

SAMSUNG MEDISON DIAGNOSTIC ULTRASOUND SYSTEM

# HS50A/HS60A Service Manual



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SAMSUNG MEDISON DIAGNOSTIC ULTRASOUND SYSTEM

# Version 1.00 HS50A/HS60A Service Manual

English

SM-HS50A/HS60A-ENG-01

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# **Safety Classifications**

#### Classification

- Type of protection against electric shock: Class I
- Degree of protection against electric shock (when the patient is in physical contact): Type BF or type CF applied part
- Degree of protection against harmful ingress of water: Ordinary equipment
- Degree of safety of use in the presence of flammable anesthetic agent mixed with air, oxygen, or nitrous oxide: Equipment not suitable for use in the presence of 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 Standards: 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 Standards: 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, A1:1991, A2:1995]
- Medical Electrical Equipment, Part 1-1: General Requirements for Safety Collateral Standards: General Requirements for Medical Electrical Systems [IEC 60601-1-1:2000]
- Medical Electrical Equipment, Part 1-2: General Requirements for Safety Collateral Standards: Electromagnetic Compatibility - Requirements and Tests [IEC 60601-1-2:2001, A1:2004]
- Medical Electrical Equipment, Part 1-4: General Requirements for Safety Collateral Standards: Programmable Electrical Medical Systems [IEC 60601-1-4:1996, A1:1999]
- Medical Electrical Equipment, Part 2-37: Particular Requirements for the Basic Safety and Essential Performance of Ultrasonic Medical Diagnostic and Monitoring Equipment [IEC 60601-2-37:2001, A1:2004, A2:2005]
- Medical Devices Application of Risk Management [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 [ISO 10993-1: 2009]
- Standard Means for Reporting the Acoustic Output of Medical Diagnostic Ultrasonic Equipment [IEC 61157:2007]

#### Declarations



CSA mark with the indicators "C" and "US" means that the product is certified for both US and Canadian markets according to the applicable US and Canadian standards.



This mark certifies that the product conforms to applicable EEC standards, and that it has been certified by the European certification agency.

CE

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



This is the GMP symbol for Korean Good Manufacturing Practice quality system regulation.

# **Precautions for Use**

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

- Keep this service manual near the product and refer to it when using the product.
- Be sure to familiarize yourself with the safety information contained in 'Chapter 2. Safety' and 'Chapter 10. Maintenance and Storage' in particular.
- This service manual does not include diagnosis results or opinions. In addition, please consult the reference for each study area before evaluating the measurement result of an application.
- This product is an ultrasound diagnostic system and cannot be used with your personal computer. If you use this product in such an environment, we cannot be held responsible for any resulting problems.
- This product must be used by a person who possesses clinical pathology training and/or certification. Use by unqualified persons is prohibited.
- The manufacturer is not liable for any problems with the system caused by careless operation and/or improper control by the operator.
- Product orders are based on individually agreed-upon specifications and may not include all functions specified in this service manual.
- Some functions or options, probes, and the like may not be used in certain countries.
- All reference materials on standards, regulations, and related revisions are valid at the time of publication of this service manual.
- Screen images in this service manual are examples only (may differ from the actual screen or system).
- The content of this service manual is subject to change without prior notice.
- Products that are not manufactured by Samsung Medison are indicated with the trademarks of their respective owners.
- The following terms are used to highlight the safety precautions that the user must be aware of:



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



Follow these instructions to prevent serious accidents or damage to property.



Follow these instructions to prevent minor accidents or damage to property.



A piece of information useful for installing, operating, and maintaining a system; not related to any hazard.

# **Revision History**

The revision history of this service manual is as follows:

Version	DATE	REASON FOR CHANGE	
1.00.00	2016.07.15	Initial Release	

#### If You Need Assistance

If you need a service manual or any assistance with the product, please contact the Samsung Medison customer service department or your local vendor.

# **Patient Privacy Policy**

#### **Treatment of Patients' Personal Information**

One of Samsung's social responsibilities is to recognize the importance of patient privacy and handle and protect the personal information provided by patients in an appropriate manner.

Patient information stored in repaired and demo products should be handled as follows:

- Patient Information: IDs, names, DOBs, and images are information used to identify patients.
- Patient Information Management: Personal information provided by patients must be protected during repairs and demonstrations. Do not use, distribute, or lose patient information to third parties.

#### Management of Patient Information on Demo and Trade Products

- Patient information stored on a product during the course of its use must be handled as the patient desires. (delete or backup)
- When any demo or trade product is collected, patient information must be deleted if requested by the patient to prevent its unintended distribution.

#### Management of Patient Information on Repaired Hospital Products

- Before removing the product from hospital premises for repairs, all patient information should be backed up to an external HDD or a memory device.
- Before removing the product from hospital premises, each patient should sign the patient privacy agreement.

#### **Request for Repairs and Patient Privacy Agreement**

Date: MM/DD/YY

#### [Customer Information]

Hospital	
Handler	

[Product Information]

Product name	
Software version	
S/N	
Symptom	
Stored item	□ None □ Main unit □ HDD □ DVD/CD □ USB □ Photo □ Other ( )
Outsourced product	<ul><li>□ None</li><li>□ Provide details if applicable ( )</li></ul>

#### [Administration]

Handling date	MM/DD/YY		
Customer service representative			

\* Please sign inside the box below if you agree to the following:

- Data saved on memory devices -- for example, hard disks -- may be lost during tests and repairs.
- □ Data saved on a product being repaired must be backed up by the customer.
- $\hfill\square$  Samsung will not be held responsible for any loss of data that are not backed up.
- □ Samsung neither uses nor modifies patient information nor provides it to third parties.

#### [Customer Signature]

I entrust my product to (		) for repair and agree to the policies above.		
Date:	MM/DD/YY	Name:	(Signature)	

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# **Chapter 1**

# Introduction

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# 1.1. Product Specifications

Physical Dimensions	Height: 1344 mm (with Monitor) Width: 529 mm Depth: 767 mm (with Keyboard) Weight: 79.8kg (without accessories) Weight: Approx. 98kg (with Safe Working Load)
Imaging Modes	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 Simultaneous Mode Combined Mode Zoom Mode
Gray Scale	256 (8 bits)
Focusing	Transmit focusing, maximum of eight points (four points simultaneously selectable) Digital dynamic receive focusing (continuous)
Probes (Type BF/IPX7)	Linear Array LA3-14AD, LA2-9A, LA3-16AI, LA4-18BD, LA3-16A Curved Array CA1-7AD, CA2-9AD, CA2-6BM, CF4-9 Endo Cavity ER4-9, EA2-11B Phased Array PA1-5A, PA3-8B, PE2-4 3D CV1-8AD, V5-9 CW CW6.0, DP2B

		<ul> <li>HS50 does not su LA4-18BD, PA1-5</li> <li>HS60 does not su</li> </ul>	upport LA2-9A and LA 5A. upport PE2-4 and ER4	3-16AI, EA2-11B, I-9.
	3 Probe Connec	tors, 4 Probe Conne	ectors for option	
	$\wedge$		HS50	HS60
Probe Connections		3 PORT	0	Х
	NOTE	4 PORT	O (Option)	0
	CW Probe Connec	ctor		
Monitor	Main Monitor         Number of Pixel: 1920 x 1080         21.5 inch LCD Monitor (LED Backlight unit, hereafter referred to as "LCD monitor")         Touch Screen Monitor         Number of Pixel: 1280 x 800         10.1 inch LCD Monitor (LED Backlight unit, hereafter referred to as "LCD monitor")			
ECG	USB Type (Type CF)			
Rear Panel Input/Output Connections	Audio Output Pc VGA monitor LAN USB Port HDMI output	rt (Right/Left)		
Image Storage	Maximum 45,00 Maximum 14,00 Image filing syst	0 frames for Cine m 0 Lines for Loop me em	emory emory	
Application	Obstetrics, Gyne Parts, TCD, MSI	ecology, Urology, Al K, Pediatric	odomen, Cardiac, V	ascular, Small
Electrical Parameters	100-240VAC, 80	0VA, 50/60Hz		
Measurement Packages	Abdomen, Obste Vascular, Cardia * For additional i Calculations' in t	etrics, Gynecology, ic, Fetal Heart nformation, refer to he user manual.	MSK, Pediatric, Sm the 'Chapter 8. Mea	all Parts, Urology, asurements and

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Signal Processing (Pre- processing)	Acoustic Power Control Dynamic Aperture Control Dynamic Apodization Control Dynamic LPF Control			
Signal Processing (Post- processing)	Digital TGC Control Slider TGC Control Mode-Independent Gain Control Black Hole/Noise Spike Filtering 1D Lateral/Axial Filtering 2D Edge/Blurring Filtering Frame average M/D Mode Sweep Speed Control Zoom Image View Area Control Image Orientation (left/right and up/down)			
Measurement	Trackball operation of multiple cursors 2D mode: Linear measurements and area measurements using elliptical approximation or trace M mode: Continuous readout of distance, time, and slope rate Doppler mode: Velocity and trace			
Auxiliary	DVD Multi-Drive Digital B/W Video Printer Digital Color Video Printer USB Printer DVD Recorder Foot switch (IPX8) USB Flash Memory Media USB HDD USB ECG Monitor			
User Interface	English, German, French, Spanish, Italian, Portuguese			
Pressure Limits	Operating: 700 – 1060hPa Storage: 700 – 1060hPa			
Humidity Limits	Operating: 30 – 75% Storage & Shipping: 20 – 90%			
Temperature Limits	Operating: 10 – 35°C Storage & Shipping: -25 – 60°C			

#### **1.2. Product Configuration**

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



[Figure 1.1 Front of the Product]

- ① Monitor
- ② Monitor arm
- ③ Keyboard
- $\textcircled{4} \quad \text{Control panel}$
- ⑤ Lift
- 6 Probe holder
- 1 DVD drive
- ⑧ USB port
- 9 Speaker
- 10 Probe port
- 1 Wheel
- 12 Location of ID Label
- 13 Brake
- (1) Gel warmer
- Internal peripheral devices outlet



[Figure 1.2 Back of the Product]

- 1 Handle
- ② Storage compartments
- 3 Ventilation
- ④ Rear panel
- 5 Power connection part
- 6 ID label

#### 1.2.1. Monitor

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

#### 1.2.1.1. Screen Layout

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



[Figure 1.3 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.



For information on User Key Setup, please refer to 'Chapter 3. Utilities' in the user manual.

#### TIP 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.

#### 1.2.2. Control Panel

The system can be controlled by using the control panel.



[Figure 1.4 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.

#### 1.2.2.1. 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. Utilities' and later in the user manual.

On/Off	Button	Turns the system on/off.
End Exam	Button	Finishes the exam of the currently selected patient and resets the related data.
SonoView	Button	Displays the screen for viewing and managing stored images.
Report	Button	Displays the Report screen that shows the measurement results of the current application and other information.
Menu	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 Menu 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.
() Markerflet	Dial- button	<ul> <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>
	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.
R	Button	Compares two independent images. The active image mode is on the right.
Depth	Switch	Adjusts the scanning depth of the image.
Focus	Switch	Moves the focus to the target area for observation.
Zoom	Dial- button	Makes the Zoom Box appear. In order to close the Zoom mode, press the Exit button.
9	Button	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.
	Button	Pauses/resumes scanning.
	Button	Stands for User Key; functions can be assigned to these buttons as desired. The function for each button can be assigned in Setup > Customize > Buttons > User Key.
M	Dial- button	Start or end M Mode. Rotate this dial-button to adjust Gain. Also, turning this dial-button when in 3D View rotates the image along the x-axis.
(PW)	Dial- button	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.

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C	Dial- button	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.
PD	Button	Press this button to start/stop Power Doppler mode.
Cw	Button	Press this button to start/stop CW Spectral Doppler mode. Available only with the phased array probe.
(2D)	Dial- button	Press this button to start 2D mode. Rotate this dial-button to adjust Gain.
(3D/4D)	Button	Press this button to turn 3D/4D Mode on/off.
<b>⊕</b> Set/Exit	Button	<ul> <li>Set or Exit function may be assigned to this button. The function for each button can be assigned in Setup &gt; Customize &gt; Set/Exit Key.</li> <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>S</b> Clear	Button	Deletes text, Arrow, BodyMarker, measurement results, etc. displayed on an image.
Pointer	Button	When this is pressed, an arrow marker appears to point to parts of the displayed image.
Change	Button	Changes the current trackball function.
Τ	Button	Allows the user to place text on an image.
Calculator	Button	Starts measurements by application.
Trackball	Trackball	Moves the cursor on the screen. Also scrolls through Cine images.

#### Keyboard

The keyboard is used to type in text.

Esc	Help	Patie	nt Pa Int	tient in in	nage do.	Spooler	Arrow	Home	Set Home	Word	Delet	e Se	tup		sert Delet
.)	1	@ 2		# 3	\$ 4	% 5	6	8 7	* 8	( 9	)		- 1	+ =	Backspac
Tab →	Q	Ä	NÅ	E	R	T	Y Ű	Ú	]]ı	'][c	ò	PÖ	{ [	}	1
Caps &		Å	s	D	PF	] [ G	Дн	][	<sup>a</sup> K	2	ø	];	•]["	][€	nter
介sh	ift	z	Æ	x	c	[v]	в	Ň	M	<,	¢ >		?	습 shi	ft
Ctrl		Fn		A						AR	Ctrl	11	PgL	ip)[]3	¥†
											L	JI.	- df -	•	*1 11.

[Figure 1.5 Keyboard]

Help	Displays the Help Manual on the screen.
Patient	Displays the General Information on the screen.
Patient info.	Shows or hides the patient information on the screen.
Image Info.	Shows or hides the Image Parameters on the screen.
DICOM Spooler	Displays the DICOM Spooler on the screen.
Arrow	Initiates Arrow mode.
Home	Moves the cursor to the Home position in Annotation mode.
Set Home	Specifies the Home position in Annotation mode.
Delete Word	Deletes the last text entered in Annotation mode.
Delete All	Deletes all the text that has been entered in Annotation mode.
Setup	This displays the Setup screen.
Insert	Select an input method.
Delete	Deletes text.
<b>↓</b> ))→	Turns up the speaker volume.
<b>↓</b>	Turns down the speaker volume.

#### 1.2.2.2. 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 1.6 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.



For further details about setting up Quick Preset, please refer to 'Setup > System > Quick Preset' in 'Chapter 3. Utilities' in the user manual.

- 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.



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  $\triangleleft$  and  $\triangleright$  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.

#### TIP 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.

#### 1.2.2.3. Adjusting the Control Panel



- 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.

#### 1.2.3. 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.

#### 1.2.3.1. Rear Panel

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



[Figure 1.7 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.

#### 1.2.3.2. Power Connection Part

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



[Figure 1.8 Power Connection Part]

- 1 Power switch/breaker: Turns on the power of the product, and cuts off power if overcurrent or overvoltage occurs.
- ② Power inlet: Accepts the power cord, which connects to an external power supply.
- ③ Equipotential Terminal: This should be connected to the equipotential connection part in the exam room.

#### 1.2.3.3. 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 th detach it.

[Figure 1.9 Removing the Probe Holder]

#### TIP Hockey Stick Probe Holder

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

#### 1.2.4. Peripheral Devices

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



- Do not install peripheral devices that are not listed in the 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 1.10 Patient Environment]



Refer to the user manual of the peripheral device for its operating information.

#### 1.2.4.1. 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
   Min. 64Gbytes SATA SSD

#### 1.2.4.2. 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.



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.

**TIP** 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



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

#### Foot Switch

- 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


- 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.

# 1.2.5. Probes

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



For information on probes, refer to 'Chapter 9. Probes' and the Reference Manual.

# 1.2.5.1. Connecting Probes

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

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.

Turn the connector-locking handle clockwise.



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



[Figure 1.11 Probe Connector]

# 1.2.6. Accessories

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



[Figure 1.12 Accessories]

# 1.2.7. Optional Functions

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

Option	HS50	HS60
4D	0	0
3D XI	0	0
DICOM	0	0
Ez Exam+	0	0
MultiVision	0	Basic option
5D NT	0	0
CW Function	0	0
Cardiac Measurement	0	0
Strain+	Х	0
Auto IMT+	0	0
ElastoScan	0	0
E-Strain	Х	0
Panoramic	0	0
XI STIC	0	0
SEE Stream (RU region only)	0	0
Needle Mate+	0	0
CEUS+	Х	0
Realistic Vue	0	0
HDVI	Х	0
Mobile Export	0	0
5D Follicle	0	0

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

# Chapter 2

# Safety

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# 2.1. Purpose of Use

Ultrasound diagnostic system and probes were designed for obtaining ultrasound images and analyzing human blood. Below are the clinical applications:



For detailed information on applications and presets, refer to "Chapter 1. Introduction" and "Chapter 9. Probes" in this manual.

# 2.1.1. Restrictions

This product must not be used for ophthalmological application or any other use that involves the ultrasound beam passing through the eyeball.



For information on the use or clinical application of this product, refer to "Chapter 6. Starting Diagnosis" and "Chapter 7. Diagnosis Mode" in the user manual.

# 2.2. Safety Information

Read the following safety information before using this product: This provides an explanation about the ultrasound system, probes, recording devices, and any of the optional equipment.

This product is intended for use by, or by the order of, and under the supervision of a licensed physician who is qualified to use medical devices directly.

Prolonged use of three-dimensional ultrasound (3D, 4D) by an unqualified individual, such as to produce commemorative photograph or video of the fetus, may have an adverse effect on the fetus.

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

# 2.2.1. Safety Symbols

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

Symbols	Description
	Warning: Follow these instructions to prevent serious accidents or damage to property.
$\wedge$	Caution: Follow these instructions to prevent minor accidents or damage to property.
i	Refer to the user manual.
<b>K</b>	Follow the user manual.
Â	Caution: Risk of electric shock
Ϋ́	Type BF applied part (Classification based on degree of protection against electric hazard)
	Defibrillation-proof type CF applied part (Classification based on degree of protection against electric hazard)
Ċ	Power on/off

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Symbols	Description		
	Power on		
$\bigcirc$	Power off		
$\odot$	Product is partially powered on		
Ō	Power off for part of the product		
V~	AC (alternating current) voltage source		
	DC (direct current) voltage source		
4	Dangerous voltage (over 1000V AC or 1500V DC)		
	Protective earth (ground)		
$\checkmark$	Equipotential terminal		
÷	Data output port		
$\rightarrow$	Data input port		
<b></b>	Data input/output port		
$\rightarrow$	Input port		
$\bigcirc$	Output port		
	Print remote output		

Symbols	Description
×	Foot switch port
_∕~	Electrocardiograph (ECG) port
4	USB port
	Network port
Ŷ	Microphone port
	Probe port
IPX 1	Dripping-proof device: Protected against vertically falling water
IPX 7	Immersion-proof device: Protected against the effects of non- continuous immersion in water
IPX 8	Submersion-proof device: Protected against the effects of continuous immersion in water
i.	Caution: The device is sensitive to electrostatic discharge (ESD)
	Do not sit on the product.
×	Do not push the product.
X	Do not lean against the product.

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Symbols	Description
	Mind the space. Do not place a hand, a finger, or any other part of the body in the empty space.

# 2.2.2. LABEL

Phrases containing the words 'Warning' and/or 'Caution' are displayed on the product's surface in order to protect the product.

# 2.3. Electrical Safety

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

# 2.3.1. Prevention of Electric Shock

In a hospital environment, dangerous electric current may occur as a result of the potential difference between a contactable conductive part and the connected equipment in treatment rooms. The solution to the problem is consistent equipotential bonding. The equipotential terminal of an item of medical equipment must be connected to the equipotential bonding network in a treatment room, as shown in the figure below.



[Figure 2.1 Equipotential Bonding]

Additional equipment connected to medical electrical equipment must comply with the pertinent IEC standards (e.g., IEC 60950/EN 60950 for data processing equipment, IEC 60601-1/EN 60601-1 for medical devices). Furthermore, all components of the product shall comply with the requirements for medical electrical systems IEC 60601-1-1/EN 60601-1-1. Any person connecting additional equipment to the signal input and output ports of medical electrical equipment must verify that the equipment complies with IEC 60601-1-1/EN 60601-1-1.

•



- Electric shock may occur if this system, including all of its externally mounted recording and monitoring devices, is not properly grounded.
- Never open the cover of the product. The interior of this product contains dangerous high-voltage electricity. All internal component repairs and part replacements must be performed by Samsung Medison's customer service department.
- 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 (for example, cracked or chipped) or if the cable is worn.
- · Always disconnect the system from the wall outlet prior to cleaning it.
- All patient contact devices, such as probes and ECG leads, must be removed from the patient prior to the application of a high-voltage defibrillation pulse.
- Never use the product in the presence of flammable anesthetic gas or oxidizing gases (N2O). Doing so may cause an explosion.
- Avoid installing the system where it is difficult for the operator to disconnect it from the power source.
- Do not use HF surgical equipment with the system. Any malfunctions in the HF surgical equipment may cause burns to the patient.
- The system must be connected to a power supply with protective earth to prevent electric shock.



- 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. This continues to operate even when the system is on standby.
- Do not immerse the power cable in any liquid. Cables are not waterproof.
- Make sure that the inside of the system is not exposed to or immersed in any liquid. Otherwise, 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 peripheral devices other than those listed in this manual to the auxiliary socket outlets of the system. It may pose an electrical hazard.
- Do not touch the SIP/SOP and the patient simultaneously. There is risk of electric shock from leaking current.

# 2.3.2. Related Information



- This product does not support ECG monitoring. Therefore, it will not recognize incompatible ECG signals.
- Do not use the ECG electrodes of HF surgical equipment. Any malfunctions in the HF surgical equipment may cause burns to the patient.
- Do not use ECG electrodes during cardiac pacemaker procedures or other electrical stimulators.
- Do not use ECG leads and electrodes in an operating room.

# 2.3.3. ESD

Electrostatic discharge (ESD), commonly referred to as 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. Static shock, or ESD, is a discharge of the electrical energy buildup from a charged individual to a lesser or an uncharged individual or object. ESD occurs when an individual with electrical energy build-up comes in contact with conductive objects such as metal doorknobs, filing cabinets, computer equipment, and even other individuals.



- The level of electrical energy discharged from a system user or a patient to an ultrasound system can be significant enough to cause damage to the system or probes.
- Always perform anti-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.

#### 2.3.4. EMI

This product complies with EMI (Electromagnetic Interference) standards. Note, however, that using the system inside an electromagnetic field can lower the quality of ultrasound images and even damage the product.

If this occurs often, Samsung Medison suggests a review of the environment where 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. Nearby radios, TVs, or microwave transmission equipment can also cause interference.



In cases wherein EMI is causing disturbances, it may be necessary to relocate the system.

#### 2.3.5. 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).

#### 2.3.5.1. Guidance and Manufacturer's Declaration - Electromagnetic Emissions

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

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

# 2.3.5.2. Approved Cables, Probes, and Peripherals for EMC

#### Cables

Cables connected to this product may affect its electromagnetic emissions. Therefore, use only the appropriate cable of the types and lengths listed below.

Cables	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	Non-shielded	Any
ECG 3-lead	Shielded	Normal

#### Probe

The image probe used with this product may affect its electromagnetic emission. The probes listed in 'Chapter 9. Probes' of this manual have been tested to comply with the Group 1, Class A requirements of the CISPR 11 standard.

#### Peripherals

Peripherals used with this product may affect its electromagnetic emissions.



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



The use of cables, probes, and peripherals other than those specified may result in increased emissions 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	The quality of the power mains 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	The quality of the power mains should be that of a typical commercial or hospital environment.	
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	5% <i>U</i> τ for 0.5 cycles (>95% dip in <i>U</i> τ) 40% <i>U</i> τ for 5 cycles (60% dip in <i>U</i> τ) 70% <i>U</i> τ for 25 cycles (30% dip in <i>U</i> τ) 5% <i>U</i> τ for 5 seconds (<95% dip in <i>U</i> τ)	5% <i>U</i> τ for 0.5 cycles (>95% dip in <i>U</i> τ) 40% <i>U</i> τ for 5 cycles (60% dip in <i>U</i> τ) 70% <i>U</i> τ for 25 cycles (30% dip in <i>U</i> τ) 5% <i>U</i> τ for 5 seconds (<95% dip in <i>U</i> τ)	The quality of the power mains should be that of a typical commercial or hospital environment. If the user of this product requires continued operation during interruptions in the power mains, it is recommended that this product be powered by an uninterruptible power supply or a battery.	
Power frequency magnetic field (50/60Hz) IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment.	
Note: OT is the AC main 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	3Vrms 150kHz ~ 80MHz	3V	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. This distance is calculated using the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80MHz to 800MHZ $d = 2.3\sqrt{P}$ 800MHz to 2.5GHz	
Radiated RF IEC 61000-4-3	3V/m 80MHz ~ 2.5GHz	3V/m	Where <i>P</i> is the transmitter's maximum output power rating in watts (W) according to the transmitter's manufacturer and <i>d</i> is the recommended separation distance in meters (m). Field strengths <sup>a</sup> from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range ( <sup>b</sup> ). Interference may occur in the vicinity of equipment marked with the following symbol:	
Note 1) At 80MHz and 800MHz, the higher frequency range applies. Note 2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.				
<ul> <li><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 broadcasts, and TV broadcasts cannot be predicted accurately. 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 where 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 reorienting or relocating the Ultrasound System or using a shielded location with higher RF shielding effectiveness and filter attenuation.</li> <li><sup>b</sup> Beyond the frequency range from 150kHz to 80MHz, field strengths should be less than 3 V/m.</li> </ul>				

# 2.3.5.3. Recommended Separation Distances between This Product and RF Communications Equipment

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

Rated maximum	Separation distance according to the frequency of transmitter [m]			
output power of transmitter [W]	$150$ kHz – $80$ MHz $d = 1.2\sqrt{P}$	$80 \text{MHz} - 800 \text{MHz}$ $d = 1.2 \sqrt{\text{P}}$	800MHz – 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 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's manufacturer.

Note 1) At 80MHz and 800MHz, the separation distance for the higher frequency range applies.

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

# 2.3.5.4. Electromagnetic environment guidance

It is recommended to use ultrasound systems in shielded locations offering RF shielding effectiveness, with shielded cables. Field strengths outside the location shielded 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.



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

# 2.3.5.5. Avoiding Electromagnetic Interference

Typical interference on ultrasound imaging systems varies depending on electromagnetic phenomena. Refer to the following table:

Imaging mode	ESD <sup>1</sup>	RF <sup>2</sup>	Power Line <sup>3</sup>
2D	When changing the operating mode or system settings or resetting the system, brief flashes appear 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 that are sometimes more pronounced on the sides of the image.	White dots, dashes, diagonal lines, or diagonal lines near the center of the image.
М		Increase in 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 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 noises in the audio, or both.

1. ESD caused by the discharging of electric charge build-up on insulated surfaces or persons.

2. RF energy from RF transmitting equipment such as portable phones, hand-held radios, wireless devices, commercial radio and TV, and so on.

3. Conducted interference on power lines or connected cables caused by other equipment, such as switching power supplies, electrical controls, and natural phenomena such as lightning.

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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 systems do not generate electromagnetic interference in excess of the referenced standards.

The Ultrasound System is designed to receive signals at radio frequency; therefore, it is 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 with only one probe operating at the same frequency or with several probes?
- Do two different probes 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 lies with the system or the scanning environment. Answer each of the questions and contact Samsung Medison's customer service department.

# 2.4. Mechanical Safety

# 2.4.1. Moving the Equipment



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 whether the wheel brakes are unlocked. In addition, be 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 shock. Note, however, that excessive shock -- for example, if the product falls over -- may cause serious damage.

If the product does not work properly after transfer, contact Samsung Medison's Service Department.

#### 2.4.1.1. Brake

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 locking the brakes when using the product.

#### 2.4.1.2. Precautions on Ramps

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



Mind the castors, especially when moving the system. Samsung Medison recommends exercising caution when moving the product up or down ramps.

If you leave the product on an incline, the product may fall over even if the brakes are engaged. Do not leave the product on ramps.

# 2.4.2. Safety Notes



- 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 pieces of metal, do not enter the system.
- Do not block the ventilation slots.
- Do not pull the power cord to unplug it. Doing so can damage the cord and cause short-circuit and cord snapping. Always unplug by pulling the plug itself.
- Excessive bending or twisting of cables or parts that are applied to the patient may cause failure or intermittent operation of the system.
- Improper cleaning or sterilization of parts applied to the patient 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.

Refer to 'Chapter 10. Maintenance and Storage' for detailed information on protecting, cleaning, and disinfecting the equipment.

#### 2.4.2.1. Monitor Safety Caution

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



[Figure 2.2 Monitor Safety Caution]

# 2.4.2.2. Control Panel Caution



- Do not press on the control panel with excessive force or lean against it.
- Do not sit on the control panel or apply too much pressure to it.

When adjusting the control panel's height or position, mind the space between the panel and the lift. Getting your fingers or other body parts caught in it may result in injury.



[Figure 2.3 Control Panel Caution]

# 2.5. Biological Safety

For safety information on the probe and biopsy, refer to 'Chapter 9. Probes.'



- Ultrasound waves may have damaging effects on cells and consequently harm the patient. If there is no medical benefit, minimize the exposure time and maintain the ultrasound wave output at low levels. 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. Take note of the error code, turn off power to the system, and call Samsung Medison's 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; the ultrasonic wave output observes the American FDA regulations.

# 2.5.1. ALARA Principle

Guidance for the use of diagnostic ultrasound is defined by the '(As Low As Reasonably Achievable)' (ALARA) principle. The decision as to what is reasonable has been left to the judgment and insight of qualified personnel. No set of rules that would be sufficiently complete to dictate the correct response to every circumstance can be formulated. By keeping ultrasound exposure as low as possible while obtaining diagnostic images, users can minimize the 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 the exposure time with the diagnostic image quality. To ensure diagnostic image quality and limit the 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 given rise to the need for increased and improved information to guide the user. Based on a variety of ultrasound output data, the output indices are designed to provide important information for executing the ALARA principle.

There are a number of variables that affect the way in which the output display indices can be used to implement the ALARA principle. These variables include mass, body size, location of the bone relative to the focal point, attenuation in the body, and ultrasound exposure time. Exposure time is an especially useful variable, because the user controls it. Unlike other variables, exposure time is entirely controlled by the operator of the ultrasound system.

#### 2.5.1.1. Applying ALARA

The system-imaging mode used depends on the information needed. 2D-mode and M-mode imaging provide anatomical information, whereas 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, whereas an unscanned mode like M-mode or Doppler concentrates ultrasonic energy. Understanding the nature of the imaging mode being used allows the sonographer to apply the ALARA principle with informed judgment. The probe frequency, system setup values, scanning techniques, and operator experience aid the sonographer in adhering to 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 potential localized heating of the patient due to probe surface temperatures. Prudent use of the system is secured 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 the exposure time is an effective way of accomplishing 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.

#### 2.5.1.2. Direct Controls

Application selection and 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 priorities required during any exam. For example, peripheral vascular intensity levels are not recommended for fetal exams. Some systems automatically select the proper range for a particular procedure, whereas others require manual selection. Ultimately, the user bears the responsibility for proper clinical use. Samsung Medison's systems provide both automatic and user-definable settings.

Output has direct impact on acoustic intensity. Once the application has been established, output control can be used to increase or decrease the output intensity. Output control lets you select intensity levels that are lower than the defined maximum. Prudent use ensures good image quality while employing the lowest output intensity.

#### 2.5.1.3. Indirect Controls

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

The choice of imaging mode determines the nature of the ultrasound beam. 2D-mode is scanned mode; Doppler is stationary or unscanned mode. A stationary ultrasound beam concentrates energy on a single location. Moving or scanned ultrasound beam disperses the energy over a wide area, with the beam concentrated only on a given area for a fraction of 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. Pulse repetition frequency is affected by several controls such as 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. Maintaining or increasing 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 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, lower probe frequency is required. Using more gain and output beyond a point without corresponding increases in image quality can mean that 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.

#### 2.5.1.4. Additional Considerations

Ensure that scanning time is kept to a minimum, and that only medically required scanning is performed. Never compromise quality by rushing an exam. A poor exam will require 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.

#### 2.5.1.5. Output Display Features

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

The mechanical index is continuously displayed over the range of 0.0 to 1.9, in increments of 0.1. The thermal index consists of three indices, and only one of these is displayed at all times. Each diagnostic probe application has a default selection. The TIb or TIs is continuously displayed over the range of 0.0 to maximum output, based on the probe and application, in increments of 0.1.

The default setting of the application-specific nature is also an important factor of index selection. A default setting is a system control state that 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 power is turned on, new patient data is entered into the system database, or change of application occurs.

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

Appropriate index for the application: TIs is used for imaging soft tissue, and TIb, for focus at or near a bone. Elements such as fluid, bone, and blood flow may act as elements that increase or decrease TI. A highly attenuating tissue path, for example, may cause the potential for local zone heating to be lower than the thermal index displays.

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

Always limit the ultrasound exposure time. Do not rush the exam. Make sure 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. MI accounts for these two factors. The higher the MI value, the greater the likelihood of mechanical bioeffects occurring. Note, however, that there is no specific MI value that means that a mechanical effect will actually occur. The MI should be used as a guide for implementing the ALARA principle.

#### Thermal Index (TI) Display

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

The bone thermal index (Tlb) informs the user of 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 (Tlc) informs the user about the potential heating of bone at or near the surface -- for example, the cranial bone. The soft tissue thermal index (Tls) informs the user about the potential for heating within soft homogeneous tissue. Tlc is displayed when you select a trans-cranial application.

Go to Setup > Imaging > Application/Preset > Thermal Index Type to select TI for display.

#### Precision and Accuracy of Mechanical and Thermal Indices Displays

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

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

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

Many of the assumptions used in the process of measurement and calculation are conservative in nature. Over-estimation of actual *in situ* exposure, for the vast majority of tissue paths, is built into the measurement and calculation process. For example, the acoustic output values measured underwater are de-rated using a conservative, industry-standard, attenuation coefficient of 0.3dB/cm-MHz.

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

A steady-state temperature rise is assumed in the industry-standard TI models, and the ultrasound probe is assumed to be held steadily in one position long enough for a steady state to be reached.

A number of factors that are considered when estimating the accuracy of display values include hardware variations, algorithm accuracy estimation, and measurement variability. 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 on parameter variations. Differences in 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, particularly in underwater measurements, non-linear propagation and saturation losses occur as pulse voltages increase.

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

#### 2.5.1.6. Control Effect- Controls Affecting the Indices

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

#### Power

Power controls the system's acoustic output. Two real-time output values are on the screen: TI and 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 will be a dominant contributor to this total; the displayed MI will be from the mode with the largest peak pressure.

#### 2.5.1.7. 2D Mode Controls

#### 2D Mode Size

Narrowing the sector angle may increase the frame rate. This will increase the TI. The pulse voltage may be automatically lowered by the software controls to keep the TI below the system maximum. A decrease in pulse voltage will decrease the MI.

#### Zoom

Increasing the zoom magnification may increase the 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 TI and MI by changing the frame rate or focal depth automatically. Lower frame rates decrease the TI. The displayed MI will correspond to the focal zone with the largest peak intensity.

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#### Focus

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

#### 2.5.1.8. Color and Power Controls

#### Color Sensitivity

Increasing the color sensitivity increases the TI and the time spent on scanning 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; the TI will also increase. The system may automatically decrease the pulse voltage to 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 primary mode, and the TI change will be small.

#### Color Sector Depth

Deeper color sector depth may automatically decrease the color frame rate or change the 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. The MI will correspond to the peak intensity of the dominant pulse type, which is a color pulse. If pulsed Doppler is also enabled, however, then pulsed Doppler will remain the primary 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 below the system maximum. A decrease in pulse voltage will also decrease the MI.

#### 2D Mode Size

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

#### 2.5.1.9. M Mode and Doppler Controls

#### Simultaneous and Update Methods

Use of combination modes affects both 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 below the system maximum. A decrease in pulse voltage will decrease the MI.

#### 2.5.1.10. Others

#### ■ 2D, Color, M-Mode, PW, and CW Modes

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

#### Probes

Each probe model available has unique specifications for contact area, beam shape, and center frequency. Settings 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 displayed MI is that of the zone with the largest peak intensity.

#### Application

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

#### 2.5.1.11. Related Guidance Documents

For more information on 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)

#### 2.5.1.12. Acoustic Output and Measurement

Since the first use 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 the 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 use have been published by groups such as WFUMB (World Federation of Ultrasound in Medicine and Biology), AIUM, and BMUS.

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

#### 2.5.1.13. In Situ, De-rated, and Water Value Intensities

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

In Situ = Water [ $e^{-(0.23alf)}$ ] where: In Situ = In Situ Intensity Value Water = Water Value Intensity e = 2.7183 a = Attenuation Factor Tissue a(dB/cm-MHz) Brain .53 Heart.66 Kidney .79 Liver .43 Muscle .55 I = skin line to measurement depth (cm)

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

Since the ultrasonic path during an examination is likely to pass through varying lengths and types of tissue, it is difficult to estimate the true *in situ* intensity. A 0.3 de-rating factor is used for general reporting purposes. Therefore, the *in situ* value is commonly reported using the

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

following formula:

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

#### 2.5.1.14. 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 <sub>aprt</sub>	-12dB OUTPUT BEAM AREA, ultrasonic beam area induced by -12dB output beam size (unit: cm <sup>2</sup> )	
d <sub>eq</sub> at max. I <sub>pi</sub>	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 Zb location, expressed as an equivalent beam area (unit: cm <sup>2</sup> )	
Dim of Aaprt	-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 <sub>awf</sub>	ACOUSTIC WORKING FREQUENCY, the arithmetic average of f1 and f2 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)	
$I_{\text{pa},\alpha}$ at max. MI	The average attenuated pulse strength at the location with maximum Mechanical Index (MI) (unit: W/cm <sup>2</sup> )	
I <sub>ta, α</sub> (Ζ)	Attenuated average strength over time at a specific focal length (z) (unit: $mW/cm^2$ )	
MI	MECHANICAL INDEX, a variable representing potential cavitations within the human body (unit: N/A)	
Ρ	OUTPUT POWER, time average power of an ultrasonic transducer's emissions into a free field through specified media such as water (unit: mW)	
$P_{\alpha}(z)$	ATTENUATED OUTPUT POWER, the power of ultrasonic output calculated at a specific distance from the transducer after attenuation occurs (unit: mW)	

ATTENUATED PEAK-RAREFACTIONAL ACOUSTIC PRESSURE, the peak rarefactional acoustic pressure calculated at a specific distance after attenuation occurs (unit: MPa)	
The peak rarefactional acoustic pressure at the location where PULSE- INTENSITY INTEGRAL is maximal (unit: MPa)	
PULSE REPETITION RATE, the inverse number of the time interval between two contiguous acoustic pulses (unit: Hz)	
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)	
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)	
Soft tissue thermal index in scanning mode (unit: N/A)	
Soft tissue thermal index in non-scanning mode (unit: N/A)	
PULSE DURATION (unit: us)	
Location with maximum PULSE-INTENSITY INTEGRAL (unit: cm)	
DEPTH FOR BONE THERMAL INDEX (unit: cm)	
BREAK-POINT DEPTH, which is the EQUIVALENT APERTURE DIAMETER multiplied by 1.5 (unit: cm)	
DEPTH FOR SOFT-TISSUE THERMAL INDEX, distance from a plane where the product of minimum attenuated output power, ATTENUATED SPATIAL-PEAK TEMPORAL-AVERAGE INTENSITY, and 1 cm <sup>2</sup> maximum 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)	

#### 2.5.1.15. Acoustic Measurement Precision and Uncertainty

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

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

#### Systematic Uncertainties

For the pulse intensity integral, de-rated rarefaction pressure (Pr.3), center frequency, and pulse duration, the analysis includes considerations of the effects on accuracy of:

Hydrophone calibration drift or errors.

Hydrophone / Amp frequency response.

Spatial averaging.

Alignment errors.

Voltage measurement accuracy, including.

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

The 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 the 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.

#### 2.5.1.16. 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 Samsung Medison's service department or any of the customer support centers worldwide.

## 2.6. Protecting the Environment



- You must consult the manufacturer or follow a proper procedure for disposal to dispose safely of the system and/or peripherals that have reached the end of their service life
- 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.

## Chapter 3

# **Installing Product**

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## 3.1. Transporting

This product is a finely tuned piece of medical electronic equipment; careful attention is required when transporting it.

## 3.1.1. Caution on Transporting

This product and its package box are designed to protect the product from physical impacts. Note, however, that dropping and external impact may cause serious damage to the product.

- Before transporting the product, check whether the wheel brakes are unlocked. In addition, be 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.

## 3.1.2. Brake

To control the movement of the product, you can use the brakes. The brakes are placed on the center of the console pedal; you can use the pedal to control the wheels simultaneously. To lock the brakes, press the front part of the brake with your foot. To unlock the brakes, press the back of the pedal.

We recommend locking the brakes when using the product.

## 3.1.3. Precautions on Ramps

Always make sure that the control panel is facing the direction of movement. If you leave the product on an incline, the product may fall over even if the brakes are engaged. Do not leave the product on ramps.



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



Mind the castors especially when moving the system. Samsung Medison recommends exercising caution when moving the product up or down ramps.

## 3.1.4. Humidity and Temperature

[Table 3-1. Product's Humidity and Temperature Tolerance] below presents the temperature and humidity ranges for transporting, storing, and operating the product.

Category	Temperature °C	Humidity %
Transporting	-25 – 60	20 – 90
Storage	-10 — 50	20 – 90
Operating	10 – 35	30 – 75

[Table 3.1. Product's Humidity and Temperature Tolerance]

## 3.2. Unpacking the Product

## 3.2.1. Dismantling the Product Box

- 1. Open the box.
- 2. Remove the protective cover.
- 3. Take out the probe box and accessory box and store them in a safe place.
- 4. Unlock the brakes on wheels.
- 5. Grab the rear handle on the product and move it to the installation site.



[Figure 3.1 Dismantling the Product Box]

## 3.2.2. Accessories

An accessory box containing the items below is supplied with the product. If it is not consistent with your order, contact Samsung Medison's customer service department or your local vendor.

## 3.2.3. Release of the Locking Mechanism

When this product is being transported, the monitor arm is secured in place with the locking mechanism to ensure safety. Release the locking mechanism based on the following procedure before using the product:

1. Pull down the locking mechanism on the center of the monitor arm to release the lock.



[Figure 3.2 Release of the Locking Mechanism]

## 3.3. Installation Environment

## 3.3.1. Caution

When installing the product, pay attention to the following: For more information on use and setup, refer to the accompanying manual for this product.



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

## 3.4. Installing the Product

## 3.4.1. Installation Safety

The power receptacle and equipotential terminal are located at the back of the product.



[Figure 3.3 Power Receptacle and Equipotential Terminal]

- ① Power inlet: Accepts the power cord, which connects to an external power supply.
- ② Equipotential terminal: This should be connected to the equipotential connection part in the exam room.

## 3.4.1.1. Power Cord Connection

Prior to connecting a power cord, verify that the voltage indicated on the power cord matches the voltage rating of the installation site.



The product may be shipped with the power cable connected to the console.



- If the product needs to be transported or stored for an extended duration, the temperature and humidity of the environment must be checked.
- A sudden change in temperature may cause condensation and lead to product failure.

Temperature °C	-20	-15	-10	-5	0	5	10 – 35	45	50	55	60
Waiting time <b>Hour</b>	16	10	8	6	4	2	Use immediately	2	4	6	10

Refer to "[Table 3-2. Operational Temperature of the Product]" before turning the product on.

[Table 3.2 Operational Temperature of the Product]

## 3.4.1.2. Connecting the Equipotential Terminal

In a hospital environment, dangerous electric current may occur as a result of the potential difference between a contactable conductive part and the connected equipment in treatment rooms. The solution to the problem is consistent equipotential bonding. The equipotential terminal of an item of medical equipment must be connected to the equipotential bonding network in a treatment room, as shown in the figure below.

## **3.4.1.3. Probe Connection**

Be sure to turn off power before connecting or disconnecting a probe 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 (five including CW) probes may be connected. The CW probe should be connected only to its own connector.
- 2. To install, turn the connector turning handle clockwise.



[Figure 3.4 Probe Connector]

## 3.4.2. Connecting Peripherals

•



- Do not install peripheral devices other than those listed in this Service Manual within the patient environment. Installing an unlisted device in the patient environment may pose an electrical hazard.
- Do not connect additional external peripheral devices to the auxiliary socket outlet. Doing so may decrease the safety level.



[Figure 3.5 Patient Environment]



For more information on the recommended peripheral devices, refer to 'Chapter 3. Installing Product.'

## 3.4.2.1. Internal Peripheral Devices

These are peripheral devices mounted in the system.

DVD-Multi

DVD-RW, DVD+RW, DVD-R, DVD+R, CD-R, CD-RW, CD-ROM

Solid State Device

Min. 64Gbytes SATA SSD

## 3.4.2.2. 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.



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



- When removing the removable disk, use Utility > Storage manager.
- USB ports are located on both the console and its rear panel. We recommend that you connect USB storage devices (flash memory media, etc.) to the ports on the console and other USB peripheral devices to the rear panel for convenience.

#### USB Video Printer

The following products are recommended:

- BW: Mitsubishi P-95DE (Japan: Mitsubishi P95D), Sony UP-D897, Sony UP-X898MD, Samsung ML-2955DW, Sony UP-D898MD
- Color: Mitsubishi CP-30DW, Sony UP-D25MD, Samsung CLP-615ND



- You must install a printer and a driver compatible with the English version of Microsoft Windows 7. Contact Samsung Medison's customer service department for inquiries about printer driver installation.
- When connecting the printer, make sure that the printer is configured under Microsoft Windows or system setup and has been chosen as the default printer.
- Check the port used by the printer before connecting. Printers should be connected to the printer port; the USB printer should be connected to the USB port.
- USB to RS-232C Serial Cable
- Foot Switch
- WLAN Card

#### Others

Flash Memory Media



- The system cannot recognize USB 1.1 flash memory. Remove the flash memory from the console and mount again with an appropriate device.
- When using a flash memory device that supports functions other than saving files, check first if it is possible to save the file on a desktop PC.
- Do not use flash memory media containing anti-virus programs or which are defective. Otherwise, the product may fail to work properly.

## 3.5. System Power

Boot up the system for use.



Be sure to connect the probes and peripheral devices that will be used before powering on the system. If you attempt to connect them during system use, it may lead to patient injury or irreparable damage to the console.

## 3.5.1. Turning the Power On

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



Before starting the diagnosis, you must register the patient information.

- If the power switch near the power connection port on the rear panel of the product has been switched off, wait for 10 seconds before turning on the product.
- Do not press keyboard keys or buttons while booting is in progress. Doing so may cause the system to malfunction.
- If you turn on power after turning it off abruptly, the system may turn on and off momentarily. This is a feature of the built-in Intel PC Main Board of the product and is not a system error.

## 3.5.2. Shutting down the System

Press the **On/Off** button while using the system to initiate shutdown. Click **Shut Down** on the screen to shut down the system or **Cancel** to cancel.



- When the system is not turned off, holding down the On/Off button for five seconds or longer forces the product to power off.
- If the ultrasound system is unplugged while working or turned off by forcibly shutting down, files may get corrupted, and such may result in system down or data loss.
- To ensure that electrical power is safely cut off, set the power switch at the rear of the product to Off position after using the product.
- Press the On/Off button twice to turn off the system. The Select Next Operation window appears when you press the On/Off button once. The system will turn off if you press it again.

## 3.6. System Settings

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

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

## TIP Selecting a tab

You can select a desired tab in 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 the settings and exit. Click **Exit** on the monitor screen, tap **Exit** on the touch screen, or press the **Exit** button on the control panel to switch to Scan Mode.



[Figure 3.6 Setup – Touch Screen]

## 3.6.1. ECG Setup

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



You may show or hide the ECG on the screen for each Preset at Setup > Application/Preset > Preset Setting.

## 3.6.1.1. Starting and Terminating an ECG

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

## 3.6.1.2. ECG Setup

Sweep Speed

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

Invert

Tap the Invert button in 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 in 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.



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

## 3.6.2. General System Settings

On the *Setup* screen, select the **System** tab. Or, tap **System** on the touch screen. From this tab, you can configure the general system settings.

## 3.6.2.1. General

On the Setup screen, select the General tab in the System category.

Setup							2015-07-04 11:23:45 AM
System	Ceneral Display	Patient Quick Pre					
Unaging	Location			Video -			
Application	bratikate	Language		Volue Setting	Format		
Measurement		ingitith			NISS		
Report	Date and Time			See Saind			
Annotation	Date Fermat	Time Termat		Track Screen		100	-
Body Marker	TTTT MM CD	~ 12 Hour		Score of the			
Customize				Cantool Pareci	Set / Est	· Ce	off
Peripherals	Data and Ten	t din	aZone		Save	= Ce	OIL
Connectivity	Trackball Spred				Other	. Qe	017
Service	Scan Mode	Star Norm	ul Fast	Accest			
	Weensteinert	Sise Room	al 👘 fart	Uner:		Uner A	zourt Merager
Save							
bit							
0 5							

[Figure 3.7 Setup - System - General]

1. 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, Russian, Simplified Chinese, Portuguese)

2. Date and Time

Set the date and time for use in the system.



- Before starting diagnosis, 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.



- 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 on 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. Press the button to display the Date and Time window.

- ① Set the date and time by using the trackball and the **Set** button on the control panel.
- ② Press Saveto 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* window 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. Click **Cancel** to cancel.
- 3. 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 more precise measurements.

#### 4. Video

Format

Select either NTSC or PAL.

- 5. Beep Sound
  - Touch Screen

Set the sound level when using the touch screen. Set this to on or off using the trackball.

Control Panel

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

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

6. Account

Register a user ID and a password.

• User Log-in

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

Screen Saver

- Accessing SonoView/Patient
- Search window for Patient
- User Account Manager

This is the exclusive administrator function for the 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 the settings.

User Account Mana	ager	×
User Login 🧕 O	n 🔵 Off	
User Account List		
Administrator	ADMINIS	STRATOR
Cr	eate Change Passi	word
		Close

[Figure 3.8 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.



- 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.

#### 3.6.2.2. Display

On the Setup screen, select the Display tab in the System category.

Configure the settings for displaying images.

Setup			2016-06-08 06:24:20 PM
System	General Phatey	Patient Ould Preset Sultanter	
Imaging	Distay		
Application	- System Lage	AMILING HIM	
Measurement	Direction Marker	* 1000 C HON C .	
Report	Street Search		
Annotation		or v	
Body Marker			
Customice	System Power Button	<ul> <li>Aak me what to be Shut Dewn</li> </ul>	
Peripherals	Dythen	Australiana 10 - + Miles	
Connectivity		🐼 Prompt for Sava on Exit	
Service		📝 Beet up Cape Lock De	
	Bouth Server Registration		
Save			
bit			
• II			

[Figure 3.9 Setup – System – Display]

- 1. Display
  - System Logo

Choose SAMSUNG or HS60/ HS50.

• Direction Marker

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

Screen Saver

Select the waiting time (in minutes) for the screen saver. Use the trackball to set it off or to 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: 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 system booting.
- Touch Screen Brightness

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

## 3.6.2.3. Patient

On the Setup screen, select the Patient tab in the System category.

Setup					2015-07-04 11:23:59 AM
System	General Obplay	ocient Quick Pres	es Extram-		
Imaging	Publicite Dana			Usek Bellinist List	
Application	Norme Siliplay	t Middle First 1	Lest Molde		
Measurement	The Multi-			Operator 👻	
Report	Lander	· Date of Birth	A44 .		
Annotation	Time I Market DR Disease	an example	and in a		
Body Marker				UER	
Customize	Leve Pellent Pege as Pist Image	9 On	off		
Peripherals	Other ID	Other ID			
Connectivity		Other ID Format			
Service					
Contract.					
Salar					
Ero.				Delitte All	* *

[Figure 3.10 Setup – System – Patient]

- 1. Patient Data
  - Name Display
    - Last, First Middle: Display the name of the patient in order of last name, first name, and then middle name.
    - First Last Middle: Display the name of the patient in order of first name, last name, and 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 the patient's 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 Patent 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.
- 2. User Defined List

You can 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 scans the patient.
- Diag. Physician: You can save the name of the physician who diagnosed the patient.
- Ref. Physician: You can save the name of the referring physician.
- Indication: You can save information on the patient's medical history.
- Description: You can save up to 20 diagnostic memos per application.

## 3.6.2.4. Quick Preset

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

Setup						2016-06-08 06-26-44 PM
System						
Imaging	Quick Preset					
Application				Bolds Preset 2	Quick Press	
	Product					
	Application		uplication.	Application	Application	
	and in		1021	Product.	Basia	
	Provine					
Sevie						

[Figure 3.11 Setup – System – Quick Preset]

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

## 3.6.3. Customize

## 3.6.3.1. Buttons

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

tup							2016-06-0 07:06:55 Pt
System		7: Menu					
Imaging							
Application	Searcale way	<ul> <li>Settlet</li> </ul>	tsir. Exitose				
Measurement	Tribular	- Tribler	The Assess				
Report							
	End Exam	End Coam + Patient	· End Exam Only	10 HW Mesuli			
Body Marker						Sector	
Customize	City Store Type	Retistpective	· Prospettive	US StorePrint			
Peripherals		Cip Length bend	Number of Heart Cycles		Print	Serry UP Dest	
Concertivity	Colli Sonta Messini				Stars	dip	
		Time before Heart Cycle (	(m)	US Incorption			
Service					rimt	Sony OF-Dest	
		Table efter Heers Cycle (m	n)				
				US EW Measure			
		Left Midde	Right				
	Feet Switch	tim - Press			State	ciji .	
Save							
Dit.					Print	Skery UP DBST	

[Figure 3.12 Setup – Customize – Buttons]

- 1. 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 left and 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.
- 2. Pointer

Select Pointer or Arrow.

- 3. End Exam
  - End Exam + Patient

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

End Exam Only

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

- 4. Clip Store Type
  - Retrospective

Click the **Save** button to save currently open images.

• Prospective

When saving images, images that appear after the button is pressed are saved.

- 5. 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 is completed.

6. 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.
- 7. 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.

## 3.6.4. Peripherals

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

## 3.6.4.1. Peripherals

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

You can configure the peripheral devices connected to the product.

Setup						2016-07-04 11:52:00 AM
System						
Imaging	Plane					
Application	Printer Sections					
Measurement	Serry UK-DB37		- Render			
Report						
Annotation	Serry UK-DBS7		Chear Print Queue			
Body Marker	Select All Printer					
Gustomize	Local Printing Area					
Peripherais	Full Screen	Video Out	Emage Only			
Connectivity						
Service	Prove Packate Date					
Save:						
Brit						

[Figure 3.13 Setup – Peripherals – Peripherals]

- 1. 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 to cancel a work of the printer 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 printing job.

Select All Printers

Select this checkbox to cancel the printing jobs of all the connected printers.



A printing 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 to 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: Prints the image area only.
- Hide Patient Data

Select whether or not to display the patient information.

## 3.6.4.2. Device

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

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

Setup							2016-06-08 07:08:17 PM
System	Peripherals						
Imaging			Label	TotalSite	Time State		
Application	#A)	Removable	Frink	175.7 40	46.118	-	
Measurement.							
Report							
Annotation							
Body Marker							
Gustomize							
Peripherals						Map Notwick Schoo	
Connectivity							
Service							
Save							
Det							
• II							

[Figure 3.14 Setup – Peripherals – Device]

1. Map Network Drive

Connect to a network.

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

## 3.6.5. Connectivity

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

## 3.6.5.1. DICOM

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



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

Setup								2016-01-18 11:23:41 AM
System			Network					
treaging	System Config	and the second			General D	integration		
Application	Station Nar		Part No.	AT TIDe	18 Ferm	et.		
Measurement	Set Statler	Nome	1995	MEDISON	Gener	l fegert	Score SA at En	of of faum
Report								
Annotation		evice	Alter	AETIN	Hart	Part No.	Ping	verity
Body Marker								
Customize								
Periphetals								
Connectivity								
Service								
Save								
Exit					24			
• 1								

[Figure 3.15 Setup - Connectivity - DICOM]

#### 1. System Configuration

Shows information about the DICOM server that is being used by the system.

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.



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 for 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.

- 2. General Configuration
  - SR Format

Select a format to be used to save SR between 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.

3. Adding DICOM Services

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

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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.

4. Storage Server Information

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

Setup							2015-05-09 05:03:36 PM
	DKD9 HL7 Network						
Imaging	DECOM Service Options Starage						
Application	Transfer Made	DECH Compress	in l		BICOM Server		
Measurement	Send After Acquisition	Single Frank.	<b>Unsampresied</b>		Allen		
			<ul> <li>JHU Baseline</li> </ul>				
Report	Send Manually		Compression		AL VIDE		
Annotation							
	Transfer Typet	TAXABLE INCOME.			HDEE		
Body Marker	🖌 Irolada Matti Parre	Rental of Amore	· PEG Samine		Part No.	194	
Customize	Include 30 Volume		Compression:				
Part August					Connect Timeout		
Peripheras	Convert to Grayerale		Frame hate Full		Haad Mewput Retry Interval	1.00	
Connectivity	<ul> <li>Ne Somethint</li> </ul>						
Service	Altruagets						
	KYN JINIGHL OTNY				Madmin Batries		
	(enclose)	WHI LUT Datum					
	Include Placing	Window Center Window Width			Packet Nee	16306	
Save	1						
Ext.						Andy	

[Figure 3.16 DICOM Configuration – Storage]

• Transfer Mode

Select a transfer method:

- Send after acquisition: Sends an image whenever you press the Store button to save it.
- Send on end exam: Sends all saved images when you press the End Exam button.
- Send manually: Send an image selected by the user 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.



Select this option only if you use a storage service that supports the 3D volume data format used by Samsung Medison.

· Convert to Gray scale

Select the grayscale conversion type for the image for which the DICOM service will be used.

- No Conversion: Send the original image without converting it.
- All Images: Convert all images into grayscale before sending them.
- B/W Image only: Only images that do not have color are converted into 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, that only 2D and 2D Color Mode images are supported. In Dual and Quad Modes, 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 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 with 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. Relative to 128, a higher value results in a darker image. Note that this function can be used only when it is supported by the storage service.

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- 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
  higher than 256 will result in lower contrast. Note that this function is available only
  when it is supported by the storage service.
- 5. SC Server Information

Select 'SC' (Storage Commitment) as **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.

Setup				2016-07-04 11:25:00 AM
System				
Imaging	DECOM Service Don			
Application Measurement	Associated live ap	a Samar	NCOM Server	
Report			At Title	
Annotation				
Body Marker			Part No.	
Customize				
Peripherals			Connect Timesort	
Connectivity			Read Streeter	
Service			Harry Internal	
			Maximum Netries	
			Packet Size	16308
Save				
Ent				Alaty Cancel

[Figure 3.17 DICOM Service Options - SC]

Associated Storage Server

Select an Image Storage server to connect to.

6. Worklist Server Information

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

Setup				2016-01-18 11-27:40 AM
System		REWORK		
Imaging	BECOM Service Options	WORKLIST		
Application	Query Setting		DICOM Server	
Measurement.	Modelley US		Allas	
Report			AT Title	
Annotation	Exam Description.	have Descriptions		
Body Marker	etolati 50075 Scheetuled Process		Part No.	104
Customiue				
Peripherals			Connect Timeout	
Connectivity			Read Timenor	
Service			Ketry Interval	
			Masimum Retries	
			Packet Site	11.000
Save	f .			
Ext				Apply Cancel

[Figure 3.18 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).
- **TIP** After setting up the Worklist service, press the **Patient** button on the control panel to go to the Worklist page.

#### 7. Print Server Information

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

Setup							2016-01-18 11:28:30 AM
System		7 Network					
Imaging	DICOM Service Optio	es Paulat					
Application	Transfer Made		A subject families		Diff Old Tax and		
Measurement	Penet		TOW		Allas		
Report	Print Print	on End Exam. Manually	Column		AL TITLE		
Annotation					. vient		
Body Marker	Printer Setup	Gravita	Casting 1+971		Pers No.	114	
Guetomize	Distan	PORTBAT	Res Size	all of the			
Peripherals					Considers Timesaut		
Connectivity	Magionation		sumption of 1984.		Read Time out		
Service	Burdet Density		Empty Density	WHETE	Betry Interval		
	Proving		Min Density		Musimum Retches		
	Destination				Partiel Title	11000	
	Medum Type		Carriguration Into				
Ext						Austy	Cancel

[Figure 3.19 DICOM Configuration – Print]



- You can configure only the printers connected to the DICOM network.
- Depending on the printer, some of the following functions may not be available: Before configuring a printer, 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: Prints all saved images when you press the End Exam button.
- Print manually: Print an image selected by the user 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 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 Paper, Clear Film, Blue Film, Mammo Clear Film, or Mammo Blue Film.
- Copies(1–99): Enter the number of copies between 1 and 99.
- Film Size: Select a paper size from 8 x 10 inches, 8.5 x 11 inches, 10 x 12 inches, 10 x 14 inches, 11 x 14 inches, 11 x 17 inches, 14 x 14 inches, 14 x 17 inches, 24 x 24 cm, 24 x 30 cm, A4, and A3.
- Smoothing Type: This option is available only when Magnification is set to CUBIC. Enter the value for the printer as 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. Refer to the DICOM Conformance Statement for the printer.
- 8. PPS Server Information

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

Setup		2016-03-18 11-29-35 AM
System		
Imaging	DICOM Anvier Options	
Application	Sector Se	2000a 2
Meanurement	Always Complete Examp.	Allan
Report		AETOIN
Body Marker		And and a second s
Customiae		Post No. 104
Peripherals		Connect Timesal 30
Connectivity		Next Timesut 30
Sector		Anny Innerval at
		Mastrum Kettles 1
		Falint Ease 1000
Sive		
		Apply Cantel

[Figure 3.20 DICOM Service Options – PPS]

Always complete exams

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

#### 9. Storage SRServer Information

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

Setup					2016-0 11:30:05	5.15 5 AM
System						
smaging	DICOM Service Options	STORAGE SR				
Appleation	Transfer Mode			DOCUM Server		
Mossurement	Send After Accusioon			Allan		
Report	Send on End Exemp.					
				10.00		
Body Marker					1932	
Customiae						
Peripherals				Connect Timoout		
Contractivity				Intel Timesut		
Gentles				itetry Interval		
				Mastrium Kettles		
				Pariet See	1000	
Site						
					Apply Cantol	

[Figure 3.21 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.
- 10.QR Server Information

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

11. 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. Click Cancel to cancel.

12. Deleting DICOM Services

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

13.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.

#### 3.6.5.2. 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.

Setup			2016-06-08 07:17:10 PM
System			
Imaging			
Application		HLP Coeffiguration	
Measurement		IK2 Hanager	
Report			
Annotation			
Body Marker			
Customire			
Peripherals			
Connectivity			
Service			
Save			
Exit			
• 1			

[Figure 3.22 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 the 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).

HL7		
Convert Timeout 120		
in the second	Greet	

[Figure 3.23 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.
  - Colums: The user can select the columns to check.
  - Retry: The user can retry a Failed job.
  - 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.

HL7 Man	iger		
Republicary			These just Scores
			Column Bury Dolma
			🐼 Show AB Delete Archives: Job Status After (days), 10 Dange
			No Suma Nety Reserved DK Publick Rate Adul
			a fail, a stratight traightair. That
			2 AAE & MINUSEREITETER MALE TWO
			E GAD IN EXCLUSION INC.

[Figure 3.24 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. (Note, however, that there must be patient information; a warning message asking for a valid patient ID will appear if the information has not been entered.)



[Figure 3.25 Report - HL7 Export]

#### 3.6.5.3. Network

On 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.

Setup		2016-06-09 05:32:18 PM
System		
Imaging	Retwork Configuration	
Application	Automatic Contiguration(DHCP)	
Measurement		
Report		
Body Marker		
Customize		
Peripherats		
Connectivity		
Service		
Save		

[Figure 3.26 Setup - Connectivity - Network]

1. 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 restore the default settings.

• Apply

Use the currently entered information to set up the IP.

#### 3.6.6. Service



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.

- Restores saved basic patient information and images or changes the software.
- Enables or disables optional software or hardware.
  - Option: Shows 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.

#### 3.6.7. Help

Press the **Help** button on the keyboard. The electronic manual will appear on the monitor screen. Pressing the button again causes it to disappear.



The Help screen does not provide a Return key.

# Chapter 4

# **Product Inspection**

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# 4.1. Inspecting the Functions

After installation, inspect the device and use the major functions to verify that the product works properly.

#### 4.1.1. Basic Inspections

#### 4.1.1.1. Monitor

Check the screen for color, focus, dots, afterimage, stain, and blurriness.

Check the screen while applying impact on the monitor and check the signal while shaking the cable to the left and right.

#### Control Panel and LED Status

Press any keys on the control panel and see if text appears or breaks. Verify that the Keyboard LEDs turn on.

#### BodyMark Key

Check if a BodyMarker image appears correctly and whether selection works properly.

#### Indicator Key

Check whether the trackball works properly by rolling it up, down, left, and right.

#### Clear Key

Check whether all texts and measurements are properly cleared.

#### Check Zoom Functioning

Check the zoom function for proper action and make sure that there are no errors.

#### Check SonoView

Save Images and Cine Images in each mode. Check for errors in saving images.

Check whether Backup & Restore function properly.

#### Measure

Check the operation of Distance, Caliper, Calc, etc.

#### Patient

Enter information in Patient and check whether the same Patient information is displayed in Report, SonoView, etc.

#### End Exam

Make an arbitrary measurement in New Patient and see whether the measurement is erased when you press End Exam.

#### Probe Key

Perform a Probe Change and check whether it functions correctly.

#### 4.1.2. Detailed Inspections

#### 2D Mode

- 1. Perform a Knife Test to check whether part of the image is not displayed.
- 2. Perform a Phantom to check for errors in image.
- 3. Check the Freeze Cine actions (broken image, Auto Run, Auto Run Speed, Trackball Cine).
- 4. Check for changes in image brightness when you adjust Gain.
- 5. Check whether TGC Gain operates correctly by adjusting it and check for changes in image brightness in accordance with depth.
- 6. Perform Left/Right Flip, Up/Down Direction, and Rotation to check whether the image changes its orientation correctly.
- 7. Check whether the Select Image menus (EE, DR, View Area, Tissue, Frame Rate) work properly.
- 8. Check for errors in frequency (Phantom, Res, Pen, Gen).
- 9. Check for changes in image in accordance with the changes in depth.
- 10. Check for changes in image by depth when you change the focus.
- 11. Check whether or not Image Compensation Mode works.

#### Dual Mode

- 1. Perform a Phantom to check for errors in image.
- 2. Perform Left/Right Flip, Up/Down Direction, and Rotation to check whether the image changes its orientation correctly.
- 3. Check the proper operation of Select Image menus (EE, DR, View Area, Tissue, Frame Rate, Power).
- 4. Check for errors in frequency (Phantom, Res, Pen, Gen).
- 5. Check for changes in image in accordance with the changes in depth.
- 6. Check for changes in image by depth when you change the focus.
- 7. Check for errors in operations related to left and right image Cine (number of pages, Cine progression order, broken image, Auto Run, Auto Run Speed, Track Ball Cine).

#### M Mode

- 1. Perform a Phantom to check for errors in image.
- 2. Check whether the M-Line's information is displayed in the Image area.
- 3. Check for changes in image brightness when you adjust Gain.
- 4. Perform Left/Right Flip, Up/Down Direction, and Rotation to check whether the image changes its orientation correctly.
- 5. Check whether the Select Image menus (EE, DR, View Area, Tissue, Frame Rate, Same Angle, Power) operate correctly.
- 6. Check for changes in image in accordance with the changes in depth.
- 7. Check for changes in image by depth when you change the focus.
- 8. Check for changes in speed when you change Speed gradually and for errors in the information.
- 9. Check whether the image becomes inverted when Negative is performed.
- 10.Check for errors in Top Down Format and Side by Side Format images when Loop Format is selected.
- 11. Check for changes in Format B-Mode and M Line area sizes.
- 12.Check the Freeze Cine actions (broken image, Auto Run, Auto Run Speed, Trackball Cine).

#### Color Doppler/Power Doppler Mode

- 1. Perform a Phantom to check for errors in image.
- 2. Check the operations related to the Select Image menus (Balance, Sensitivity, Color Mode, Display, CFR).
- 3. Check for changes in image in accordance with the changes in depth.
- 4. Check the Freeze Cine actions (broken image, Auto Run, Auto Run Speed, Trackball Cine).
- 5. Check for changes in image brightness when you adjust Color Gain.
- 6. Check for noises and breaks in image (B or C Mode Noise) when you move the ROI Box.
- 7. Check for noises and breaks in image (B or C Mode Noise) when you resize the ROI Box.
- 8. Adjust the Scale up and down to check whether or not the frequency changes and if the speed range of blood flow is adjusted. (Check by actually performing a scan.)
- 9. Operate Filter to check whether small signals are removed by stage.
- 10. Check whether or not Color Bar is inverted when you operate the Invert key.
- 11. Move the Baseline up and down to check whether the speed range of blood flow moves to the "+" or "-" position.

#### PW Spectral Doppler Mode

- 1. Perform a Phantom to check for errors in image.
- 2. Check whether Doppler's PRF value changes when you set Simultaneous to on/off.
- 3. Check for errors in the Doppler spectrum.
- 4. Change the Scale to check the change in velocity range.
- 5. Move the Baseline up and down to check whether the spectrum range moves to the "+" or "-" position.
- 6. Check whether changing Filter removes low signals from the Spectrum.
- 7. Check whether the Doppler wave form is inverted when you operate Invert.
- 8. Perform Angle action.
- 9. Change the position and size of SV, and then check for errors.
- 10. Check whether Spectrum's image changes when you change Spectrum's Type.
- 11. Check for errors in Sound Volume.
- 12.Perform Auto Calc and check whether the line is displayed without breaks; check whether the calculated results are carried out automatically.
- 13. Check for errors in Top Down Format and Side by Side Format images when Loop Format is selected.
- 14. Check the Cine/Loop (broken image, Auto run, Auto run speed, Trackball Cine) operations.

#### 3D/4D Mode

- 1. Check whether loading is performed correctly when you proceed with Free Hand 3D SCAN and when you skip to Freeze; check for broken images and noise while proceeding.
- 2. Check whether loading is performed correctly when you proceed with Static 3D Scan; check for broken images and noise while proceeding. Check the probe for noise and whether the probe's motor works normally.
- 3. Check whether loading is performed correctly when you proceed with Live 3D Scan; check for broken images and noise while proceeding. Check the probe for noise and whether the probe's motor works normally.
- 4. Check for errors in ROI 3D, ABC 3D, and Full images.
- 5. Check whether the 3D image changes to the selected angle.
- 6. Check whether the 3D image's contrast changes to the selected value.
- 7. Check for errors in the image when you change the size of the image.
- 8. Check the Display Format Image (ACB, Volume CT Image)
- 9. Step Angle, Rotation Angle, Rot. Axis, and then proceed with Cine; check whether Cine Loading works in accordance with the Setting items and check for breaks and errors in the image.

# Chapter 5

# **Product Structure**

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# 5.1. Overview

This is an ultrasound diagnostic imaging system utilizing software DSC.

It features a 21.5-inch Full HD Wide LED monitor and a 10.1-inch LED touch screen monitor, provides high-resolution ultrasound images, and includes premium-grade features. Samsung Medison's new proprietary technology is incorporated into the latest spec PC and ultrasound system interface to enhance processing speed. Enhanced processor speed means faster processing speed of the product, which in turn reduces exam time. The major specifications are as follows:

Monitor	<ul> <li>Main Monitor 21.5 inch LCD monitor (LED Backlight unit, hereafter referred to as "LCD monitor")</li> <li>Touch Screen Monitor 10.1 inch LCD monitor (LED Backlight unit, hereafter referred to as "LCD monitor")</li> </ul>		
PC	Advantech, COM Express Module		
CPU	Intel Haswell (4th core) I3-4100E		
Memory	mory DDR3 SDRAM 8GB		
OS	64bit Windows 7 Embedded Standard		
Storage	SSD 512GB		
VGA	<ul> <li>HS60 (External VGA): GTX 750TI</li> <li>HS50 (Internal VGA): Intel HD Graphics 4600</li> </ul>		
Chanel TX 128 CH			
Probe port	4-Probe Port (with 1-port Dummy probe port)		
3D Driver	BE B/D		
Moving CP Up/Down, Swivel CP using Handle and Gas Spring			

Ultrasound System Part	<ul> <li>PSA(Probe Select Assembly) 4 Ports</li> <li>BF(Beamformer Board) 1ea 128ch</li> <li>BE(Back End Board)</li> <li>USB ECG Module</li> <li>USB Foot Switch</li> <li>Gel Warmer</li> <li>FAN Module</li> </ul>
User Interface Part	<ul> <li>21.5 inch LCD for main monitor</li> <li>10.1 inch LCD for touch panel</li> <li>Key Matrix Board</li> <li>Up/Down, Swivel, CP</li> <li>1.2" Track Ball</li> </ul>
PC Part	<ul> <li>PC Module: Advantech , Com Express Module CPU: Intel Haswell(4th core) I3-4100E</li> <li>RAM: DDR3 SDRAM 8GB</li> <li>Storage: SSD 512GB</li> <li>VGA: HS50 Intel HD Graphics 4600 HS60 GTX 750TI</li> </ul>
Power Module	ADM

The major structure of this product includes the following:

# 5.2. System Block Diagram



## 5.2.1. System Block Diagram

[Figure 5.1 System Block Diagram]

# 5.2.2. System Rack Design



Name	Full Name
PSA	Probe Select Assembly
СР	Control Panel
BF	Beamformer
BE	Back End
BP	Back Plane

[Figure 5.2 System Rack Design]

# 5.3. Basic Structure of the Product

This product consists of the Ultrasound System Part and the User Interface Part. In the aspect of electronic structure, it consists of a Front End Part, a Back End Part, a User Interface Part, and a Power Part. The electronic structure of HS50/HS60 can be explained as follows:

#### 5.3.1. Electronic Structure

Front End Part

It consists of the PSA (Probe Select Assembly) and the BF (Beamformer). The Front End Part delivers High-Voltage Pulser to the probe to generate ultrasonic waves and amplifies the returning echo signal to process Digital Beamforming. The RF signal generated here is sent to the Back End Part.

Back End Part

It consists of the BE (Back End) of the Ultrasound System Part as well as the PC Module. Raw data required to make diagnostic images (e.g., BW, Color Doppler, PW Doppler, and CW Doppler) from the RF signal generated by the BF (Beamformer) go through image processing in the form of DMA Packet by BE (Back End) and get transferred to the PC Module. Then, the data are displayed on screen via several steps of post-processing at the PC Module. New technologies such as MultiVision and ClearVision are adopted to show the image more clearly.

User Interface Part

It consists of LED monitor, control panel, and touch screen.

Power Part

It takes AC voltage and supplies AC power to the ADM and AUX Output via the circuit breaker. The ADM converts AC power into DC power, so it can supply voltage to the boards of the Ultrasound System as well as the PC module.

## 5.3.2. Ultrasound System Part

It processes ultrasound data up to the stage before SW Post-Image Processing. This detects probes and performs TX Focusing and RX Focusing based on system and application information from the host in accordance with the user environment. When high-voltage Pulser is sent to the probe according to TX Focusing, ultrasonic waves are generated. Echo signals returning from the body due to the ultrasonic waves go through amplification and ADC to process Digital Beamforming. The RF signal obtained here goes through various filtering and processing to generate I/Q signals such as BW, Color Doppler, PW Doppler, CW Doppler, and Power Doppler, which are sent to the PC Part to generate image signals via SW Post-Image Processing.

The AC to DC Power Module supplies power to the Ultrasound System Part.

The Ultrasound System Part consists of the following:

- PSA(Probe Select Assembly) Board
- BF(Beamformer) Board
- BE(Back End) Board
- ADM (AC to DC Power Module)

#### 5.3.3. PC Part

This displays the ultrasound information generated by the Ultrasound System Part. It consists of the Scan Converter and image output circuits. It also performs control panel and interface functions.

The ADM supplies power to the PC Part.

The PC Part consists of the following:

- PC Module: Advantech , Com Express Module
- CPU: Intel Haswell(4th core) I3-4100E
- RAM: DDR3 SDRAM 8GB
- Storage: SSD 512GB
- VGA Card: HS60: GTX 750TI / HS50: Intel HD Graphics 4600

#### 5.3.4. User Interface Part

It consists of LED monitor, control panel, and touch screen, so that users can view and control ultrasound images. Images are sent by the Ultrasound Part to the LED monitor and peripherals. Image output includes VHS, S-VHS, Composite, and HDMI. In addition, the User Interface Part provides a function of setting the customized status through the control panel and touch screen.

The User Interface Part consists of the following:

- Monitor: 21.5" Full-HD Wide LED Backlight Panel (1920\*1080)
- Touch Screen: 10.1" LED Backlight Panel (1280\*800)
- Control Panel Board
- Trackball
- Key Matrix Board
- Alphanumeric K/B

#### 5.3.5. Power Part

It converts external 110/230V AC voltage into DC voltage that should be supplied as required to each part of the Ultrasound System. The ADM supplies power to the PC Part as well. The ADM switch also works as a power circuit breaker and prevents any possible troubles due to overcurrent.

ADM

# 5.4. Ultrasound System Part

# 5.4.1. Main Functions of the PSA (Probe Select Assembly)

The PSA connects the system to the probes. This product is equipped with four probe connectors (408-pin) and one CW-probe. It has 3D Probe Drive Path, Probe Insert Path, Port Select Path, and CW Path as well as the Relay circuit to select one out of four probes.



[Figure 5.3 PSA Board Location Image]



Port	SEL A	SEL B	SEL C
PORT # A	0	0	0
PORT # B	1	0	0
PORT # C	1	1	0
PORT # D	1	1	1

[Figure 5.4 PSA Board Block Diagram]

#### 5.4.1.1. Specification

- 4 Probe Port Support
- CW Pencil Probe Port Support
- Probe Insert Check, ID read, Port selection
- Motor driving signal path for 3D probe

#### 5.4.1.2. Description

#### Probe Selection

It consists of circuits to choose one of four probes. It can use the relay of the latched type to select a probe chosen by the user.

The relay is operated by the probe select signal transmitted from the control logic (CPLD) of the CW (Continuous Wave Board). Probe Select signals are connected via the Back Plan Connector.

#### CW Pencil Probe Connection

The Static CW Probe uses the coax-pin LEMO Connector.

The LEMO Connector is located on a separate Connector Board and is connected to the PSA via cable.

This connector consists of 2 coax-pins and 6 pins. 2 coax-pins are used for the TX/RX of Static CW, and 6 pins are used for the personality of Static Probe.

#### 5.4.2. Beam Former Board

The Beamformer board is located between the PSA and Back End; it sends an ultrasound signal focused on a specific position of the body and amplifies the received signal to convert it into a Digital signal. Then, it beamforms the signal and relays the Focused data to the Back End for Mid-processing. The BF Board consists of Pulser, TR Switch, AFE, TX FPGA, ADC, and BF FPGA.



[Figure 5.5 BF Board Image]

- Pulser: It consists of one 128-channel board and operates 192 element probes. The Pulser amplifies the entered firing signal into High-Voltage Pulse.
- TR Switch: It adjusts the High Voltage from probes so that it cannot flow to the AFE
- AFE: This amplifies the entered echo signal to a sufficient level, and then compensates the signal to a certain level. Finally, it converts the compensated signal into digital signal for RX Focusing.
- BF FPGA: The BF FPGA covers 64 TX Channels per unit and outputs the TX Wave Data focused on TX. Moreover, it performs RX Focusing for 64 channels of RX echo signal per unit. Finally, it sums 128 channels of RX Focusing Data and sends them to the BE Part.



[Figure 5.6 BF Block Diagram]



[Figure 5.7 PCB Layout]



[Figure 5.8 BF Signal Flow]

#### 5.4.2.1. Spectification

- TX Pulser + TR Switch 16 ea(HDL6M5585, 8CH)
  - Pulser applied with built-in Limiter
- Limiter 64CH
- ALL IN ONE AFE 16 ea (MAX2079, 8CH), LNA+VGA(TGC)+ADC +CW I,Q
- BF FPGA (XC7K325T-2FFG900, 2 ea)
  - RX Dynamic Aperture
  - RX Apodization
  - Synthetic Aperture
  - Trapezoidal imaging
  - Multi-line receiving
  - TX Focal point
- CWD processing

#### 5.4.2.2. Description

#### Transmit Channel

Transmit Channel performs a function of applying high-voltage signal to the probe element, thereby generating ultrasound waves. It generates high-voltage pulse to transmit arbitrary waveforms from the BF FPGA.

The Transmit Part consists of the BF FPGA and Pulser.

1 BF FPGA

The BF FPGA uses RTC signal to calculate the delay time for TX focusing and outputs a firing pulse to each TX channel.

2 Pulser

The Pulser amplifies the entered Firing Pulse signal into a high-voltage signal that is outputted to each element of probes. As a result, the probes vibrate to generate ultrasound waves.

#### Receive Channel

Receive Channel amplifies the echo reflected from the medium in the human body. This signal is converted from analog into digital for beamforming at the BF FPGA. The BF FPGA sums the focused signal of each channel and sends the signals to the BE Board. The Receive Part consists of TR Switch, AFE, and BF FPGA.

1 TR Switch

Each element of the probes is connected in parallel to the TX Channel and RX Channel. Up to 180 Vpp Tx Pulse and mV-range Echo signals are mixed with each other. The RX data actually required is the echo signal in the mV range, which is a very weak signal. The TR Switch prohibits the high-voltage Tx Pulse from flowing into AFE input and permits low-level echo signals to pass.

#### 2 AFE

HS50/HS60 uses the all-in-one type of AFE. One AFE performs the roles of LNA, TGC, and ADC for existing equipment. The AFE amplifies the mV-range echo signal input and performs gain compensation over time. It also transmits digitized RX Data to the BF FPGA.

③ BFX FPGA

The BF FPGA performs RX focusing for each RX Channel data received from the AFE and sums the whole channel data. It then transmits the summed data to the BE Board.

#### 5.4.3. Back End Board

The Back End Board (Below BE Board) includes three key features as follows:

- RTC (Real Time Controller) / Host Interface
- DMA (Direct Memory Access) Control
- IQ Digital Signal Processing

The RTC generates the control signals of the system and goes through the RF data entered in the BF board, and then transfers the DMA through the path.

Digital Signal Processing implements some functions of the Mid Processor that is present in previous systems and transfers data to the SW DSC via DMA. Data reconfiguration for image implementation is handled by the FPGA, and image implementation is handled by the SW DSC.



[Figure 5.9 Back End Board Top Side]



[Figure 5.10 Back End Board Block Diagram]



[Figure 5.11 Back End Layout and Signal Flow]

#### 5.4.3.1. Specification

- Focused RF Data Interface
- BW Data Processing
- Color Doppler Data Processing
- IQ + Digital Signal Processing
- Digital Signal Processing (Pre Processing, Post Processing)
- CW IQ data Interface(CWD)
- Direct Memory Access
- 3D Probe Motor Driver
- Diagnostic Signal Processing
- RTC(Real Time Controller)
- PCI-express Interface

#### 5.4.3.2. Digital Signal Processing (DSP) Part

The Back End Board's MID FPGA (KINTEX325T) comprises the Digital Signal Processing Part, which transforms the Focused RF Data inputted by the BF Board into Base-Band IQ Data.

The inputted RF Data goes through Gain Control, High-Pass Filtering, Quadrature Demodulation, and Decimation processes, and then gets sent to the DMA FPGA so that the Base-Band IQ Data can be transmitted to the PC SW Module.

#### 5.4.3.3. Host Interface & RTC Part

#### Host Interface

The Host Interface integrated into the MID FPGA (KINTEX325T) is connected to the PC on PCI-Express 1Lane through PCI-Express Switch. The Host Interface converts the Host Command from the PC into Local Bus, so it provides an interface with each board of the Ultrasound System.

#### RTC Part

The RTC (Real Time Controller), which is integrated into the MID FPGA, controls the operation of the system by generating the standard signals needed for the operation of the entire system in real time. It generates PRF (Pulse Repeat Frequency), OF (One Frame), RP (Rate Pulse), Linotype, and Scan Line, which are required for the BF Board and DSP Part of the BE Board.

#### 5.4.3.4. DMA Part

The Direct Memory Access (DMA) Part, which is integrated into the Back End Board's MID FPGA (KINTEX325T), consists of PCI-Express Gen1 1Lane to transfer large-capacity Base-Band IQ Data at high rate and performs the function of PCI-Express Interface within the FPGA.

It has DDR3 SODIMM (4Gbyte) external memory in order to save large-capacity Base-Band IQ Data by frame.

# 5.5. PC Part

### 5.5.1. PC Module

Certain functions of Digital Signal Processing, which were previously handled by hardware, are implemented by the Software Program. This module provides various peripheral ports for connecting the 1 Lane and user interface for controlling the Ultrasound System and receiving Base-Band IQ Data. This module consists of Dual Port VGA Card for the output of the Main Monitor and Touch Panel as well as Rear Module for the output of various external images.

#### 5.5.1.1. Specification

- PC Module: Advantech, Com Express Module
- CPU: Intel Haswell(4th core) I3-4100E
- RAM: DDR3 SDRAM 8GB
- Storage: SSD 512GB
- OS: Windows 7 64bit
- Monitor: 21.5 Inch Full-HD(1924 x 1080) LED Display
- VGA:
  - HS50: Intel HD Graphics 4600
  - HS60 GTX 750TI



[Figure 5.12 PC Module & Storage & VGA (HS60 only)]

#### 5.5.2. Rear IO Board

It serves as In/Out Interface with external devices and as data interface with the control panel. This board handles image output on screen display and touch screen. It provides VHS, S-VHS, and DVI Port to support a variety of external image storages.



[Figure 5.13 Rear IO Board & Layout]



[Figure 5.14 Rear IO Block Diagram]

# 5.5.2.1. Specification

- Internal Port
  - HDD
  - Speaker L/R
  - ODD
  - External Port
    - Monitor VGA Out
    - S-Video Out
    - Audio L/R Out
    - MIC In

# 5.5.3. Software DSC

The image data generated by the BE board is transferred to the PC Memory. The DSC Part processes image data inputted in various forms of video image and outputs them to the VGA card.



[Figure 5.15 DSC Block Diagram]

# 5.5.3.1. Specification

- Cine for 5,140 frame
- Loop Review for 8,192 lines
- Zoom
- Edge Enhancement
- Multi-Slice View
- Dynamic MR (Optional)
- Quick Scan
- Real-Time Auto Calculation time Doppler Auto Trace
- Free Angle M-Mode
- Post measurement
- Post image optimizing process Arbitrary M mode
- Help function

# 5.6. User Interface Part

#### 5.6.1. Control Panel

It serves as the interface between the user and the system. It connects to the Key Matrix Board, Touch Screen, Trackball, and more via USB hub and operates as commanded by the user.

## 5.6.1.1. Control Panel Module







[Figure 5.17 Control Panel Block Diagram]
## 5.6.1.2. Specification

- Input part
  - Consists of Key Switch, Encoder, and Trackball
- Control part
  - ① ATMEGA640(8bit Microcontroller)

Processes input data and relays it to CP\_USB B/D.

- ② MAX II EPM1270 (Altera CPLD)
  - Touch Panel power on/off Control
  - LED outputs / Knob control
  - Trackball power on/off control
- ③ PIC18F14K50 (USB Mouse Controller)
  - Track ball interface
- CP\_USB Part
  - User USB 2 Port

### 5.6.2. Main Monitor

21.5-Inch Samsung Full-HD Wide LED Panel is applied.



[Figure 5.18 Main Monitor]

#### 5.6.2.1. Specification

ITEM	SPECIFICATION	UNIT
Display area	21.5 Inch Samsung Display	Inch
Number of Pixels	1920 x 1080 RGB stripe arrangement	Pixels
Pixel Pitch	0.2475 (H) x 0.2475 (V)	mm
Electrical Interface	LCD Panel Input: HDMI	
Display colors	16.7M colors (Hi-FRC)	
Viewing angle	89°/89°/89°/89° (CR≥10)	
Display mode	Normally Black	

### 5.6.3. Touch-Screen

10.1-Inch Samsung Panel is applied.



[Figure 5.19 Touch Screen]

## 5.6.3.1. Specification

ITEM	SPECIFICATION	UNIT
Display Size	10.1 Inch Samsung Panel	mm
Display colors	16.2M	colors
Number of pixel	1280 x 800 (16:9)	pixel
Pixel arrangements	RGB vertical stripe	
Pixel pitch	0.1695 (H) x 0.1695 (V)	mm
Display Mode	Normally Black	
Surface treatment	Hardness (3H)	

## 5.6.4. Display Layout



[Figure 5.20 Display Layout]

## 5.7. Power Part

#### 5.7.1. ADM



[Figure 5.21 ADM Image]







[Figure 5.23 ADM Layout]

## 5.7.2. Power Block Diagram



[Figure 5.24 HS50/HS60 ADM Block Diagram]

## 5.8. Interconnect Diagram

#### 0 PSU 0 0 BE board PC Block Back End Block P1 (10-1000) (100) Manage 40 P10 F2 0 PB BF hoard 0 P4 11111 **(3** x REAR IO board 010 000 010 0 0 0 2027 D BE board . 0 0 40 0 0 (58) (510) 56 ) Gender 55 ( 53 0 0 F7 \$4 Usor (57 U682.0 BOTTOM r

## 5.8.1. HS50/HS60 Interconnect Diagram 1/2









## 5.8.3. Cable Description

## 5.8.3.1. Power cable

NO	CIS-CODE	Description				
P1	MI39-02027A	MID FAN ASSY				
P2	MI39-02057A	HS50 SATA POWER				
P3	MI39-02024A	HS50 Monitor Power_1				
P4	MI39-02063A	HS50 CP Power				
P5	MI39-02023A	HS50 Monitor Power_				
P6	MI39-02029A	Bottom FAN EXT				
P7	MI39-02028A	Bottom FAN ASSY				
P8	MI39-02062A	HS50 Touch Power				
P9	MI39-02064A	HS50 Gel Warmer				
P10	MI39-02056A	Printer Power Cable				

[Figure 5.27 Power cable list]

#### 5.8.3.2. Signal Cable

NO	CIS-CODE	Description			
S1	MI39-02058A	HS50 SATA			
S2	MI39-02067A	HS50 Sound			
S3	MI39-02022A	HS50 CP USB A			
S4	MI39-02021A	HS50 CP USB B			
S5	MI39-02025A	HS50 ECG USB			
S6	MI39-02030A	BW Printer USB Cable			
S7	MI39-02055A	Color Printer USB Cable			
S8	MI39-02059A	HS50 Monitor HDMI_1			
S9	MI39-02066A	HS50 Monitor HDMI_2			
S10	MI39-02060A	HS50 Touch HDMI			
S11	MI39-02061A	HS50 Touch USB			

[Figure 5.28 Power cable]

## Chapter 6

# **Service Mode**

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## 6.1. Service Mode

Chapter 6 describes the Service Mode for servicing HS50/HS60.

This chapter explains how to update the version, back up the system, and shift to Service Mode as well as how to add options and perform diagnostics.

#### 6.1.1. How to Shift to Service Mode

- 1. Press the Setup button on the alphanumeric keyboard.
- 2. Click the Service Mode on the lower left.
- 3. Make sure that Select User Level is set to Service Engineer.
- 4. Enter "\*\*\*\*\*\*\*\*\* in the password box.
- 5. If the password is correct, you can go to Service Mode.

Setup				2016-0 11:36:21	7-01 E AM
System					
Imaging	Service				
Application					
Measurement	Service				
Report					
Annotation					
Body Marker					
Customize					
Peripherals					
Connectivity					
Service					
Save					
Exit					
. ID					

[Figure 6.1 Service Mode screen]

## 6.2. Service Information

Service Information shows details about the hardware and software version of the product as well as the version information of each board.



[Figure 6.2 Service Information screen]

- Workstation: Displays information on the system, hardware, and software version of the workstation.
- License Information: Displays information on the license used in software.
- Atom Information: Displays information about Atom.

## 6.3. Configuration

#### 6.3.1. Clock

Here, you can change the date, time, and time zone of the Windows System.



[Figure 6.3 Clock screen]

## 6.3.2. Keyboard/Region

- Keyboard Type: international, French, German...
  - \* Caution: System restart is required when changing the type.
- Region: Select a region (WW, US, CN, RU...)
- Apply button: Apply the region you select.

#### 6.3.3. TCP/IP

- Commands: Check the PC's IP Config information on the Result screen on the right.
- LAN: Set the properties of wired network connection.
- WLAN: Set the properties of wireless network connection.
- Support: Add a new device, install drivers, and run Device Manager.

C Serviczinformation	J. Configuration	Qi symm	C, the	griestiläi	📄 backup And Restore	E) Report	Demoinary	
and a	A LANDARY COMMAND	NAME 1						
Keyboard/Region	Configuration=107	5d#						
TEP/IP	Network Texts							
Opeon								
User Account		NUMBER OF THE						
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				- 42.				
							-	

[Figure 6.4 TCP/IP screen]

#### 6.3.4. Option

- This is a menu for managing licensed applications.
- Unlock All Options: Disable all the options displayed in the sublist.
- Install: Install the option you select.
- Uninstall: Disable the option installed.



[Figure 6.5 Option screen]

#### 6.3.5. User Account and User Account Management

- Reset: Reset all the user accounts managed by the User Account Manager.
- User Account Manager: Setup → System → Account
- If User Login status is enabled, the user is automatically logged out.

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Association									
				Setup					
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				1000					
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# T									

[Figure 6.6 User Account screen]

#### 6.3.6. Printer

- Printer: Apply the default printer settings.
- Properties: Apply the default printing settings of the printer you select.
- Add Printer: Install a new printer driver.
- System restart is required to install the new printer driver.



[Figure 6.7 Printer screen]

## 6.4. System

## 6.4.1. Upgrade Software

Install ultrasound software and check its patch version.



[Figure 6.8 Upgrade Software screen]

## 6.4.2. System Serial Number

Change the System Serial Number of ultrasound software.

Service Service Desition							
() ServiceInformation	Configuation	🔅 System	Q. Degressio	📑 Backup And Restore	E Report	DemoRay	
UpgradeSoftware		and the second					
SystemSerialNumber	Sintem: Systemize	nabiumber					
Window Explorer	System SrN	( Start					
Install RecoverySystem		0 m					
e 6	7					2016-0	

[Figure 6.9 System Serial Number screen]

#### 6.4.3. Window Explorer

- Displays the Windows Explorer, so you can check the information of Windows Local Directory.
- In case of System, only E: (DATA) drive gets enabled.



[Figure 6.10 Windows Explorer screen]

## 6.4.4. Install Recovery System

- Reboot the system.
- Enter the OS environment for software recovery.



[Figure 6.11 Install Recovery System screen]

## 6.5. Diagnostics

#### 6.5.1. Control Panel Test

Testing each button of the Control Panel

#### 6.5.2. Keyboard Test

Testing each button of the Keyboard

#### 6.5.3. Power On Self Test

Testing the self-diagnosis of the PIST System

#### 6.5.4. Built in Self Test

Testing the self-diagnosis of the BIST System

#### 6.5.5. Monitor Test

Testing the color sense and brightness of monitor



[Figure 6.12 Monitor screen]

## 6.6. Backup and Restore

#### 6.6.1. Backup

- Backs up the user data files you select.
- External storages like USB or CD are required.

#### 6.6.2. Restore

- Restores the user data files you select.
- Previously stored backup data are required.

#### 6.6.3. Log Backup

- Using this menu, any log and DB file stored at the system can be copied to a storage.
- Storage media like USB are required before starting the system.



[Figure 6.13 Log Backup screen]

## 6.7. Report

#### 6.7.1. Report

Shows the log information stored in the system regarding State, Temperature, Diagnostic SW, POST, BIST, and Connectivity.

Service Service Desktip									
() Serwaintomation a	Configuration	Q System	C. Deprestics	b Backup And Restore	E Rook	DencPlay			
System State Temperature Diagnestic SW	Report System Stat								
POST									
BET :	2010002 102502		en State Log ###	1000 C					
Connectivity	1 20100622 112159	# Memo	8/0116-09-221522522528282781-5558287845115-07482929- # Memory Value: VM-56350488, PMA-7208288, VM-5216608, PM-5216008, PM-6216488, VM-5216548, HC-441						
	2010042, 10009 2010042, 10028 2010042, 10028 2010060, 10280 2010008, 10280 2010008, 10000 2010007, 10070 2010007, 10070 2010007, 10070 2010007, 10070 2010007, 10070 2010007, 10070 2010007, 10070 2010007, 10070	4 State 4 Alerna 4 Alerna 4 Alerna 4 Alerna 4 Alerna 5 State 4 Alerna 6 State 4 Alerna 6 State 8 Alerna 8 Alern	6-21 12-525 2018/001 41.0.XMU y Janus WS-6810888, WM-7 y Janus WS-7811208, IMM-7 so 12 12-525.2019/11-301 6-21 12-525.2019/11-301 y Janus WS-71817208, IMM-7 y Janus WS-71817208, IMM-7 42 11:525544,003971 - donata y Janus WS-71807208, IMM-7 42 11:52544,003971 - donata y Janus WS-71807208, IMM-7 42 11:52544,003971 - donata	LC MAX. CECKETE: COF. PARKLELLISMA- SSERER, WAA-SARROWER, WS-6CHAB SSERER, WAA-SARROWER, WS-75812 (COmponent Informatione Valorized, PMA-S2748KR, WS-75812 SSERER, PMA-S2748KR, WS-102 (D) Environment	22 KB, PM-67556KB, VM-542K KB, PM-67556KB, VM-56724 KB, PM-65568KB, VM-5542 S55KB, PM-68552KB, VM-45 S55KB, PM-68572KB, VM-45 S55KB, PM-68572KB, VM-45 S55KB, PM-68572KB, VM-45	000, IC-449 1848, IC-474 900, IC-479 8651288, IC-416 1799483, IC-425 952888, IC-416 companium - Start, -			
	20100603,110003 20100603,1103702 20100603,1103702 20100603,1103702 20100603,1103705 20100603,1103705	(92016-3 # Merna 82016-3 # Merna 02016-3 * Alerna	- 122 15:25 54:87 24075 - (The back y Status: PWD=11001,000, PPM= 6-22 15:25 54:0134075 - (The back y Status: PWS=111011,000, PPM= 6-22 15:25 54:85 54075 - (The main 6-22 15:25 54:85 54075 - (The main y Status: PWS=111011,001, PPM=	kup database file delection was star 1925/2008, PNA+6542008, NYS+10 Rup database file delection was corr 1925/2008, PNA+6558008, NS+10 in database file capytos the backup o 1925/3008, PNA+65580008, NS+111	ed.) 44003, PM-9331 293, VM-45 oleted.) 66403, PM-9375393, VM-45 issubase filoj was started 33603, PM-9360063, VM-45	5882748, HC+632 5680988, HC+632 5883248, HC+632			

[Figure 6.14 Report screen]

## 6.8. Demo Play

#### 6.8.1. Demo Play

- Play: Plays the image already stored in the system.
- Import: Saves the image from USB or CD to a specified storage.
- Delete: Deletes any image stored.
- Interval: Adjusts the time interval between the images being played.

Service Service Deskte						
() Servicebelonder	of Configuration	O System	C Degrantics	🔂 Backup And Bastors	aport .	Committing .
Demo Play	Reputier Deput					
	Play					
	Import	broken (				
	Delete	Gelene				
	Internal	<b>.</b>				
	P					2016-07-013226-18-3 W 3.8M

[Figure 6.15 Demo Play screen]

## 6.9. Entering the Installation Key

Register the system after installing the software.

1. Once the system reboots after installation, the System Installation screen will be displayed.

System I	nstallation
Code : Installation Key :	ADAM_PV#9
Authentication	Cancel

[Figure 6.16 System Installation input window]

2. Enter the Installation Key.

The Installation Key can be acquired from Samsung Remote Service.

#### TIP Samsung Remote Service

Samsung Remote Service is used to issue the installation keys required for product authentication. Please enter the required information, such as product name, user, and distributor.

URL: http://www.samsungremoteservice.com/rm/identity/anonymous/ussInstKey.html

- 1. Enter product name, user, and distributor information.
  - Serial No: Enter the product serial number. The serial number is located on the label on the exterior of the product.
  - Code: Enter the code shown on the System Installation screen.
  - Enter the name of the hospital and your vendor information in the Hospital Info and Distributor field.
- 2. Press Install key Generate to acquire your installation key.

USS Product	Install Key	
1. Product Inf	io	
Serial No		
Code		
2. Hospital In	fo	
Name [	]	
Phone		
3 Distributor		
Namo		
Phone		
	Install Key Generate	

[Figure 6.17 Samsung Remote Service]

3. Press Authentication to complete the authentication process.

## Chapter 7

# Troubleshooting

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## 7.1. Power Issues

#### 7.1.1. Power Does Not Turn on

The power cord may be unplugged, the ADM may have failed to output the necessary voltage, or the power receptacle may have failed.

- 1. Make sure the power cord is properly plugged and the power switch is on.
- 2. Connect a different appliance to the power outlet to see whether it works.
  - If the appliance works, the power connection part has failed.
  - If the appliance does not work, the power outlet has failed.
- 3. Check if the system fan works.
  - If the fan works, the problem is likely to have been caused by reasons other than the power connection part.
  - If the fan does not work, it is likely that the PC Power has failed.
- 4. Check the output voltage of the ADM.
- 5. Check the PC Power and DDM.

#### 7.1.2. Power Does Not Turn off

A software error may have occurred, or the PC Motherboard and/or Main Board may have failed.

- 1. Press and hold the Power button for at least 3 seconds, and power will turn off automatically.
  - Note, however, that power will not turn off if hardware such as the printer has not yet stopped working or if an OS error has occurred.
- 2. If power does not turn off even by the method in paragraph 1 above, it is likely that the PC board and/or BE board have (has) failed.

#### 7.1.3. Power Turns off by Itself

It is likely that the Power Cord, PC Mother, Main Board, Cable & Connector Pin (shorted), AIM, and ADM PSU have failed.

- 1. Make sure the power cord is properly plugged and the power switch is on.
- 2. Connect a different appliance to the power outlet to see whether it works.
  - If the appliance works, the power connection part has failed.
  - If the appliance does not work, the power outlet has failed.
- 3. Check the LED status of the ADM.
- 4. If the problem is not solved by the methods in paragraphs 1 and 2 above, it is likely that the PC Motherboard, PCI Board, DVI Board, LCD IF Board, AIM, and/or ADM have (has) failed.

## 7.2. Monitor

#### 7.2.1. Nothing Is Displayed on the Screen

The DVI Cable and/or VGA Cable may have failed, or the Monitor and/or PC part may have failed.

- 1. Check the status of the product with the printer output.
- 2. Check the status of the monitor connection cable.
- 3. If the problem is not solved by the method in paragraphs 1 and 2 above, it is likely that the Monitor and/or PC Part have (has) failed. Check the DVI board and VGA card of the PC Part.

#### 7.2.2. Screen is Discolored

The Monitor and DVI cable may have failed, or the Monitor and/or PC Part may have failed.

- 1. Check the status of the monitor connection cable.
- 2. If the problem is not solved by the method in paragraph 1 above, it is likely that the Monitor and/or PC Part have (has) failed. Check the DVI board and VGA card of the PC Part.

## 7.3. Error Messages

#### 7.3.1. Error Occurs During Booting

This may be a temporary software error, or it may indicate product failure.

- 1. Turn power off, and then turn it back on in 1-2 minutes.
- 2. If the problem is not solved even by the method in paragraph 1 above, determine when the error message is shown. If the error occurs while WINDOWS is initiating, it is likely that the OS and/or PC part have (has) failed. If the error occurs after the logo is displayed, it is likely that the System Software or Ultrasound System part has failed.

## 7.4. Image

#### 7.4.1. 2D Mode: There is No IMAGE ECHO or IMAGE FORMAT

Contact between the probe and the product may be poor, or the Main Board or DDM may have failed.

- 1. Check whether the contact between the probe and the system is poor.
- 2. Check the probe for vibrating sound. If you can hear the sound, it is likely that the DDM has failed.
- 3. If the problem is not solved even by the methods in paragraphs 1 and 2 above, it is likely that the Main Board has failed.

#### 7.4.2. Lines (Noise) Appear in 2D Mode Image

Power noise and/or Main Board failure may have occurred.

- 1. Check whether the product is sharing the power outlet with another appliance.
- 2. Sharing a power outlet with a motor or other appliance that consumes large amount of power may cause noise.
- 3. Check whether the symptom persists when you plug the system into an outlet in a different room.
- 4. If the noise occurs, it is caused by power noise.
- 5. If the problem is not solved even by the methods in paragraphs 1 and 2 above, it is likely that the Main B Board has failed.

#### 7.4.3. M, C, PW, CW Mode Trouble

It is likely that the Main Board has failed.

## 7.5. USD Device Detection Failure

#### 7.5.1. Failed to recognize the USB (Removable device) device

It is related to Windows 7, and it may cause the storage volume of the removable device not to be recognized if such removable device has been shut down after connecting it to the device for the first time.

This issue can be fixed by reinstalling the volume.

1. Launch Windows Explorer, type "devmgmt.msc," and then start Device Manager



- 2. Choose "Storage Volumes" from the device list
- 3. Choose "Unknown device" under "Storage Volumes" and uninstall it

b Device Manager	
File Action View Help	
(+ +) 🖬 🖬 🕫 🕸 🕵 🗗	
HSSASA-ULDIGGD  HSSASA-ULDIGGD  Komputer  Disk drives  Disk drives  Disk vives  D	

4. Run "Scan for hardware changes" from Device Manager

## 7.6. Trouble Shooting Tree

• System power does not turn on.



• No image appears in the monitor.



• Noise occurs in the image format.


• System power does not turn on.



• System power does not turn off.



# **Chapter 8**

# Disassembly and Assembly

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# 8.1. Power Issues

This chapter describes the procedure for disassembling the HS50/HS60 system. Refer to this chapter when upgrading or servicing the system's hardware.



- Samsung Medison's customer service department or authorized engineers are allowed to repair or replace the parts of the products.
- The interior of this product contains dangerous high-voltage electricity. Do not disassemble the product. Otherwise, short-circuit may occur.
- Do not wear an antistatic wrist strap while working with the product in powered on state. Otherwise, you may sustain electrical injury.

#### 8.1.1. Preparation

You will need the following items: Phillips (+) screwdriver, antistatic gloves, and antistatic wrist strap.

Turn off the power of the product and disconnect the battery.



Wear antistatic gloves and wrist strap when disassembling or reassembling the product. They help prevent accidents for the engineer and product failure caused by static electricity.



[Figure 8.1 Antistatic Gloves and Wrist Strap]

# 8.2. Disassembling the Product

## 8.2.1. Rear Side Disassembly

1. First, disconnect the Power Cord. Remove 8 screws and detach the rear cover. Next, remove 5 screws and detach the Cable Protection Cover.



2. Disconnect 7 cable connectors. At this time, make sure that the connectors are disconnected while holding down their locking mechanism. Remove 6 screws and detach the Shield Cover.





3. Remove 2 screws and detach both BE module and BF board.



4. Remove 5 connectors and 4 screws and detach the ADM Module.



# 8.2.2. HDD Disassembly

1. First, disconnect the Power Cord. Remove 8 screws and detach the rear cover. Next, remove 5 screws and detach the Cable Protection Cover.





2. Remove 2 HDD mounting screws and detach the HDD.





## 8.2.3. Front End Disassembly

1. First, remove 2 screws on the bottom of the Foot Cover and detach the Foot Cover. As shown in the figure below, use your hands to pull the Front Cover forward and detach it. (no screw used)



2. Remove 10 screws and pull up the handles mounted on the PSA Board. Use your hands to pull the handles forward to detach the PSA.





# 8.2.4. Control Panel Disassembly

1. First, remove 14 screws on the bottom of the CP Panel and carefully lift the upper plate of the CP Panel. Then, remove 6 connectors and detach the upper plate of the CP Panel.





2. Remove 2 screws and 1 connector of the Track Ball and detach the Track Ball.



# 8.2.5. Touch Panel Disassembly

Remove 4 screws on the bottom of the CP Panel and detach 2 connectors. Take care when detaching the CP Panel and Touch Panel so that the surface of the Touch Panel is not scratched.











# 8.2.6. Dust Filter and Fan Disassembly

First, pull out the Dust Filter on the bottom of the system to the left. Detach the Foot Cover and the Front Cover. On the bottom of the PSA, remove 2 screws and detach the Fan Power Connector. Finally, detach the FAN Module.







#### 8.2.7. ODD Disassembly

1. First, detach the Rear Cover of the system. As shown in the figure below, remove 2 screws and open the Case right and left to detach it.





2. Remove 8 screws and lift the upper plate to detach it.



3. Remove 2 screws and 1 connector and pull out the ODD forward.



# 8.2.8. Monitor Disassembly

1. First, remove 2 screws on the rear bottom of the Monitor.









# **Chapter 9**

# **Probes**

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# 9.1. 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.

#### 9.1.1. Probe List

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

#### Probe Application and Presets

The types of probes, applications, and presets available with this product are as follows:

Туре	Probes	Application	Preset
		Abdomen	Abdomen, Renal, Bowel, Aorta
		MSK	General, Superficial, Deep, Spine
		Small Parts	Breast, Thyroid, Testicle
	LA3-14AD	Vascular	Carotid, Arterial, Venous, TCD
		ОВ	1st Trimester, 2nd Trimester, 3rd Trimester, Fetal Heart
		GYN	Uterus, Adnexa
Linear array		Pediatric	Neo Head, Ped Abd, Ped Hip
		Abdomen	Abdomen, Renal, Bowel, Aorta
		MSK	General, Superficial, Deep, Spine
		Small Parts	Breast, Thyroid, Testicle
	LA2-9A	Vascular	Carotid, Arterial, Venous, TCD
		ОВ	1st Trimester, 2nd Trimester, 3rd Trimester, Fetal Heart
		GYN	Uterus, Adnexa
		Pediatric	Neo Head, Ped Abd, Ped Hip
	LA3-16AI	Abdomen	Abdomen, Renal, Bowel, Aorta

Туре	Probes	Application	Preset				
		MSK	General, Superficial, Deep				
		Small Parts	Breast, Thyroid, Testicle				
		Vascular	Carotid, Arterial, Venous, TCD				
		ОВ	1st Trimester, 2nd Trimester, 3rd Trimester, Fetal Heart				
		GYN	Uterus, Adnexa				
		Pediatric	Neo Head, Ped Abd, Ped Hip				
		Abdomen	Abdomen, Renal, Bowel, Aorta				
		MSK	General, Superficial, Deep, Spine				
	LA4-18BD	Small Parts	Breast, Thyroid, Testicle				
		Vascular	Carotid, Arterial, Venous, TCD				
		ОВ	1st Trimester, 2nd Trimester, 3rd Trimester, Fetal Heart				
		GYN	Uterus, Adnexa				
		Pediatric	Neo Head, Ped Abd, Ped Hip				
		Abdomen	Abdomen, Renal, Bowel, Aorta				
		MSK	General, Superficial, Deep, Spine				
		Small Parts	Breast, Thyroid, Testicle				
	LA3-16A	Vascular	Carotid, Arterial, Venous, TCD				
		ОВ	1st Trimester, 2nd Trimester, 3rd Trimester, Fetal Heart				
		GYN	Uterus, Adnexa				
		Pediatric	Neo Head, Ped Abd, Ped Hip				
		Abdomen	Abdomen, Renal, Bowel, Aorta				
		MSK	General, Superficial, Deep, Spine				
Curved	041 740	ОВ	1st Trimester, 2nd Trimester, 3rd Trimester, Fetal Heart, NT				
array	CAI-/AD	GYN	Uterus, Adnexa				
		Pediatric	Neo Head, Ped Abd, Ped Hip				
		Vascular	Carotid, Arterial, Venous, TCD				

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Туре	Probes	Application	Preset
		Urology	Prostate, Bladder
		Abdomen	Abdomen, Renal, Bowel, Aorta
		MSK	General, Superficial, Deep, Spine
		ОВ	1st Trimester, 2nd Trimester, 3rd Trimester, Fetal Heart, NT
	CA2-9AD	GYN	Uterus, Adnexa
		Pediatric	Neo Head, Ped Abd, Ped Hip
		Vascular	Carotid, Arterial, Venous, TCD
		Urology	Prostate, Bladder
	CA2-6BM	Abdomen	Abdomen, Renal
		Abdomen	Abdomen, Renal, Bowel, Aorta
		MSK	General, Superficial, Deep, Spine
		ОВ	1st Trimester, 2nd Trimester, 3rd Trimester, Fetal Heart
	CF4-9	GYN	Uterus, Adnexa
		Pediatric	Neo Head, Ped Abd, Ped Hip
		Vascular	Carotid, Arterial, Venous, TCD
		Urology	Prostate, Bladder
		Abdomen	Abdomen, Renal, Bowel, Aorta
		Cardiac	Adult Echo, Ped Echo, Aortic Arch
	PAT-5A	Vascular	Carotid, Arterial, Venous, TCD
		Pediatric	Ped Abd
Phase		Abdomen	Abdomen, Renal, Bowel, Aorta
array		Cardiac	Adult Echo, Ped Echo, Aortic Arch
	FA3-0D	Vascular	Carotid, Arterial, Venous, TCD
		Pediatric	Ped Abd
		Abdomen	Abdomen, Renal, Bowel, Aorta
	FE2-4	Cardiac	Adult Echo, Ped Echo, Aortic Arch

Туре	Probes	Application	Preset
		Vascular	Carotid, Arterial, Venous, TCD
		Pediatric	Ped Abd
		ОВ	1st Trimester, 2nd Trimester, 3rd Trimester, Fetal Heart
	EA2-11B	GYN	Uterus, Adnexa
Endo		Urology	Prostate, Bladder
Cavity		ОВ	1st Trimester, 2nd Trimester, 3rd Trimester, Fetal Heart
	ER4-9	GYN	Uterus, Adnexa
		Urology	Prostate, Bladder
		Abdomen	Abdomen, Renal, Bowel, Aorta
		MSK	General, Superficial, Deep, Spine
	CV1-8AD	ОВ	1st Trimester, 2nd Trimester, 3rd Trimester, Fetal Heart, NT
		GYN	Uterus, Adnexa
20		Pediatric	Neo Head, Ped Abd, Ped Hip
3D		Vascular	Carotid, Arterial, Venous, TCD
		Urology	Prostate, Bladder
		ОВ	1st Trimester, 2nd Trimester, 3rd Trimester, Fetal Heart
	V5-9	GYN	Uterus, Adnexa
		Urology	Prostate, Bladder
		Cardiac	Adult Echo, Ped Echo
Densil	DP2B	Vascular	Carotid, Arterial, Venous, TCD
Pencii		Cardiac	Adult Echo, Ped Echo
	CVV6.U	Vascular	Carotid, Arterial, Venous, TCD



- 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' in the user manual.

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#### Function List

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

Probe	Application	Panoramic	ECG	Elasto Scan	Q Scan	СМ	TDI	PD	S-Flow
	Abdomen	0	0	х	0	х	Х	0	0
	MSK	0	0	X General (O)	0	х	х	0	0
	Small Parts	0	0	X Breast (O), Thyroid (O)	0	х	х	0	0
	Vascular	0	0	х	0	х	х	0	0
	ОВ	0	0	х	0	х	х	0	0
	GYN	0	0	х	0	х	х	0	0
	Pediatric	0	0	х	0	х	Х	0	0
	Abdomen	0	0	х	0	х	х	0	0
	MSK	0	0	х	0	х	х	0	0
	Small Parts	0	0	х	0	х	Х	0	0
LA2-9A	Vascular	0	0	х	0	х	Х	0	0
	ОВ	0	0	х	0	х	Х	0	0
	GYN	0	0	х	0	х	Х	0	0
	Pediatric	0	0	х	0	х	Х	0	0
	Abdomen	0	0	х	0	х	Х	0	0
	MSK	0	0	х	0	х	Х	0	0
	Small Parts	0	0	х	0	х	х	0	0
LA3-16AI	Vascular	0	0	х	0	х	Х	0	0
	ОВ	0	0	х	0	х	Х	0	0
	GYN	0	0	Х	0	х	Х	0	0
	Pediatric	0	0	Х	0	х	Х	0	0
	Abdomen	0	0	Х	0	х	Х	0	0
LA4-18BD	MSK	0	0	х	0	х	Х	0	0

Probe	Application	Panoramic	ECG	Elasto Scan	Q Scan	СМ	TDI	PD	S-Flow
				General (O)					
	Small Parts	0	0	X Breast (O), Thyroid (O)	0	х	х	0	0
	Vascular	0	0	х	0	х	Х	0	0
	ОВ	0	0	х	0	х	х	0	0
	GYN	0	0	х	0	х	х	0	0
	Pediatric	0	0	х	0	х	х	0	0
	Abdomen	0	0	х	0	х	х	0	0
1 43-164	MSK	0	0	X General (O)	0	х	х	0	0
	Small Parts	0	0	X Breast (O), Thyroid (O)	0	х	х	0	0
	Vascular	0	0	х	0	х	х	0	0
	ОВ	0	0	х	0	х	х	0	0
	GYN	0	0	х	0	х	Х	0	0
	Pediatric	0	0	х	0	х	х	0	0
	Abdomen	0	0	х	0	х	х	0	0
	MSK	0	0	х	0	х	х	0	0
	ОВ	0	0	х	0	х	х	0	0
CA1-7AD	GYN	0	0	х	0	х	х	0	0
	Pediatric	0	0	х	0	х	х	0	0
	Vascular	0	0	х	0	х	х	0	0
	Urology	0	0	х	0	х	Х	0	0
	Abdomen	0	0	х	0	Х	Х	0	0
	MSK	0	0	х	0	х	Х	0	0
GAZ-YAD	ОВ	0	0	х	0	Х	Х	0	0
	GYN	0	0	х	0	х	Х	0	0

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Probe	Application	Panoramic	ECG	Elasto Scan	Q Scan	СМ	TDI	PD	S-Flow
	Pediatric	0	0	х	0	х	Х	0	0
Probe         CA2-6BM         CF4-9         PA1-5A         PA3-8B         PE2-4	Vascular	0	0	х	0	х	Х	0	0
	Urology	0	0	х	0	х	Х	0	0
CA2-6BM	Abdomen	0	0	х	0	х	Х	0	0
	Abdomen	0	0	х	0	х	Х	0	0
	MSK	0	0	х	0	х	Х	0	0
	ОВ	0	0	х	0	х	Х	0	0
CF4-9	GYN	0	0	х	0	х	Х	0	0
	Pediatric	0	0	х	0	х	Х	0	0
	Vascular	0	0	х	0	х	Х	0	0
	Urology	0	0	х	0	х	Х	0	0
	Abdomen	х	0	х	0	х	Х	0	0
	Cardiac	х	0	х	0	0	0	х	Х
PA 1-5A	Vascular	х	0	х	0	х	Х	0	0
	Pediatric	х	0	х	0	х	Х	0	0
	Abdomen	х	0	х	0	х	Х	0	0
	Cardiac	х	0	х	0	0	0	х	Х
PA3-8B	Vascular	х	0	х	0	х	Х	0	0
	Pediatric	х	0	х	0	х	Х	0	0
	Abdomen	х	0	х	0	х	Х	0	0
	Cardiac	х	0	х	0	0	0	х	Х
PE2-4	Vascular	х	0	х	0	х	Х	0	0
	Pediatric	х	0	х	0	х	х	0	0
	ОВ	х	0	х	0	х	Х	0	0
EA2-11B	GYN	x	0	0	0	Х	Х	0	0
	Urology	x	0	Prostate(O),	0	х	Х	0	0

Probe	Application	Panoramic	ECG	Elasto Scan	Q Scan	СМ	TDI	PD	S-Flow
				Bladder(X)					
	ОВ	х	0	х	0	х	Х	0	0
ER4-9	GYN	х	0	0	0	х	Х	0	0
	Urology	х	0	Prostate(O), Bladder(X)	0	х	х	0	0
	Abdomen	0	0	х	0	х	Х	0	0
	MSK	0	0	х	0	х	Х	0	0
	ОВ	0	0	х	0	х	Х	0	0
CV1-8AD	GYN	0	0	х	0	х	Х	0	0
	Pediatric	0	0	х	0	х	Х	0	0
	Vascular	0	0	х	0	х	Х	0	0
	Urology	0	0	х	0	х	х	0	0
	ОВ	х	0	х	0	х	Х	0	0
V5-9	GYN	х	0	0	0	х	Х	0	0
	Urology	х	0	Prostate(O), Bladder(X)	0	х	х	0	0
	Cardiac	х	0	х	х	х	Х	х	х
DP2B	Vascular	х	0	х	х	х	Х	х	Х
	Cardiac	х	0	х	х	х	Х	х	х
CVV6.U	Vascular	х	0	х	х	х	Х	х	х

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Probe	Application	Biopsy	TDW	cw	Multi Vision	Clear Vision	S-Har.	Har
	Abdomen	0	Х	Х	0	0	0	0
	MSK	0	Х	Х	0	0	0	0
	Small Parts	0	Х	Х	0	0	0	0
LA3-14AD	Vascular	0	Х	Х	0	0	0	0
	ОВ	0	Х	х	0	0	0	0
	GYN	0	Х	х	0	0	0	0
	Pediatric	0	Х	х	0	0	0	0
	Abdomen	0	х	х	0	0	0	0
	MSK	0	х	х	0	0	0	0
	Small Parts	0	х	х	0	0	0	0
LA2-9A	Vascular	0	Х	х	0	0	0	0
	ОВ	0	Х	х	0	0	0	0
	GYN	0	х	х	0	0	0	0
	Pediatric	0	х	х	0	0	0	0
	Abdomen	Х	х	х	0	0	0	0
	MSK	х	х	х	0	0	0	0
	Small Parts	Х	х	х	0	0	0	0
LA3-16AI	Vascular	Х	Х	х	0	0	0	0
	ОВ	Х	х	х	0	0	0	0
	GYN	Х	Х	х	0	0	0	0
	Pediatric	х	х	х	0	0	0	0
	Abdomen	0	Х	х	0	0	0	0
	MSK	0	х	Х	0	0	0	0
LA4-18BD	Small Parts	0	х	х	0	0	0	0
	Vascular	0	Х	х	0	0	0	0
	ОВ	0	Х	Х	0	0	0	0

Probe	Application	Biopsy	TDW	CW	Multi Vision	Clear Vision	S-Har.	Har
	GYN	0	Х	Х	0	0	0	0
	Pediatric	0	х	Х	0	0	0	0
	Abdomen	0	Х	Х	0	0	0	0
	MSK	0	х	Х	0	0	0	0
	Small Parts	0	х	Х	0	0	0	0
LA3-16A	Vascular	0	х	х	0	0	0	0
	ОВ	0	х	х	0	0	0	0
Probe         LA3-16A         CA1-7AD         CA2-9AD         CA2-6BM         CF4-9	GYN	0	х	Х	0	0	0	0
	Pediatric	0	х	Х	0	0	0	0
	Abdomen	0	х	Х	0	0	0	0
	MSK	0	х	Х	0	0	0	0
	ОВ	0	х	Х	0	0	0	0
CA1-7AD	GYN	0	х	Х	0	0	0	0
	Pediatric	0	х	Х	0	0	0	0
	Vascular	0	х	Х	0	0	0	0
LA3-16A CA1-7AD CA2-9AD CA2-6BM CF4-9	Urology	0	х	Х	0	0	0	0
	Abdomen	0	х	Х	0	0	0	0
	MSK	0	х	Х	0	0	0	0
	ОВ	0	х	Х	0	0	0	0
CA2-9AD	GYN	0	х	Х	0	0	0	0
	Pediatric	0	х	Х	0	0	0	0
	Vascular	0	Х	Х	0	0	0	0
	Urology	0	Х	Х	0	0	0	0
CA2-6BM	Abdomen	Х	х	Х	0	0	0	0
	Abdomen	Х	х	Х	0	0	х	Х
UF4-9	MSK	Х	х	Х	0	0	х	Х

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Probe	Application	Biopsy	TDW	CW	Multi Vision	Clear Vision	S-Har.	Har
	ОВ	Х	х	х	0	0	х	Х
	GYN	Х	х	х	0	0	х	Х
	Pediatric	Х	х	х	0	0	х	Х
	Vascular	х	х	х	0	0	х	х
	Urology	Х	х	х	0	0	х	х
	Abdomen	Х	х	0	х	0	0	0
	Cardiac	Х	0	0	х	0	0	0
FAT-5A	Vascular	Х	х	0	х	0	0	0
	Pediatric	Х	х	0	х	0	0	0
	Abdomen	Х	х	0	х	0	0	0
	Cardiac	Х	0	0	х	0	0	0
PA3-8B	Vascular	Х	х	0	х	0	0	0
	Pediatric	х	х	0	х	0	0	0
	Abdomen	х	х	0	х	0	0	0
	Cardiac	Х	0	0	х	0	0	0
PE2-4	Vascular	Х	х	0	х	0	0	0
	Pediatric	Х	х	0	х	0	0	0
	ОВ	0	х	х	0	0	0	0
EA2-11B	GYN	0	х	х	0	0	0	0
	Urology	0	х	х	0	0	0	0
	ОВ	0	х	х	0	0	0	0
ER4-9	GYN	0	х	х	0	0	0	0
	Urology	0	х	х	0	0	0	0
	Abdomen	0	х	х	0	0	0	0
CV1-8AD	MSK	0	х	х	0	0	0	0
	ОВ	0	х	х	0	0	0	0

Probe	Application	Biopsy	TDW CW		Multi Vision	Clear Vision	S-Har.	Har
	GYN	0	Х	Х	0	0	0	0
	Pediatric	0	х	Х	0	0	0	0
	Vascular	0	х	х	0	0	0	0
	Urology	0	х	х	0	0	0	0
	ОВ	0	х	х	0	0	0	0
V5-9	GYN	0	х	х	0	0	0	0
	Urology	0	х	х	0	0	0	0
0020	Cardiac	Х	х	0	х	Х	х	Х
DP2B	Vascular	х	х	0	х	х	х	х
CIME 0	Cardiac	х	х	0	х	х	х	х
Cvv6.0	Vascular	х	х	0	х	Х	х	х



- 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.

# 9.1.1.1. 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. Refer to the following table:

Probes	Application	Preset	Thermal Index
	Abdomen	Abdomen, Renal, Bowel, Aorta	TIs
	MSK	General, Superficial, Deep, Spine	TIs
	Small Parts	Breast, Thyroid, Testicle	TIs
	Vascular	Carotid, Arterial, Venous, TCD	TIs
	OP	1st Trimester, 2nd Trimester	The
	ОВ	3rd Trimester, Fetal Heart	115
	GYN	Uterus, Adnexa	TIs
	Pediatric	Neo Head, Ped Abd, Ped Hip	TIs
	Abdomen	Abdomen, Renal, Bowel, Aorta	TIs
	MSK	General, Superficial, Deep, Spine	TIs
	Small Parts	Breast, Thyroid, Testicle	TIs
LA2-9A	Vascular	Carotid, Arterial, Venous, TCD	TIs
	ОВ	1st Trimester, 2nd Trimester, 3rd Trimester, Fetal Heart	TIs
	GYN	Uterus, Adnexa	TIs
	Pediatric	Neo Head, Ped Abd, Ped Hip	TIs
	Abdomen	Abdomen, Renal, Bowel, Aorta	TIs
	MSK	General, Superficial, Deep	TIs
1 42 1641	Small Parts	Breast, Thyroid, Testicle	TIs
LAS-TOAT	Vascular	Carotid, Arterial, Venous, TCD	TIs
	ОВ	1st Trimester, 2nd Trimester, 3rd Trimester, Fetal Heart	TIs
	GYN	Uterus, Adnexa	TIs

Probes	Application	Preset	Thermal Index
	Pediatric	Neo Head, Ped Abd, Ped Hip	TIs
	Abdomen	Abdomen, Renal, Bowel, Aorta	TIs
	MSK	General, Superficial, Deep, Spine	TIs
	Small Parts	Breast, Thyroid, Testicle	TIs
LA4-18BD	Vascular	Carotid, Arterial, Venous, TCD	TIs
	ОВ	1st Trimester, 2nd Trimester, 3rd Trimester, Fetal Heart	TIs
	GYN	Uterus, Adnexa	TIs
	Pediatric	Neo Head, Ped Abd, Ped Hip	TIs
	Abdomen	Abdomen, Renal, Bowel, Aorta	TIs
	MSK	General, Superficial, Deep, Spine	TIs
	Small Parts	Breast, Thyroid, Testicle	TIs
	Vascular	Carotid, Arterial, Venous, TCD	TIs
LA3-16A	0.5	1st Trimester, 2nd Trimester	<b>T</b> 1-
	OB	3rd Trimester, Fetal Heart	IIS
	GYN	Uterus, Adnexa	TIs
	Pediatric	Neo Head, Ped Abd, Ped Hip	TIs
	Abdomen	Abdomen, Renal, Bowel, Aorta	TIs
	MSK	General, Superficial, Deep, Spine	TIs
	ОВ	1st Trimester, 2nd Trimester, 3rd Trimester, Fetal Heart, NT	TIs
CA1-7AD	GYN	Uterus, Adnexa	TIs
	Pediatric	Neo Head, Ped Abd, Ped Hip	TIs
	Vascular	Carotid, Arterial, Venous, TCD	TIs
	Urology	Prostate, Bladder	TIs
040.015	Abdomen	Abdomen, Renal, Bowel, Aorta	TIs
CAZ-9AD	MSK	General, Superficial, Deep, Spine	TIs

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Probes	Application	Preset	Thermal Index
	ОВ	1st Trimester, 2nd Trimester, 3rd Trimester, Fetal Heart, NT	TIs
	GYN	Uterus, Adnexa	TIs
	Pediatric	Neo Head, Ped Abd, Ped Hip	TIs
	Vascular	Carotid, Arterial, Venous, TCD	TIs
	Urology	Prostate, Bladder	TIs
CA2-6BM	Abdomen	Abdomen, Renal	TIs
	Abdomen	Abdomen, Renal, Bowel, Aorta	TIs
	MSK	General, Superficial, Deep, Spine	TIs
	ОВ	1st Trimester, 2nd Trimester, 3rd Trimester, Fetal Heart	TIs
CF4-9	GYN	Uterus, Adnexa	TIs
	Pediatric	Neo Head, Ped Abd, Ped Hip	TIs
	Vascular	Carotid, Arterial, Venous, TCD	TIs
	Urology	Prostate, Bladder	TIs
	Abdomen	Abdomen, Renal, Bowel, Aorta	TIs
	Cardiac	Adult Echo, Ped Echo, Aortic Arch	TIs
PA1-5A	Vascular	Carotid, Arterial, Venous, TCD	TIs
	Pediatric	Ped Abd	TIs
	Abdomen	Abdomen, Renal, Bowel, Aorta	TIs
	Cardiac	Adult Echo, Ped Echo, Aortic Arch	TIs
PA3-8B	Vascular	Carotid, Arterial, Venous, TCD	TIs
	Pediatric	Ped Abd	TIs
	Abdomen	Abdomen, Renal, Bowel, Aorta	TIs
	Cardiac	Adult Echo, Ped Echo, Aortic Arch	TIs
PE2-4	Vascular	Carotid, Arterial, Venous, TCD	TIs
	Pediatric	Ped Abd	TIs

Probes	Application	Preset	Thermal Index
	ОВ	1st Trimester, 2nd Trimester, 3rd Trimester, Fetal Heart	TIs
EA2-11B	GYN	Uterus, Adnexa	TIs
	Urology	Prostate, Bladder	TIs
	ОВ	1st Trimester, 2nd Trimester, 3rd Trimester, Fetal Heart	TIs
ER4-9	GYN	Uterus, Adnexa	TIs
	Urology	Prostate, Bladder	TIs
	Abdomen	Abdomen, Renal, Bowel, Aorta	TIs
	MSK	General, Superficial, Deep, Spine	TIs
	ОВ	1st Trimester, 2nd Trimester, 3rd Trimester, Fetal Heart, NT	TIs
CV1-8AD	GYN	Uterus, Adnexa	TIs
	Pediatric	Neo Head, Ped Abd, Ped Hip	TIs
	Vascular	Carotid, Arterial, Venous, TCD	TIs
	Urology	Prostate, Bladder	TIs
	ОВ	1st Trimester, 2nd Trimester, 3rd Trimester, Fetal Heart	TIs
V5-9	GYN	Uterus, Adnexa	TIs
	Urology	Prostate, Bladder	TIs
	Cardiac	Adult Echo, Ped Echo	TIs
DP2B	Vascular	Carotid, Arterial, Venous, TCD	TIs
	Cardiac	Adult Echo, Ped Echo	TIs
CVV6.U	Vascular	Carotid, Arterial, Venous, TCD	TIs



• The default thermal index may vary, corresponding to the presets.

 You can change the thermal index can in Setup > Imaging > Application/Preset > Preset Settings > Thermal Index Type.

#### 9.1.2. Ultrasound Transmission Gel

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



- 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 (dioctylphtalate) or denatured alcohols.
  - Glacial acetic acid and iodine.
  - All types of lotions or gels that contain aromatic substances.

#### 9.1.2.1. Gel Warmer (Optional)

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



- 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.



- 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 9.1 Gel Warmer Label – Example]

#### 9.1.3. 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.



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

#### 9.1.3.1. 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.

#### 9.1.4. Probe Safety Precautions

• 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.

## 9.1.4.1. Use and Infection Control of the Probe



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.



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.

#### 9.1.4.2. Electric Shocks

The probe uses electrical energy. If it touches conductive materials, there are risks of electric shocks to the patient or the user.



- 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.

#### 9.1.5. Cleaning and Disinfecting the Probe

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



- 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.

#### 9.1.5.1. 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 critical, semi-critical, or non-critical devices based on the standards of FDA guidance\*, proper disinfection, cleaning 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

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

	Disinfectants																			
Names	Tristel Duo	Tristel Sporicidal Wipe	T-Spray II	T-Spray	Sani-Cloth HB	Sani-Cloth Plus <sup>7)</sup>	Sani-Cloth Active	Sani-Cloth AF Germicidal	Sani-Cloth AF3 Germicidal	Sani-Cloth Bleach Germicidal <sup>7)</sup>	Septiwipes	Cleanisept Wipes	Ster-Bac Blu	Cleanisept wipe forte	Transeptic Spray	Incidin Foam	Super Sani-Cloth	Sani-Cloth Germicidal		
Туре	S	w	s	s	w	w	w	w	w	w	w	w	L	w	S	S	w	w		
Disinfectant Level (High/Low)	н	н	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L		
Active Ingredient	obivola odvola?		Quaternary Ammonium (N-Alkyl)						Quaternary Ammonium (N-AlkyI)							Ammonium Chlorides		Quaternary	(N-Alkyl)	
LA3-14AD	•	•	•		•				•	•		•		•						
LA2-9A			٠	٠	0															
LA3-16AI	٠	•		•	•				٠	•		٠		•						
LA4-18BD																				
LA3-16A			•		•					•										
CA1-7AD	٠	•	•		•				٠	•		•		•						
CA2-9AD	•	•	•		•				•	•		٠		•			•			
CA2-6BM					•															
CF4-9			•	•	O										٠					
PA1-5A	•	•	•		•	•			•	•	•			•			•			

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								Di	sinfe	ectan	Its							
Names	Tristel Duo	Tristel Sporicidal Wipe	T-Spray II	T-Spray	Sani-Cloth HB	Sani-Cloth Plus <sup>7)</sup>	Sani-Cloth Active	Sani-Cloth AF Germicidal	Sani-Cloth AF3 Germicidal	Sani-Cloth Bleach Germicidal <sup>7)</sup>	<ul> <li>Septiwipes</li> <li>Septiwipes</li> <li>Cleanisept Wipes</li> <li>Ster-Bac Blu</li> <li>Ster-Bac Blu</li> <li>Cleanisept wipe forte</li> <li>Transeptic Spray</li> <li>Incidin Foam</li> <li>Super Sani-Cloth</li> </ul>							Sani-Cloth Germicidal
Туре	S	w	S	S	w	w	w	w	w	w	w	w	L	w	S	S	w	w
Disinfectant Level (High/Low)	н	н	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L
Active Ingredient CHIO							Ousternand	Ammonium	(N-AIKYI)					Ammonium Chlorides		Quaternary	(N-Alkyl)	
PE2-4			•	٠	•	•		٠	٠	٠								
EA2-11B			٠	٠	$\bigcirc$													
ER4-9				٠	•													
CV1-8AD	•	•	•		•				•	•		٠		•				
V5-9			•	•	$\odot$													
DP2B			•	•	$\odot$													
CW6.0			٠	٠	0													
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							Di	sinfe	ctant	s						
Names	Asepti-Wipes	Asepti-Wipes II	CaviWipes <sup>7)</sup>	MetriWipes	Cidex <sup>7)</sup>	Cidex OPA <sup>2,3,7)</sup>	Cidex 2%	Cidex Plus <sup>2)</sup>	Metricide <sup>2,7)</sup>	Metricide 14	Metricide 28 <sup>7)</sup>	Metricide 30 <sup>7)</sup>	Metricide OPA Plus	Omnicide 28	Omnicide 14NS	Omnicide - FG2
Туре	w	w	w	w	L	L	L	L	L	L	Soak	Soak	Soak	L	L	L
Disinfectant Level (High/Low)	L	L	L	L	н	н	н	н	н	н	н	н	н	н	Η	н
Active Ingredient		Quaternary Ammonium (N-Alkyl)		Alcohol	Glutaraldehyde	Ortho-phthalaldehyde				Glutaraigenyge			Ortho-Phthalaldehyde		Glutaraldehyde	
LA3-14AD					•	•		•					•			•
LA2-9A								$\diamond$								
LA3-16AI					•	•	•	•			•	•	×			•
LA4-18BD						•	•									
LA3-16A					•	•	•	•			•	•				•
CA1-7AD					•	•		•					•			•
CA2-9AD					•	•		•			•	•				•
CA2-6BM						•		•								
CF4-9						•		$\diamond$								
PA1-5A		•	•		•			•	•		•	•		•	٠	•
PA3-8B					•	•	•	•	•		•	•		•	•	
PE2-4					•	•	•	•	•		•	•		٠	•	
EA2-11B								$\diamond$								
ER4-9					•	•		•								•

# Chapter 9. Probes 9 - 25

	Disinfectants										Disinfectants									
Names	Asepti-Wipes	Asepti-Wipes II	CaviWipes <sup>7)</sup>	MetriWipes	Cidex <sup>7)</sup>	Cidex OPA <sup>2,3,7)</sup>	Cidex 2%	Cidex Plus <sup>2)</sup>	Metricide <sup>2,7)</sup>	Metricide 14	Metricide 28 <sup>7)</sup>	Metricide 30 <sup>7)</sup>	Metricide OPA Plus	Omnicide 28	Omnicide 14NS	Omnicide - FG2				
Туре	W	W	w	w	L	L	L	L	L	L	Soak	Soak	Soak	L	L	L				
Disinfectant Level (High/Low)	L	L	L	L	H	H	н	H	H	H	н	н	н	н	н	H				
Active Ingredient		Quaternary Ammonium (N-Alkyl)	,	Alcohol	Glutaraldehyde	Ortho-phthalaldehyde			Clutomodo	Glutalalueilyue			Ortho-Phthalaldehyde		Glutaraldehyde					
CV1-8AD					•	•		•					•			•				
V5-9			•		•			$\diamond$		•			•							
DP2B					•			$\diamond$		•										
CW6.0								$\diamond$												

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	Disinfectants														
Names	Nuclean	Wavicide-01 <sup>3)</sup>	Sekusept Extra	Salvanios pH 7	Salvanios pH 10	Steranios 2%	Surfaces Hautes	Sekusept Plus	Milton	Bleach 5.25%	Virkon <sup>7)</sup>	Sporox	Sporox II <sup>7)</sup>	Gigasept	Gigasept AF <sup>3)</sup>
Туре	L	L	L	L	L	L	s	L	L	L	L	L	L	L	L
Disinfectant Level (High/Low)	L	н	н	н	н	н	н	н	L	L	н	н	н	н	н
Active Ingredient	Alcohol				Glutaralgenyde			Nonionic surfactant		зоанит пуростоле	Potassium peroxymonosulfate		Hyarogen Peroxiae	Succindialdehyde, formaldehyde	Quaternary Ammonium
LA3-14AD	٠	•							•			•			
LA2-9A															0
LA3-16AI	×	×							•				•		
LA4-18BD					•	•									
LA3-16A	٠	•							•			×			
CA1-7AD	•	•							•			•			
CA2-9AD	•	•							•			•			
CA2-6BM		•											•		
CF4-9															O
PA1-5A	•	•				•			•				•		
PA3-8B		•			•	•			•						
PE2-4		•			•	•			•						
EA2-11B															O
ER4-9	•	•							•				×		
CV1-8AD	٠	•							•			•			

# Chapter 9. Probes 9 - 27

							Disi	nfect	ants						
Names	Nuclean	Wavicide-01 <sup>3)</sup>	Sekusept Extra	Salvanios pH 7	Salvanios pH 10	Steranios 2%	Surfaces Hautes	Sekusept Plus	Milton	Bleach 5.25%	Virkon <sup>7)</sup>	Sporox	Sporox II <sup>7)</sup>	Gigasept	Gigasept AF <sup>3)</sup>
Туре	L	L	L	L	L	L	S	L	L	L	L	L	L	L	L
Disinfectant Level (High/Low)	L	н	н	н	н	н	н	н	L	L	н	н	Н	н	Н
Active Ingredient	Alcohol			Chind children of the	Giulaiaideilyde			Nonionic surfactant	Codine Uncohlorito		Potassium peroxymonosulfate	Description		Succindialdehyde, formaldehyde	Quaternary Ammonium
V5-9								0							$\bigcirc$
DP2B															$\bigcirc$
CW6.0															0

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		Dis	infecta	ants		Cleaner							
Names	Gigasept FF	Hibitane <sup>7)</sup>	PeraSafe	Anioxyde 1000	STERIS REVITAL OX RESERT	Enzol	Alkazyme	Cidezyme	Klenzyme	Isopropyl alcohol (70%)	Isopropyl alcohol (80%)	Ethanol 75%	
Туре	L	L	Р	Soak	L	L	L/W	L	L	L	L	L	
Disinfectant Level (High/Low)	н	-	н	н	н								
Active Ingredient	Bersteinsaure	Chlorhexidine gluconate solution	Citric Acid	Peracetic Acid	Accelerated Hydrogen Peroxide	Dodecylphenolethoxylate, Sodium Xylene Sulfonate		Proteolytic Enzymes			Alcohol		
LA3-14AD			×	•				•	•	•			
LA2-9A	O	0											
LA3-16AI			•	•				•	•				
LA4-18BD							•	•	•				
LA3-16A								•	•	•			
CA1-7AD			•	•				•	•	•			
CA2-9AD			•	•				•	•	•			
CA2-6BM						•			•				
CF4-9	$\bigcirc$	O											
PA1-5A			•	•				•	•	•			
PA3-8B						•			•	•			
PE2-4						•			•	•			
EA2-11B	0	0											
ER4-9								•	•	•			

# Chapter 9. Probes 9 - 29

		Dis	infecta	nts		Cleaner							
Names	Gigasept FF	Hibitane <sup>7)</sup>	PeraSafe	Anioxyde 1000	STERIS REVITAL OX RESERT	Enzol	Alkazyme	Cidezyme	Klenzyme	Isopropyl alcohol (70%)	Isopropyl alcohol (80%)	Ethanol 75%	
Туре	L	L	Ρ	Soak	L	L	L/W	L	L	L	L	L	
Disinfectant Level (High/Low)	н	-	н	н	н								
Active Ingredient	Bersteinsaure	Chlorhexidine gluconate solution	Citric Acid	Peracetic Acid	Accelerated Hydrogen Peroxide	Dodecylphenolethoxylate, Sodium Xylene Sulfonate		Proteolytic Enzymes			Alcohol		
CV1-8AD			•	•				٠	•	•			
V5-9									●				
DP2B	0	0											
CW6.0	0	0											

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	Clea	aner		Gel								
Names	Metrizyme	McKesson	Natural Image	Aquasonics 100 <sup>3)</sup>	GE Ultrasound Contact Gel	Clear Image	Kendall	SCAN	Wavelength	Sonogel	Trophon	Antigermx S1
Туре	L	L	G	G	G	G	G	G	G	G		
Disinfectant Level (High/Low)												
Active Ingredient	Propylene Glycol	PCMX (Chloroxylenol)	Ammonium Chlorides				NA					
LA3-14AD	•	•		•								
LA2-9A				•				•		•	•	
LA3-16AI	•	•		•								
LA4-18BD											•	
LA3-16A	٠	•		•								
CA1-7AD	•	•		•							•	
CA2-9AD	•	•		•							•	
CA2-6BM	•		•									
CF4-9				•				•		•	•	
PA1-5A	•	•		•							•	
PA3-8B	•			•							•	•
PE2-4	•			•							•	•
EA2-11B				•				•		•		
ER4-9	•	•									•	

	Clea	aner				G	el					
Names	Metrizyme	McKesson	Natural Image	Aquasonics 100 <sup>3)</sup>	GE Ultrasound Contact Gel	Clear Image	Kendall	SCAN	Wavelength	Sonogel	Trophon	Antigermx S1
Туре	L	L	G	G	G	G	G	G	G	G		
Disinfectant Level (High/Low)												
Active Ingredient	Propylene Glycol	PCMX (Chloroxylenol)	Ammonium Chlorides				NA					
CV1-8AD	•	•		•							•	
V5-9				•				•		•	•	
DP2B				•				•		•		
CW6.0				•				•		•		

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#### TIP Symbols

The significance of each symbol is as follows:

(4)	
(1)	Compatible but no EPA Registration
(2)	FDA 510(k) Cleared
(3)	Has CE mark
(4)	Discontinued
(5)	Under Development
(6)	ANVISA Registered
(7)	Health Canada Approved; Sani-Cloth Plus (DIN: 02242608), Sani-Cloth Bleach Germicidal (DIN: 02450410), CaviWipes (DIN: 02242209), Cidex (DIN: 02158418), Cidex OPA (DIN: 02239732), Metricide (DIN: 01963996), Metricide 28 (DIN: 01964461), Metricide 30 (DIN: 01964496), Virkon (DIN: 02125021), Sporox II (DIN: 02243075), Hibitane (DIN: 00053201)
S	Spray
w	Wipe
L	Liquid
Р	Powder
G	Gel
Soak	Soak
x	Not compatible (DO NOT USE)
•	Compatible
*	Staining may occur on housing parts; however, the acoustic performance and image quality are not affected.
•	Must not be used for longer than 5 minutes.
Ð	Must not be used for longer than 10 minutes.
	Must not be used for longer than 15 minutes.
•	Must not be used for longer than 20 minutes.
$\diamond$	Must not be used for longer than 25 minutes.
Ø	Must not be used for longer than 30 minutes.
	Must not be used for longer than 50 minutes.
Blank	Untested (DO NOT USE)

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

Product	Manufacturer
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
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

Product	Manufacturer
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
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

Product	Manufacturer
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.

### 9.1.5.2. Cleaning

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



- Do not use a surgical brush when cleaning probes. Even the use of soft brushes can damage the probe.
- During cleaning and disinfection, keep the parts of the probe that must remain dry higher than the other parts during wetting until all parts are dry.
- 1. Disconnect the probe from the system.
- 2. Remove any biopsy adapters or needle guides. (Adapters may be reused after disinfection.)
- 3. Remove the sheath. (Sheaths are disposable.)
- 4. Use a soft cloth, lightly dampened with mild soap or compatible cleaning solution, to remove any particulate matter and bodily fluids that remain on the probe or cable.
- 5. To remove remaining particulates, rinse with water up to the immersion point.
- 6. Wipe with a dry cloth.
- 7. If necessary, wipe first with a water-dampened cloth to remove soap residue, and wipe with a dry cloth again.

# 9.1.5.3. Disinfecting

A 10<sup>-6</sup> reduction in pathogens should be reached following the disinfection procedures in this manual and using the following Samsung Medison recommended solutions.



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



- Using a non-recommended disinfectant or not following the recommended disinfection method can damage and/or discolor the probe. This could also void the probe warranty.
- Do not immerse probes for longer than one hour, unless they are sterilizable.
- Only use liquid solutions to sterilize probes. Do not sterilize by autoclaving or using EtO gas.
- 1. Please refer to the user instructions of the disinfectant for details of proper storage, use, and disposal of the disinfectant.
- 2. Mix the disinfectant compatible with your probe according to the instructions for solution strength provided on its label.
- 3. Immerse the probe into the disinfectant as shown in the illustration below.
- 4. Follow the instructions on the disinfectant to complete the immersion procedure of the probe, and rinse the probe afterwards.
- 5. Air dry the probe or towel it dry with a clean cloth.



[Figure 9.2 Disinfection]

# 9.2. 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.

# 9.2.1. Biopsy Kit Components

The biopsy kit consists of the adapter, needle guide and needle. The components vary depending on the probe type.



[Figure 9.3 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.

# 9.2.2. Using the Biopsy Kit



- 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.

### 9.2.2.1. Before Using Biopsy Kit



- 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.

- 1. 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.
- 3. Inspect all components. Ensure that the biopsy kit you are using is the correct one for the probe, the system, and system software.

### 9.2.2.2. Biopsy Procedure

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

- 1. Ready the patient according to the procedure appropriate for the examination objectives.
- 2. Install the sheath and the biopsy kit.
- 3. Set the system controls for the biopsy procedure. If necessary, apply acoustic gel to the patient.
- 4. 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.

# 9.2.2.3. Needle Guide Alignment



- 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.

# 9.2.3. Assembling the Biopsy Kit

#### 9.2.3.1. 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.

# 9.2.3.2. 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.



TIPUsing Multi AngleUse the angle adjuster.



# 9.2.3.3. Biopsy Specifications

	Biopsy						
Probe	Model Name	Components	Adapter Material	Reusable/ Disposable	Needle Gauge	Multi Angle Depth	
		Biopsy Adapter		Reusable	14, 15, 16,	1.5, 2.5, 4 (cm)	
LA4-18BD	BP-KIT-069	Utra-Pro II Needle Guides & CIV-Flex Cover	Acetal Copolymer	Disposable	17, 18, 20, 21, 22, 23, 8.5FR		
		Biopsy Adapter		Reusable	14, 15, 16, 17, 18, 20, 21, 22, 23, 8.5FR	4, 5.5, 7 (cm)	
LA2-9A	BP-KIT-043	Utra-Pro II Needle Guides & CIV-Flex Cover	Acetal Copolymer	Disposable			
	BP-KIT-053	Biopsy Adapter	Acotol	Reusable	16, 18, 20, 22	0.591, 0.984, 1.575 (in)	
LA3-14AD	[BP-KIT-053- NG]	Needle Guide & Probe Cover	Copolymer	Disposable			
	BP-KIT-068	Biopsy Adapter	Acetal	Reusable	16 19 20	0.591, 0.984, 1.575 (in)	
	[BP-KIT-068- NG]	Needle Guide & Probe Cover	Copolymer	Disposable	22		
LA3-10A	BP-KIT-055	Biopsy Adapter	Acotal	Reusable	16, 18, 20, 22	0.591, 0.984, 1.575 (in)	
	[BP-KIT-055- NG]	Needle Guide & Probe Cover	Copolymer	Disposable			
CA1-7AD	BP-KIT-058	Biopsy Adapter	Acetal	Reusable	14, 16, 18, 20, 22, 25	1.969, 3.937, 5.906, 7.874 (in)	
	[BP-KIT-058- NG]	Needle Guide & Probe Cover	Copolymer	Disposable			
CA2-9AD	BP-KIT-054	Biopsy Adapter	Acetal	Reusable	16, 18, 22, 25	2.362, 3.150, 3.937 (in)	
	[BP-KIT-054- NG]	Needle Guide & Probe Cover	Copolymer	Disposable			
FA2-11B	BP-KIT-065	Needle Guide	Stainless	Reusable	16-18	Single Angle 2°	
	BP-KIT-066	Needle Guide	Abs	Disposable	16-18	Single Angle 2°	
ED1-0	BP-KIT-024-3	Needle Guide	Stainless	Reusable	16	Single Angle 1°	
ER4-9	BP-KIT-061	Needle Guide	Abs	Disposable	16-18	Single Angle 1°	
CV1-8AD	BP-KIT-059	Biopsy Adapter	Acetal	Reusable	14 16 19	1.969, 3.937 (in)	
	[BP-KIT-059- NG]	Needle Guide & Probe Cover	Copolymer	Disposable	20, 22, 25		
	BP-KIT-029	Needle Guide	Stainless	Reusable	18	_	
V5-9	BP-KIT-060	Needle Guide	ABS	Disposable	16–18	Single Angle 1.8°	

# 9.2.4. Cleaning and Disinfecting the Biopsy Kit



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

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

### 9.2.4.1. Cleaning and Disinfection of Stainless Steel Biopsy Kit

#### Cleaning

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

#### Disinfection

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

# 9.2.4.2. Cleaning and Disinfecting, Sterilizing of Plastic Biopsy Kit

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



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

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



- The plastic biopsy adapter is reusable.
- The plastic biopsy needle quide is disposable.
- Do not sterilize with autoclave or gas.

- · Please refer to the user manual in the biopsy kit.

# Chapter 10

# Maintenance

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# 10.1. Operational Environment

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



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.

# 10.2. Product Maintenance

# 10.2.1. Cleaning and Disinfecting

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



- 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.

#### 10.2.1.1. Cleaning



- 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.



For information on cleaning and disinfecting the probe, please refer to 'Chapter 9. Probes'.

# Touch Screen

Wipe the LCD surface with a soft dry cloth.



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



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 10.1 Removing the Trackball]



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- For information on cleaning and disinfecting the probes, please refer to 'Chapter 9. Probes' in the user manual.
- This image may differ from the actual system.

# 10.2.1.2. Disinfection



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 9. 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.

### 10.2.2. 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.



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



[Figure 10.2 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.



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

# 10.2.3. Accuracy Checks



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 measurements obtained when using the product. The product should be maintained in an optimal state to ensure reliable measurements.

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

# 10.3. Data Maintenance



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.

# 10.3.1. 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.

### 10.3.2. 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' in the user manual.

#### 10.3.3. 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.



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.



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

# Chapter 11

# **Service Parts List**

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11.3.	Monitor & Arm Parts	17
11.4.	System Parts	21
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# 11.1. Body Cover Parts

Part Category	Part Code	Part Information	Part Image
Body Cover Parts	MI61-01658C	HANGER-REAR CABLE	
Body Cover Parts	MI61-01912A	BUSH	
Body Cover Parts	MI61-03179A	ROLLER-CLUTCH- LEVER	
Body Cover Parts	MI63-01657C	COVER-CABLE FRONT	

Part Category	Part Code	Part Information	Part Image
Body Cover Parts	MI63-01658C	COVER-CABLE	
Body Cover Parts	MI63-02241A	COVER BASE- LOWER_L	
Body Cover Parts	MI63-02446A	COVER-MONITOR CABLE	
Body Cover Parts	MI63-02451A	COVER-SPEAKER FRONT	
Body Cover Parts	MI63-02452A	COVER-SPEAKER REAR	

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Part Category	Part Code	Part Information	Part Image
Body Cover Parts	MI63-02460A	COVER-SUPPORT ARM	
Body Cover Parts	MI63-02464A	COVER-SIDE-R	SAMSUNG
Body Cover Parts	MI63-02465A	COVER-SIDE-L	SAMSUNG
Body Cover Parts	MI63-02466A	COVER-REAR BODY	
Body Cover Parts	MI63-02468A	COVER-LIFT TOP	

Part Category	Part Code	Part Information	Part Image
Body Cover Parts	MI63-02470A	COVER-FOOT	
Body Cover Parts	MI64-01766B	HANDLE-CP BOTTOM	
Body Cover Parts	MI64-01770B	HANDLE-CP TOP	
Body Cover Parts	MI64-02050A	HANDLE-REAR	
Body Cover Parts	MI66-01096B	LEVER-LIFT	

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Part Category	Part Code	Part Information	Part Image
Body Cover Parts	MI68-03436A	LABEL-ID WR	<text><text><text><text></text></text></text></text>
Body Cover Parts	MI68-03443A	LABEL-SPEAKER COVER	HS50
Body Cover Parts	MI68-03447A	LABEL-MANUAL ICON	
Body Cover Parts	MI68-03448A	LABEL-CW ICON	
Body Cover Parts	MI68-03449A	LABEL-PROBE PORT 1	1

Part Category	Part Code	Part Information	Part Image
Body Cover Parts	MI68-03450A	LABEL-PROBE PORT 2	2
Body Cover Parts	MI68-03451A	LABEL-PROBE PORT 3	3
Body Cover Parts	MI68-03452A	LABEL-PROBE PORT 4	4
Body Cover Parts	MI68-03453A	LABEL-DUMMY ODD	
Body Cover Parts	MI68-03454A	LABEL-DUMMY PSA	
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Part Category	Part Code	Part Information	Part Image
Body Cover Parts	MI97-02866A	ASSY COVER-BASE LOWER-R	
Body Cover Parts	MI97-03388A	ASSY CASTER	
Body Cover Parts	MI97-03526A	ASSY COVER-TOP BODY	
Body Cover Parts	MI97-03652A	ASSY COVER-PSA 3P	
Body Cover Parts	MI97-03653A	ASSY COVER-PSA 4P	

Part Category	Part Code	Part Information	Part Image
Control Panel Parts	MI39-02065A	CBF CABLE- CP_TRACKBALL	
Control Panel Parts	MI59-01170A	TRACK BALL	
Control Panel Parts	MI61-04057A	HOLDER-PROBE S	Ħ
Control Panel Parts	MI61-04058A	HOLDER-PROBE M	
Control Panel Parts	MI61-04059A	HOLDER-PROBE L	

### **11.2. Control Panel Parts**

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Part Category	Part Code	Part Information	Part Image
Control Panel Parts	MI63-02450A	COVER-CP BOTTOM	C.S. S.L.
Control Panel Parts	MI63-02453A	COVER-CP TOP	
Control Panel Parts	MI63-02454A	COVER-TOUCH REAR	
Control Panel Parts	MI63-02459A	COVER-USB RUBBER	
Control Panel Parts	MI63-02491A	COVER-LIGHT MARKER-REF	Market/Ref
Control Panel Parts	MI63-02492A	COVER-LIGHT ANGLE	Angle
Control Panel Parts	MI63-02493A	COVER-LIGHT DEPTH	Depth

Part Category	Part Code	Part Information	Part Image
Control Panel Parts	MI63-02494A	COVER-LIGHT FOCUS	Focus
Control Panel Parts	MI63-02495A	COVER-LIGHT ZOOM	Zoom
Control Panel Parts	MI63-02516A	COVER-LIGHT EZ EXAM	Ez Exam
Control Panel Parts	MI64-01911C	KNOB-ENCORDER	
Control Panel Parts	MI64-02014A	BUTTON-ENCORDER M	
Control Panel Parts	MI64-02015A	BUTTON-ENCORDER PW	PW
Control Panel Parts	MI64-02016A	BUTTON-ENCORDER COLOR	C
Control Panel Parts	MI64-02017A	BUTTON-ENCORDER 2D	20
Control Panel Parts	MI64-02019A	BUTTON-CAP KEY 3D/4D	(JD/4D)

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Part Category	Part Code	Part Information	Part Image
Control Panel Parts	MI64-02022A	BUTTON-CAP KEY CW	Cw
Control Panel Parts	MI64-02023A	BUTTON-CAP KEY PD	PD
Control Panel Parts	MI64-02029A	BUTTON-CAP KEY FREEZE	
Control Panel Parts	MI64-02048A	BUTTON-CP RUBBER	
Control Panel Parts	MI64-02058A	BUTTON-END EXAM	
Control Panel Parts	MI64-02059A	BUTTON-SONOVIEW	
Control Panel Parts	MI64-02060A	BUTTON-REPORT	

Part Category	Part Code	Part Information	Part Image
Control Panel Parts	MI64-02071A	BUTTON-SINGLE	
Control Panel Parts	MI64-02072A	BUTTON-QAUD	
Control Panel Parts	MI64-02086A	BUTTON-U4	U4
Control Panel Parts	MI64-02087A	BUTTON-U5	<b>U</b> 5
Control Panel Parts	MI64-02088A	BUTTON-U6	UG
Control Panel Parts	MI64-02089A	BUTTON-QSCAN	Q
Control Panel Parts	MI64-02090A	BUTTON-L	
Control Panel Parts	MI64-02091A	BUTTON-R	R

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Part Category	Part Code	Part Information	Part Image
Control Panel Parts	MI64-02092A	BUTTON-U1	UI
Control Panel Parts	MI64-02093A	BUTTON-U2	U2
Control Panel Parts	MI64-02094A	BUTTON-U3	U3
Control Panel Parts	MI64-02095A	BUTTON-TRACKBALL SET L	$\bigcirc \clubsuit$
Control Panel Parts	MI64-02096A	BUTTON-TRACKBALL SET R	$\int \!$
Control Panel Parts	MI64-02097A	BUTTON-TRACKBALL POINTER	K
Control Panel Parts	MI64-02098A	BUTTON-TRACKBALL TEXT	
Control Panel Parts	MI64-02099A	BUTTON-TRACKBALL CHANGE	

Part Category	Part Code	Part Information	Part Image
Control Panel Parts	MI64-02100A	BUTTON-TRACKBALL MEASURE	
Control Panel Parts	MI64-02101A	BUTTON-TRACKBALL ERASER	
Control Panel Parts	MI67-01109A	RUBBER-CAP KEY	
Control Panel Parts	MI68-02095B	LABEL-CP DO NOT SIT	
Control Panel Parts	MI68-03421A	LABEL-CP TOP	
Control Panel Parts	MI92-02438A	ASSY BOARD-CP USB	

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Part Category	Part Code	Part Information	Part Image
Control Panel Parts	MI92-02439A	ASSY BOARD-CP	
Control Panel Parts	MI95-01304A	ASSY CAP KEY- POWER	
Control Panel Parts	MI95-01310C	ASSY CAP KEY- TOGGLE	
Control Panel Parts	MI95-01311C	ASSY CAP KEY-KNOB	
Control Panel Parts	MI95-01499A	ASSY ALPHA KEYBOARD	

Part Category	Part Code	Part Information	Part Image
Control Panel Parts	MI96-01392A	ASSY TOUCH PANEL	

### 11.3. Monitor & Arm Parts

Part Category	Part Code	Part Information	Part Image
Monitor&Arm Parts	MI63-01634B	COVER-ARM UPPER TOP ADD	
Monitor&Arm Parts	MI63-01635D	COVER-ARM UPPER TOP	
Monitor&Arm Parts	MI63-01636D	COVER-ARM UPPER BOTTOM	

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Part Category	Part Code	Part Information	Part Image
Monitor&Arm Parts	MI63-01637D	COVER-ARM LOWER TOP ADD	
Monitor&Arm Parts	MI63-01638B	COVER-ARM UPPER BACK TOP	Ε
Monitor&Arm Parts	MI63-01639B	COVER-ARM UPPER BACK BOTTOM	
Monitor&Arm Parts	MI63-01640B	COVER-ARM LOWER TOP FRONT	
Monitor&Arm Parts	MI63-01641B	COVER-ARM LOWER TOP BACK	

Part Category	Part Code	Part Information	Part Image
Monitor&Arm Parts	MI63-01642B	COVER-ARM LOWER TOP	
Monitor&Arm Parts	MI63-01643B	COVER-ARM LOWER BOTTOM	
Monitor&Arm Parts	MI63-01646C	COVER-ARM BUTTON	H
Monitor&Arm Parts	MI63-01647B	COVER-ARM BUTTON GUIDE	• 1111
Monitor&Arm Parts	MI63-01661B	COVER-ARM UPPER BOTTOM ADD	

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Part Category	Part Code	Part Information	Part Image
Monitor&Arm Parts	MI63-01662B	COVER-ARM LOWER FRONT ADD	
Monitor&Arm Parts	MI63-01981A	COVER-LINK FRONT R	
Monitor&Arm Parts	MI63-01982A	COVER-LINK FRONT L	
Monitor&Arm Parts	MI68-01977A	LABEL CAUTION	
Monitor&Arm Parts	MI68-02554A	LABEL DO NOT PUSH	

Part Category	Part Code	Part Information	Part Image
Monitor&Arm Parts	MI96-01394A	ASSY MONITOR UNIT	
Monitor&Arm Parts	MI97-03500A	ASSY ARM	

## 11.4. System Parts

Part Category	Part Code	Part Information	Part Image
System Parts	5903-005726	SSD	
System Parts	MI68-03422A	LABEL-I/O PORT	
System Parts	MI82-02355A	ASSY BOARD BE (WITHOUT PC MODULE, REAR IO BD)	

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Part Category	Part Code	Part Information	Part Image
System Parts	MI92-02454A	ASSY BOARD-BP	
System Parts	MI92-02456A	ASSY BOARD-BF	
System Parts	MI92-02457A	ASSY BOARD-REAR IO	
System Parts	MI92-02464A	ASSY BOARD-PSA 4P CW	
System Parts	MI92-02500A	ASSY BOARD-PSA 3P CW	

Part Category	Part Code	Part Information	Part Image
System Parts	MI92-02614A	ASSY BOARD-PSA 3P	
System Parts	MI92-02615A	ASSY BOARD-PSA 4P	
System Parts	MI96-01391A	ASSY POWER	
System Parts	MI96-01393A	ASSY PC MAIN BOARD-PC MODULE	
System Parts	MI96-01403A	ASSY FAN-TOP	

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Part Category	Part Code	Part Information	Part Image
System Parts	MI96-01404A	ASSY FAN-INTAKE	
System Parts	MI97-03498A	ASSY LIFT	

# 11.5. System Cable Parts

Part Category	Part Code	Part Information	Part Image
System Cable Parts	MI39-01020B	CBF CABLE	
System Cable Parts	MI39-01718A	CBF CABLE-SPEAKER	

Part Category	Part Code	Part Information	Part Image
System Cable Parts	MI39-02021A	CBF CABLE-CP_USB_B	
System Cable Parts	MI39-02022A	CBF CABLE-CP_USB_A	
System Cable Parts	MI39-02023A	CBF CABLE- MONITOR_POWER_B	
System Cable Parts	MI39-02024A	CBF CABLE- MONITOR_POWER_A	
System Cable Parts	MI39-02025A	CBF CABLE-ECG_USB	

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Part Category	Part Code	Part Information	Part Image
System Cable Parts	MI39-02028A	CBF CABLE- BOTTOM_FAN_ASSY	
System Cable Parts	MI39-02029A	CBF CABLE- BOTTOM_FAN_EXT	
System Cable Parts	MI39-02030A	CBF CABLE- BW_PRINTER_USB	5
System Cable Parts	MI39-02055A	CBF CABLE- COLOR_PRINTER_USB	
System Cable Parts	MI39-02056A	CBF CABLE- PRINTER_POWER	

Part Category	Part Code	Part Information	Part Image
System Cable Parts	MI39-02057A	CBF CABLE- SATA_POWER	
System Cable Parts	MI39-02058A	CBF CABLE-SATA	
System Cable Parts	MI39-02059A	CBF CABLE- MONITOR_HDMI_A	
System Cable Parts	MI39-02060A	CBF CABLE- TOUCH_HDMI	
System Cable Parts	MI39-02063A	CBF CABLE- CP_POWER	

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Part Category	Part Code	Part Information	Part Image
System Cable Parts	MI39-02064A	CBF CABLE- GEL_WARMER	0
System Cable Parts	MI39-02066A	CBF CABLE- MONITOR_HDMI_B	
System Cable Parts	MI39-02067A	CBF CABLE-SOUND	
System Cable Parts	MI39-02071A	CBF HARNESS- ALPHAKEY	