular	O	O	X	O	X	X	O	O
	Urology	O	O	X	O	X	X	O	O



Probe	Application	Panoramic	ECG	Elasto Scan	Q Scan	CM	TDI	PD	S-Flow
CA2-9AD	Abdomen	O	O	X	O	X	X	O	O
	MSK	O	O	X	O	X	X	O	O
	OB	O	O	X	O	X	X	O	O
	GYN	O	O	X	O	X	X	O	O
	Pediatric	O	O	X	O	X	X	O	O
	Vascular	O	O	X	O	X	X	O	O
	Urology	O	O	X	O	X	X	O	O
CA2-6BM	Abdomen	O	O	X	O	X	X	O	O
CF4-9	Abdomen	O	O	X	O	X	X	O	O
	MSK	O	O	X	O	X	X	O	O
	OB	O	O	X	O	X	X	O	O
	GYN	O	O	X	O	X	X	O	O
	Pediatric	O	O	X	O	X	X	O	O
	Vascular	O	O	X	O	X	X	O	O
	Urology	O	O	X	O	X	X	O	O
PA1-5A	Abdomen	X	O	X	O	X	X	O	O
	Cardiac	X	O	X	O	O	O	X	X
	Vascular	X	O	X	O	X	X	O	O
	Pediatric	X	O	X	O	X	X	O	O
PA3-8B	Abdomen	X	O	X	O	X	X	O	O
	Cardiac	X	O	X	O	O	O	X	X
	Vascular	X	O	X	O	X	X	O	O
	Pediatric	X	O	X	O	X	X	O	O
PE2-4	Abdomen	X	O	X	O	X	X	O	O
	Cardiac	X	O	X	O	O	O	X	X
	Vascular	X	O	X	O	X	X	O	O
	Pediatric	X	O	X	O	X	X	O	O

Probe	Application	Panoramic	ECG	Elasto Scan	Q Scan	CM	TDI	PD	S-Flow
EA2-11B	OB	X	O	X	O	X	X	O	O
	GYN	X	O	O	O	X	X	O	O
	Urology	X	O	Prostate (O), Bladder (X)	O	X	X	O	O
ER4-9	OB	X	O	X	O	X	X	O	O
	GYN	X	O	O	O	X	X	O	O
	Urology	X	O	Prostate (O), Bladder (X)	O	X	X	O	O
CV1-8AD	Abdomen	O	O	X	O	X	X	O	O
	MSK	O	O	X	O	X	X	O	O
	OB	O	O	X	O	X	X	O	O
	GYN	O	O	X	O	X	X	O	O
	Pediatric	O	O	X	O	X	X	O	O
	Vascular	O	O	X	O	X	X	O	O
	Urology	O	O	X	O	X	X	O	O
V5-9	OB	X	O	X	O	X	X	O	O
	GYN	X	O	O	O	X	X	O	O
	Urology	X	O	Prostate (O), Bladder (X)	O	X	X	O	O
DP2B	Cardiac	X	O	X	X	X	X	X	X
	Vascular	X	O	X	X	X	X	X	X
CW6.0	Cardiac	X	O	X	X	X	X	X	X
	Vascular	X	O	X	X	X	X	X	X

Probe	Application	Biopsy	TDW	CW	Multi Vision	Clear Vision	S-Har.	Har
LA3-14AD	Abdomen	O	X	X	O	O	O	O
	MSK	O	X	X	O	O	O	O
	Small Parts	O	X	X	O	O	O	O
	Vascular	O	X	X	O	O	O	O
	OB	O	X	X	O	O	O	O
	GYN	O	X	X	O	O	O	O
	Pediatric	O	X	X	O	O	O	O
LA2-9A	Abdomen	O	X	X	O	O	O	O
	MSK	O	X	X	O	O	O	O
	Small Parts	O	X	X	O	O	O	O
	Vascular	O	X	X	O	O	O	O
	OB	O	X	X	O	O	O	O
	GYN	O	X	X	O	O	O	O
	Pediatric	O	X	X	O	O	O	O
LA3-16AI	Abdomen	X	X	X	O	O	O	O
	MSK	X	X	X	O	O	O	O
	Small Parts	X	X	X	O	O	O	O
	Vascular	X	X	X	O	O	O	O
	OB	X	X	X	O	O	O	O
	GYN	X	X	X	O	O	O	O
	Pediatric	X	X	X	O	O	O	O
LA4-18BD	Abdomen	O	X	X	O	O	O	O
	MSK	O	X	X	O	O	O	O
	Small Parts	O	X	X	O	O	O	O
	Vascular	O	X	X	O	O	O	O
	OB	O	X	X	O	O	O	O
	GYN	O	X	X	O	O	O	O
	Pediatric	O	X	X	O	O	O	O

Probe	Application	Biopsy	TDW	CW	Multi Vision	Clear Vision	S-Har.	Har
LA3-16A	Abdomen	O	X	X	O	O	O	O
	MSK	O	X	X	O	O	O	O
	Small Parts	O	X	X	O	O	O	O
	Vascular	O	X	X	O	O	O	O
	OB	O	X	X	O	O	O	O
	GYN	O	X	X	O	O	O	O
	Pediatric	O	X	X	O	O	O	O
CA1-7AD	Abdomen	O	X	X	O	O	O	O
	MSK	O	X	X	O	O	O	O
	OB	O	X	X	O	O	O	O
	GYN	O	X	X	O	O	O	O
	Pediatric	O	X	X	O	O	O	O
	Vascular	O	X	X	O	O	O	O
	Urology	O	X	X	O	O	O	O
CA2-9AD	Abdomen	O	X	X	O	O	O	O
	MSK	O	X	X	O	O	O	O
	OB	O	X	X	O	O	O	O
	GYN	O	X	X	O	O	O	O
	Pediatric	O	X	X	O	O	O	O
	Vascular	O	X	X	O	O	O	O
	Urology	O	X	X	O	O	O	O
CA2-6BM	Abdomen	X	X	X	O	O	O	O

Probe	Application	Biopsy	TDW	CW	Multi Vision	Clear Vision	S-Har.	Har
CF4-9	Abdomen	X	X	X	O	O	X	X
	MSK	X	X	X	O	O	X	X
	OB	X	X	X	O	O	X	X
	GYN	X	X	X	O	O	X	X
	Pediatric	X	X	X	O	O	X	X
	Vascular	X	X	X	O	O	X	X
	Urology	X	X	X	O	O	X	X
PA1-5A	Abdomen	X	X	O	X	O	O	O
	Cardiac	X	O	O	X	O	O	O
	Vascular	X	X	O	X	O	O	O
	Pediatric	X	X	O	X	O	O	O
PA3-8B	Abdomen	X	X	O	X	O	O	O
	Cardiac	X	O	O	X	O	O	O
	Vascular	X	X	O	X	O	O	O
	Pediatric	X	X	O	X	O	O	O
PE2-4	Abdomen	X	X	O	X	O	O	O
	Cardiac	X	O	O	X	O	O	O
	Vascular	X	X	O	X	O	O	O
	Pediatric	X	X	O	X	O	O	O
EA2-11B	OB	O	X	X	O	O	O	O
	GYN	O	X	X	O	O	O	O
	Urology	O	X	X	O	O	O	O
ER4-9	OB	O	X	X	O	O	O	O
	GYN	O	X	X	O	O	O	O
	Urology	O	X	X	O	O	O	O

Probe	Application	Biopsy	TDW	CW	Multi Vision	Clear Vision	S-Har.	Har
CV1-8AD	Abdomen	O	X	X	O	O	O	O
	MSK	O	X	X	O	O	O	O
	OB	O	X	X	O	O	O	O
	GYN	O	X	X	O	O	O	O
	Pediatric	O	X	X	O	O	O	O
	Vascular	O	X	X	O	O	O	O
	Urology	O	X	X	O	O	O	O
V5-9	OB	O	X	X	O	O	O	O
	GYN	O	X	X	O	O	O	O
	Urology	O	X	X	O	O	O	O
DP2B	Cardiac	X	X	O	X	X	X	X
	Vascular	X	X	O	X	X	X	X
CW6.0	Cardiac	X	X	O	X	X	X	X
	Vascular	X	X	O	X	X	X	X



**NOTE:**

- ▶ The significance of each symbol is as follows:
  - Q Scan: Quick Scan
  - Har: Harmonic Imaging
  - S-Har: S-Harmonic Imaging
  - ECG: Electrocardiograph Imaging
  - CM: Color M
  - TDI: Tissue Doppler
  - PD: Power Doppler
  - S-Flow: Directional Power Doppler Imaging
  - TDW: Tissue Doppler Wave
  - CW: Continuous Wave
- ▶ MultiVision is only available in 2D/C Mode.

## Ultrasound Transmission Gel

For proper transmission of the acoustic beam, only use ultrasound transmission gel approved by Samsung Medison.

**WARNING:**

- ▶ The use of inappropriate ultrasound gels could result in damages in the probe. Using damaged probe could cause injuries such as electric shock in users or patients.
- ▶ Do not use ultrasound gels or contact media that contain the following contents.
  - Oils such as mineral oil, cooking oil, gasoline, solvents, rust inhibitors, lanolin, paraffin-based grease, ester and excessive silicon-based release agent
  - Alcohols such as acetone, methanol, plasticizer (dioctylphthalate) or denatured alcohols.
  - Glacial acetic acid and iodine
  - All types of lotions or gels that contain aromatic substances

**CAUTION:**

- ▶ When applying the ultrasonic gel to the probe, ensure that the tip of the injection nozzle does not touch the surface of the probe lens.
- ▶ The injection nozzle may cause damage to the probe lens.



## ❏ Gel Warmer (Optional)

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



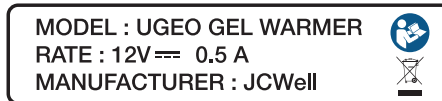
**WARNING:**

- ▶ 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.



[Figure 5.1 Gel Warmer Label – Example]



## Using 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. 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

All probes must be cleaned and disinfected after each use. Cleaning is an important procedure that must be carried out before disinfecting the probe. For cleaning the probe please refer to the appropriate chapter. Using an inappropriate disinfectant may damage 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

#### Classification of Disinfectants

To maintain the performance of ultrasound probes, proper maintenance is required.

As ultrasound probes are classified into non-critical, semi-critical or critical devices based on the standards of FDA guidance\* and the Hygiene Requirements for the Reprocessing of Medical Devices from Germany guideline of Robert Koch Institute (RKI), proper cleaning and disinfection or sterilization methods for that classification should be used.

Classification Criteria	Contact Area	Application Probe	Level Selection
Non-critical device	Intact skin	Convex, Linear array, and sector transducers	Low level disinfectant
Semi-critical device	Mucous membrane and damaged skin	Endocavity	High level disinfectant
Critical device	Blood, sterile tissue, etc.	Intraoperative, TEE	High level disinfectant or sterilization

\* Guidance for Industry and FDA Staff - Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers - Appendix D

\* It is recommended that only high level disinfectants are used for Endocavity probes.

An appropriate detergent, disinfectant or ultrasound gel should be selected for all probes.

Please use an appropriate detergent, disinfectant or ultrasound gel by referring to Samsung Medison website and the user guide. All probes are tested under IPX 7 Criteria.

- ▶ User guide: provided as a booklet when the product is purchased.
- ▶ Website: <http://samsungmedicalsolution.com>

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

Product	Manufacturer
Alkazyme	Alkapharm UK Ltd.
Anioxyde 1000	Laboratoires Anios
Aquasonics 100	Parker laboratories, Inc.
Asepti-Wipes	Ecolab
Asepti-Wipes II	Ecolab
Bleach 5.25%	-
CaviWipes	Metrex
Cidex	Advanced Sterilization Products
Cidex 2%	Advanced Sterilization Products
Cidex OPA	Advanced Sterilization Products
Cidex Plus	Advanced Sterilization Products
Cidezyme	Johnson&Johnson
Cleanisept Wipes	Dr.Schumacher GmbH
Clear Image	NEXT Medical Products
Enzol	Johnson&Johnson
Ethanol 75%	-
GE Ultrasound Contact Gel	GE Accessories
Gigasept	Schulke & Mayr GmbH
Gigasept AF	Schulke & Mayr GmbH
Gigasept FF	Schulke & Mayr GmbH
Hibitane	Regent Medical

<b>Product</b>	<b>Manufacturer</b>
Incidin Foam	Ecolab
Isopropyl alcohol (70%)	-
Isopropyl alcohol (80%)	-
Kendall	Tyco/Healthcare
Klenzyme	Steris
McKesson	McKesson Medical-Surgical Inc.
Metricide 14	Metrex
Metricide 28	Metrex
Metricide 30	Metrex
Metricide OPA Plus	Metrex
Metricide	Metrex
MetriWipes	Metrex
Metrizyme	Metrex
Milton	Procter & Gamble
Natural Image	Sonotech Inc.
Nuclean	Alkapharm
Omnicide - FG2	Coventry Chemicals Limited
Omnicide 14NS	Coventry Chemicals Limited
Omnicide (28)	Coventry Chemicals Limited
PeraSafe	ANTEC International Limited
Salvanios pH 7	Laboratoires Anios
Salvanios pH 10	Laboratoires Anios
Sani-Cloth Active	PDI
Sani-Cloth AF Germicidal	PDI
Sani-Cloth AF3 Germicidal	PDI
Sani-Cloth Bleach Germicidal	PDI
Sani-Cloth Germicidal	PDI
Sani-Cloth HB	PDI

Product	Manufacturer
Sani-Cloth Plus	PDI
Scan	Parker laboratories, Inc.
Sekusept Extra	Ecolab
Sekusept Plus	Ecolab
Septiwipes	Dr. Schumacher GmbH
Sonogel	Sonogel Vertriebs GmbH
Sporox	DSHealthcare Inc.
Sporox II	DSHealthcare Inc.
Steranios 2%	Laboratoires Anios
Ster-Bac Blu	Ecolab
Super Sani-cloth	PDI
Surfaces Hautes	Laboratoires Anios
Transeptic spray	Parker laboratories, Inc.
Tristel Duo	Tristel Solutions Limited
Tristel Sporicidal Wipe	Tristel Solutions Limited
Trophon	Nanosonics Limited
T-Spray	Pharmaceutical Innovations, Inc.
T-Spray II	Pharmaceutical Innovations, Inc.
Virkon	DuPont
Wavelength	National Therapy Products Inc.
Wavicide-01	National Therapy Products Inc.

## Cleaning the probe

The probe must be cleaned and disinfected after each use. Cleaning is an important procedure that must be carried out before disinfecting the probe.



**CAUTION:**

- ▶ Do not use brushes 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, until all parts are dry.

1. Disconnect the probe from the system.
2. Remove the biopsy adapter or needle guide. Collect the reusable parts, reusable biopsy adapter or needle guide for disinfection or sterilization and discard the disposable parts in the clinical waste bin (For cleaning and disinfection/sterilization of the reusable parts please refer to the appropriate chapter).
3. Remove and properly dispose the medical sheath in the clinical waste bin (Medical sheaths are disposables).
4. Use a soft cloth, lightly dampened with mild soap or compatible cleaning solution or compatible cleaning sheet, to remove any particulate matter and bodily fluids that remained on the probe, edges and ridges on the probe and cable.
5. Rinse with water to remove any loose particles, soap- and cleaning residue (up to the immersion point).
6. Wipe with a clean, dry soft cloth.
7. If still necessary, wipe with a clean, water-dampened cloth to remove soap residue, and wipe with a clean, dry soft cloth again.
8. Dispose the used soft cloth in the clinical waste bin.



## ❏ Disinfecting the probe

The probe must be cleaned and disinfected after each use. Cleaning is an important procedure that must be carried out before disinfecting the probe. For cleaning the probe please refer to the appropriate chapter.

Disinfect the probe to reduce pathogens to the level of  $10^{-6}$ .

### ■ Disinfecting the probe with a fluid disinfectant

Using an inappropriate disinfectant may damage the probe.



#### WARNING:

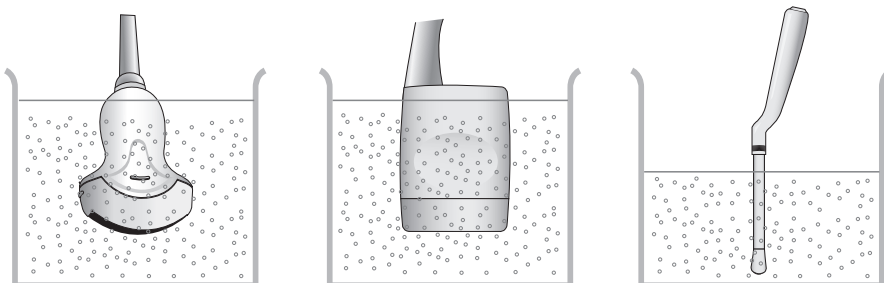
- ▶ Always use protective eyewear and gloves when disinfecting probes.
- ▶ Inspect the housing, strain relief, lens and seal for damage, and check for any functional problem after disinfecting the probe.
- ▶ Never use disinfectants after the expiration date.
- ▶ The type of tissue it will contact during use dictates the level of disinfection required for a device. Ensure that the solution strength and duration of contact are appropriate for disinfection.



#### CAUTION:

- ▶ Using a non-recommended disinfectant or not following the recommended disinfection method can damage and/or discolor the probe, and will void the probe warranty.
- ▶ Do not immerse probes for longer than one hour, unless they are sterilizable.
- ▶ Only sterilize probes by using liquid solutions. Avoid using autoclave, gas (EtO), or other non-Samsung Medison-approved methods.

1. Follow the instructions on the disinfectant label for storage, use and disposal of the disinfectant.
2. Mix the disinfectant compatible with your probe according to the instructions for solution strength provided on the disinfectant's label.
3. Immerse the probe into the disinfectant as shown in the illustration below.



[Figure 5.2 Disinfection]

4. Follow the instructions on the disinfectant to complete the immersion procedure of the probe, never leave the transducer longer than the maximum immersion duration in the fluid. Rinse the probe with sterile water afterwards.
5. Air dry the probe and store it properly (e.g. in a sterile bag), so that no new contamination may appear.

### ■ Disinfecting the probe with a disinfection wipe

Using an inappropriate disinfection wipe may damage the probe.



**WARNING:**

- ▶ Always use protective eyewear and gloves when disinfecting probes.
- ▶ Inspect the housing, strain relief, lens and seal for damage, and check for any functional problem after disinfecting the probe.
- ▶ Never use disinfection wipes after the expiration date.
- ▶ Ensure that the contact duration is appropriate for disinfection.



**CAUTION:** Using a non-recommended disinfection wipe or not following the recommended disinfection method can damage and/or discolor the probe. This could also void the probe warranty.

1. Refer to the user instructions of the disinfection wipe for details of proper use, storage and disposal of the holder.
2. Dependent on the type of wipe the active disinfectant needs to be applied to a dry wipe or has already been applied to the wipe.
3. Use the disinfection wipe to spread the active disinfectant over the full surface of the probe and ensure all areas are covered.
4. Discard the disinfection wipe to clinical waste. Do not re-use the disinfection wipe.
5. Air dry the probe as described in the user instructions of the disinfection wipe for the described time and store the probe properly (e.g. in a sterile bag), so that no new contamination may appear.

## ■ Disinfecting the probe with a disinfection system

Using a non-approved probe/disinfection system combination may damage the probe.



### **WARNING:**

- ▶ Always use protective eyewear and gloves when disinfecting probes.
- ▶ Inspect the housing, strain relief, lens and seal for damage, and check for any functional problem after disinfecting the probe.
- ▶ Ensure that the cycle duration is appropriate for the desired disinfection level.



**CAUTION:** Using a non-approved probe/disinfection system combination or not following the recommended disinfection method can damage the probe. This could also void the probe warranty.

1. Refer to the user instructions of the disinfection device for details of proper use, storage and disposal of waste.
2. Place the probe head, a part of the cable and possible marker in the disinfection device, following the user instructions of the disinfection device.
3. Start the desired disinfection process and wait until the end of the cycle.
4. Remove the probe and possible marker at the end of the cycle from the disinfection device and store the probe properly (e.g. in a sterile bag), so that no new contamination may appear.
5. Register the disinfection data for traceability according to local regulations.

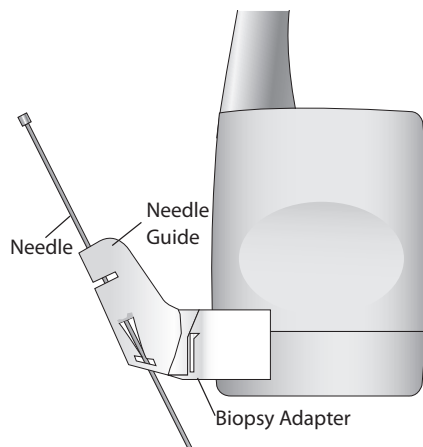
## :: Biopsy

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.



[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. The biopsy kit supplied by Samsung Medison does not contain a needle.
- ▶ **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:**

- ▶ Only use the needles approved by the country's government.
- ▶ 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.

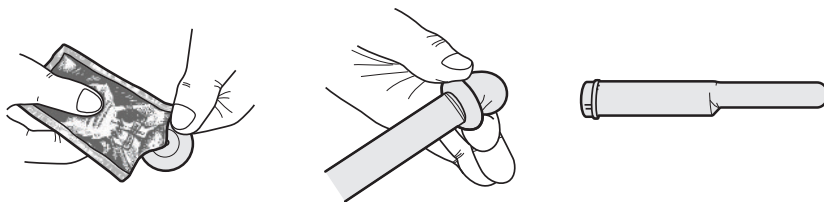
Reverberation or other tissue artifacts may produce false needle images, which can cause confusion. Ensure the needle path is along the guideline, and that you are not using a false needle image to locate the needle.

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.

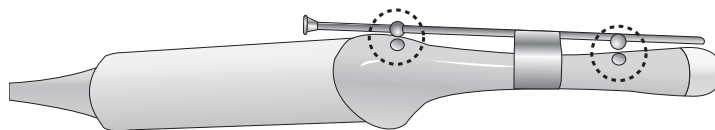
## Assembling the Biopsy Kit

### ❑ Stainless Steel Biopsy Kit

1. Place a Sheath up to the top of the probe's handle.



2. Mount the biopsy adapter onto the probe. If the surface of probe is fluted, mount the adapter in accordance with it.

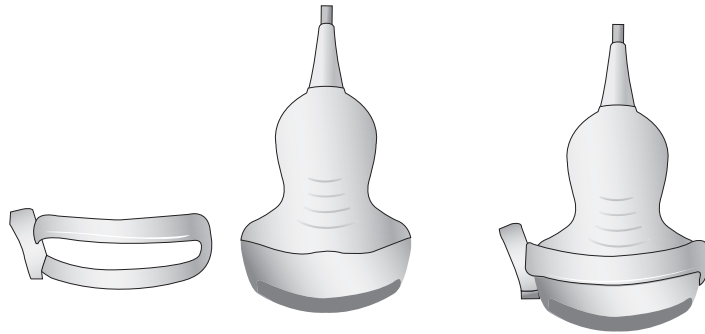


3. Install the needle into the needle guide and start the exam.

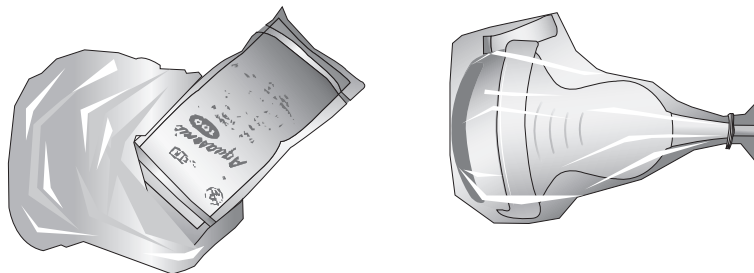


## Plastic Biopsy Kit

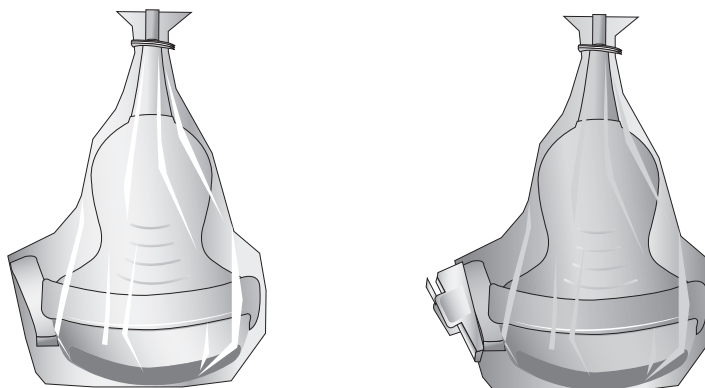
1. Mount the biopsy adapter onto the probe.



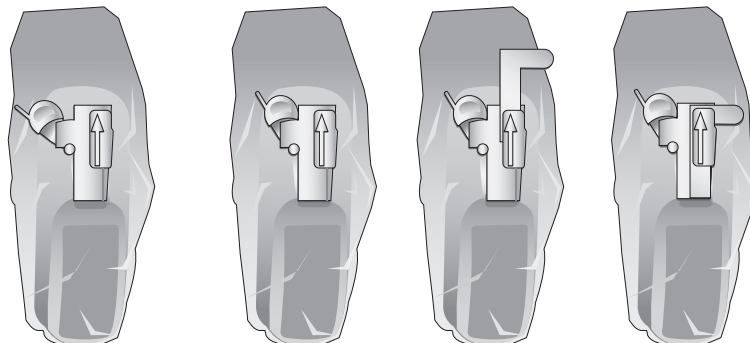
2. Insert gel into the sheath. And cover the probe completely.



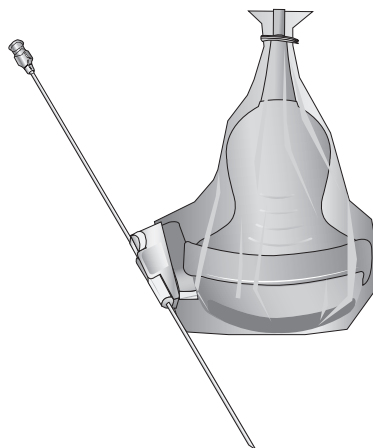
3. Install the needle guide onto the adapter.



4. Installing the Needle Guide Clip if it is included in the components.

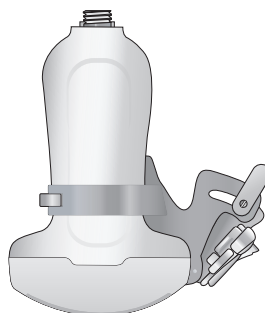


5. Install the needle into the needle guide and start the exam.



**Using Multi Angle**

Use the angle adjuster.



## Biopsy Specifications

Probe	Biopsy					
	Model Name	Components	Adapter Material	Reusable/ Disposable	Needle Gauge	Multi Angle Depth
LA4-18BD	BP-KIT-069	Biopsy Adapter	Acetal Copolymer	Reusable	14, 15, 16, 17, 18, 20, 21, 22, 23, 8.5FR	1.5, 2.5, 4 (cm)
		Ultra-Pro II Needle Guides & CIV-Flex Cover		Disposable		
LA2-9A	BP-KIT-043	Biopsy Adapter	Acetal Copolymer	Reusable	14, 15, 16, 17, 18, 20, 21, 22, 23, 8.5FR	4, 5.5, 7 (cm)
		Ultra-Pro II Needle Guides & CIV-Flex Cover		Disposable		
LA3-14AD	BP-KIT-053 [BP-KIT-053-NG]	Biopsy Adapter	Acetal Copolymer	Reusable	16, 18, 20, 22	0.591, 0.984, 1.575 (in)
		Needle Guide & Probe Cover		Disposable		
LA3-16A	BP-KIT-068 [BP-KIT-068-NG]	Biopsy Adapter	Acetal Copolymer	Reusable	16, 18, 20, 22	0.591, 0.984, 1.575 (in)
		Needle Guide & Probe Cover		Disposable		
	BP-KIT-055 [BP-KIT-055-NG]	Biopsy Adapter	Acetal Copolymer	Reusable	16, 18, 20, 22	0.591, 0.984, 1.575 (in)
		Needle Guide & Probe Cover		Disposable		
CA1-7AD	BP-KIT-058 [BP-KIT-058-NG]	Biopsy Adapter	Acetal Copolymer	Reusable	14, 16, 18, 20, 22, 25	1.969, 3.937, 5.906, 7.874 (in)
		Needle Guide & Probe Cover		Disposable		
CA2-9AD	BP-KIT-054 [BP-KIT-054-NG]	Biopsy Adapter	Acetal Copolymer	Reusable	16, 18, 22, 25	2.362, 3.150, 3.937 (in)
		Needle Guide & Probe Cover		Disposable		
EA2-11B	BP-KIT-065	Needle Guide	Stainless	Reusable	16–18	Single Angle 2°
	BP-KIT-066	Needle Guide	Abs	Disposable	16–18	Single Angle 2°

Probe	Biopsy					
	Model Name	Components	Adapter Material	Reusable/ Disposable	Needle Gauge	Multi Angle Depth
ER4-9	BP-KIT-024-3	Needle Guide	Stainless	Reusable	16	Single Angle 1°
	BP-KIT-061	Needle Guide	Abs	Disposable	16–18	Single Angle 1°
CV1-8AD	BP-KIT-059 [BP-KIT-059-NG]	Biopsy Adapter	Acetal Copolymer	Reusable	14, 16, 18, 20, 22, 25	1.969, 3.937 (in)
		Needle Guide & Probe Cover		Disposable		
V5-9	BP-KIT-029	Needle Guide	Stainless	Reusable	18	–
	BP-KIT-060	Needle Guide	ABS	Disposable	16–18	Single Angle 1.8°

## Cleaning and Disinfecting the Biopsy Kit



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

Wash and disinfect the biopsy kit to reduce pathogens to the level of  $10^{-6}$ .

Reusable Biopsy adapters must be cleaned and disinfected after each use. Disposable Biopsy adapters and disposable Biopsy kit parts need to be disposed as medical waste after each use. Cleaning is an important procedure that must be carried out before disinfecting or sterilizing reusable Biopsy adapters. Read the biopsy kit user manual carefully before cleaning and disinfecting.

### Cleaning Biopsy Kit

1. After use, the biopsy kit is removed from the probe.
2. Disassemble the biopsy kit into its component parts and discard the disposable parts in the clinical waste bin.
3. Rinse with water to remove excess soil from device.
4. Prepare an enzymatic solution (e.g. Enzol), following manufacturer instructions for proper dilution and immersion time. Immerse the parts in the detergent and allow soaking for the prescribed time.
5. Brush the parts thoroughly using a soft bristle brush. Clean the lumen using an appropriate sized brush. If any visible parts remain, continue brushing until clean.
6. Thoroughly rinse the device with water and dry the parts. Discard the used soft cloth to clinical waste.

## ❏ Disinfecting the Biopsy Kit

**CAUTION:**

- ▶ Always refer to the biopsy kit user manual for the latest information on the supported methods and disinfectants.
- ▶ A stainless steel biopsy adapter is reusable; a plastic biopsy adapter may be reusable. A plastic biopsy needle guide is in general disposable.
- ▶ Plastic biopsy kits can only be disinfected by using a chemically compatible cold-disinfectant, either manual or with a medical washer-disinfector. Do not use an autoclave, gas or radiation.

Please refer to the user manual of the disinfectant for storage, use, and disposal of the disinfectant.

1. Re-assemble the reusable parts of the biopsy adapter, if applicable.
2. Disinfect the biopsy adapter for the duration and temperature as specified in the user instructions of the adapter.
3. After disinfection, follow the proper post-disinfection procedure for the disinfection method used. (Refer to the instructions for the disinfectant, disinfecting equipment, etc.)
4. Inspect the components for damage such as cracks, rust or breakage and if damage is discovered stop using the device and contact the Samsung Medison Customer Support Department.
5. Properly pack the disinfected adapter and label it according to local regulations.

## ❏ Sterilizing the Stainless Steel Biopsy Kit

1. Re-assemble the reusable parts of the stainless steel biopsy adapter, if applicable.
2. Sterilize the stainless steel adapter by autoclaving (Steam) or using gas (Ethylene Oxide).
3. After sterilization, follow the proper post-sterilization procedure for the sterilization method used. (Refer to the instruction of the sterilization equipment.)
4. Inspect the components for damage such as cracks, rust or breakage and if damage is discovered stop using the device and contact the Samsung Medison Customer Support Department.
5. Properly pack the sterilized adapter and label it according to local regulations.