Technical Publication

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Rev. 2

$C\epsilon_{0197}$

Versana Essential User Guide

R1.x.x

Operating Documentation

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Regulatory Requirement

This product complies with regulatory requirements of the following European Directive 93/42/EEC concerning medical devices.

CE 0197

First CE Marked in 2017.

This manual is a reference for the Versana Essential ultrasound system. It applies to all revisions of the R1.x.x software for the Versana Essential ultrasound system.

Revision History

Reason for Change

REV	DATE (YYYY/MM/DD)	REASON FOR CHANGE
Rev. 1	2017/07/18	Initial release
Rev. 2	2017/09/05	Update rating plate and software features

List of Effective Pages

CHAPTER NUMBER	REVISION NUMBER	CHAPTER NUMBER	REVISION NUMBER
Title Page	Rev. 2	Chapter 2	Rev. 2
Revision History	Rev. 2	Chapter 3	Rev. 2
Regulatory Requirements	Rev. 2	Chapter 4	Rev. 2
Chapter 1	Rev. 2	Chapter 5	Rev. 2

Please verify that you are using the latest revision of this document. Information pertaining to this document is maintained on MyWorkshop/ePDM (GE Electronic Product Data Management). If you need to know the latest revision, contact your distributor, local GE Sales Representative or in the USA call the GE Ultrasound Clinical Answer Center at 1 800 682 5327 or 1 262 524 5698.

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Regulatory Requirements

Conformance Standards

The following classifications are in accordance with the IEC/EN 60601-1:6.8.1:

- According to 93/42/EEC Medical Device Directive, this is Class IIa Medical Device.
- According to IEC/EN 60601-1,
  - Equipment is Class I, Type BF Applied Parts.
- According to CISPR 11,
  - Equipment is Group 1, Class A ISM Equipment.
  - Continuous Operation.
- According to IEC 60529,
  - The footswitch rate IPx8 is suitable for use in surgical rooms.
  - Probe head (immersible portion) and cable are IPX7.

    Probe connector is not waterproof.

This product complies with the regulatory requirement of the following:

- Council Directive 93/42/EEC concerning medical devices: the CE label affixed to the product testifies compliance to the Directive.

  The location of the CE marking is shown in the Safety chapter of this manual.

  Authorized EU Representative

EC	REP

European registered place of business:

GE Medical Systems SCS

283 rue de la Minière 78530 BUC, France

Conformance Standards (continued)

- International Electrotechnical Commission (IEC).
  - IEC/EN 60601-1 Medical Electrical Equipment, Part 1 General Requirements for Safety.
  - IEC/EN 60601-1-2 Electromagnetic compatibility - Requirements and tests.
  - IEC/EN 62366(Usability), EN 1041 (Information supplied with medical devices).
  - IEC/EN 60601-2-37 Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment.
- International Organization of Standards (ISO)
  - ISO 10993-1 Biological evaluation of medical devices.
- ANSI/AAMI ES60601-1 Medical Electrical Equipment, Part 1 General Requirements for Safety.
- Canadian Standards Association (CSA).
- CSA 22.2, 601.1 Medical Electrical Equipment, Part 1 General Requirements for Safety.
- NEMA/AIUM Acoustic Output Display Standard (NEMA UD3).
- Medical Device Good Manufacturing Practice Manual issued by the FDA (Food and Drug Administration, Department of Health, USA).

Conformance Standards (continued)

Certifications

- General Electric Medical Systems is ISO 9001 and ISO 13485 certified.

Original Documentation

- The original document was written in English.

Importer Information

- Turkey

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Table of Contents

Table of Contents
Chapter 1 — Getting Started
Overview

Moving the system

System Start-Up

Probes

Beginning an Exam

Chapter 2 — Performing an Exam

Optimizing the Image

Scan Assistant

SonoBiometry (AFB)

Measurement and Analysis

Chapter 3 — After The Exam Is Over

Preset

Electronic Documentation

System Care and Maintenance

Quality Assurance

Contact Information

Chapter 4 — Safety

Owner Responsibility

Safety Precautions

Chapter 5 — Probes and Biopsy

Probe Overview

Chapter 1

Getting Started

Console Overview, Moving the System, System Start-up, Probes and Beginning an Exam

Overview

Attention

This manual is for Versana Essential.

This manual contains information to operate the system safely. Advanced equipment training may be provided by a factory trained Applications Specialist for the agreed-upon time period.

Read and understand all instructions in this manual and Basic User Manual (English) before attempting to use the Versana Essential system.

Keep this manual with the equipment at all times. Periodically review the procedures for operation and safety precautions.

NOTE: *The Online Help offers a quick way for the user to access the manual. When there are difference between Online Help and Basic User Manual/User Guide, please refer to Basic User Manual/User Guide for the only right version.*

Disregarding information on safety is considered abnormal use.

Not all features, products, probes or peripherals described in this document may be available or cleared for sale in all markets. Please contact your local GE Ultrasound representative to get the latest information.

NOTE: *Please note that orders are based on the individually agreed upon specifications and may not contain all features listed in this manual.*

NOTE: *All references to standards / regulations and their revisions are valid for the time of publication of the user manual.*

NOTE: *"Whiz" is equal to "Whizz" in all user manuals, service manuals and user interface for Versana Essential system.*

⚠ CAUTION   Safety instructions must be reviewed before operating the unit.

Attention (continued)

The Versana Essential manuals are written for users who are familiar with basic ultrasound principles and techniques. They do not include sonographic training or detailed clinical procedures.

NOTE: *The system color varies.*

NOTE: *The electronic documentation CD includes English and all translations.*

NOTE: *The screen graphics in this manual are only for illustrational purposes. Actual screen output may differ with the different software version.*

Principles of Operation

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

These echo signals are highly amplified and processed by several analog and digital circuits having filters with many frequency and time response options, transforming the high-frequency electrical signals into a series of digital image signals which are stored in memory. Once in memory, the image can be displayed in real-time on the image monitor. All signal transmission, reception and processing characteristics are controlled by the main computer. By selection from the system control panel, the user can alter the characteristics and features of the system, allowing a wide range of uses, from obstetrics to peripheral vascular examinations.

Transducers are accurate, solid-state devices, providing multiple image formats. The digital design and use of solid-state components provides highly stable and consistent imaging performance with minimal required maintenance. Sophisticated design with computer control offers a system with extensive features and functions which is user-friendly and easy to use.

Contraindication

The Versana Essential ultrasound system is not intended for ophthalmic use or any use causing the acoustic beam to pass through the eye.

Prescription Device

CAUTION: United States law restricts this device to sale or use by, or on the order of a physician.

Intended Use

The Versana Essential is intended for use by a qualified physician for ultrasound evaluation.

Indications for Use

The Versana Essential are general purposed ultrasound imaging and analysis systems providing digital acquisition, processing and display capability and clinical applications including: Abdominal, Obstetrical, Gynecological, Small parts, Vascular/Peripheral Vascular, Adult Cephalic, Pediatric, Musculoskeletal, Transcranial, Neonatal Cephalic, Transvaginal, Urological and Cardiac, Transrectal, imaging guidance of interventional procedure and biopsy.

Frequency of use   Daily (Typically 8 hours)

Operator profile
- Qualified and trained physicians or sonographers with at least basic ultrasound knowledge.
- The operator must have read and understood the user manual.

NOTE: Only qualified physicians or sonographers should perform ultrasound scanning on human subjects for medical diagnostic reasons. Request training, if needed.

Clinical applications

Specific clinical applications and exam types include:

- Abdominal
- Obstetrical
- Gynecological
- Small parts
- Vascular/Peripheral Vascular
- Transcranial
- Pediatric/Neonatal
- Musculoskeletal
- Urological
- Cardiac
- Transvaginal/Transrectal
- Biopsy

Image Acquisition is for diagnostic purposes including measurements on acquired image.

⚠ CAUTION This machine should be used in compliance with law. Some jurisdictions restrict certain uses, such as gender determination.

Site Requirements

Introduction

Do not attempt to install the unit alone. General Electric, Affiliate, or Distributor Field Engineers and Application Specialists will install and setup the system. See 'Contact Information' on *page 3-62 for more information.*

The Versana Essential does not contain any operator serviceable internal components. Ensure that unauthorized personnel do not tamper with the unit.

Perform regular preventive maintenance. See 'System Care and Maintenance' on *page 3-30 for more information.*

Maintain a clean environment. Turn off, and if possible, disconnect the system before cleaning the unit. See 'Cleaning the system' on *page 3-32*.

Never set liquids on the unit to ensure that liquid does not drip into the control panel or unit.

Before the system arrives

The ultrasound unit must operate within the proper environment and in accordance with the requirements described in this section. Before using the system, ensure that the requirements are met.

Power Requirements

- A separate power outlet with a 6.5 amp circuit breaker.
- Frequency: 50/60 Hz
- 100V - 240V AC (+/-10%)

Electromagnetic interferences

This medical equipment is approved, in terms of the prevention of radio wave interference, to be used in hospitals, clinics and other institutions which are environmentally qualified. The use of this equipment in an inappropriate environment may cause some electronic interference to radios and televisions around the equipment.

Ensure that the following is provided for the new system:

- Take precautions to ensure that the console is protected from electromagnetic interference.

  Precautions include:
  - Operate the console at least 15 feet away from motors, typewriters, elevators, and other sources of strong electromagnetic radiation.
  - Operation in an enclosed area (wood, plaster or concrete walls, floors and ceilings) helps prevent electromagnetic interference.
  - Special shielding may be required if the console is to be operated in the vicinity of radio broadcast equipment.

⚠ CAUTION — Do not operate the system in the vicinity of a heat source, of strong electric or magnetic fields (close to a transformer), or near instruments generating high-frequency signals, such as HF surgery. These can affect the ultrasound images adversely.

Environmental Requirements

The system should be operated, stored, or transported within the parameters outlined below. Either its operational environment must be constantly maintained or the unit must be turned off.

NOTE: *You may get an overheating message with regard to fan speed. Ensure adequate system/room ventilation.*

Table 1-1:   System Environmental Requirements

	Operational (with probe)	**Storage (Versana Essential)**	**Transport (Versana Essential)**
Temperature	10 - 40° C 50 - 104° F	-5 - 50° C 23 - 122° F	-5 - 50° C 23 - 122° F
Humidity	30 - 80% non-condensing	10 - 90% non-condensing	10 - 90% non-condensing
Pressure	700 - 1060hPa	700 - 1060hPa	700 - 1060hPa

CAUTION   The system cannot be used in OXYGEN rich environment.

CAUTION   Ensure that the probe face temperature does not exceed the normal operation temperature range.

Operating Environment

Ensure that there is sufficient air flow around the ultrasound unit when installed in a fixed location.

⚠ CAUTION   Do not cover the ventilation holes of the Versana Essential.

⚠ CAUTION   The Versana Essential system and probe connector are not waterproof. Do not expose the device to water or any kind of liquid.

Console graphics

The following are illustrations of the console:

Figure 1-1.   Versana Essential System - an example

1. Monitor
2. Speaker
3. Control Panel
4. Probe Connector
5. Wheel
6. USB Port

7. Probe Holder
8. Printer Box
9. Rear Panel
10. Rear Handle
11. Gel Bottle Holder
12. Body Left and Right Cover

NOTE: USB Port(6) is only for memory disk, not available for other peripheral.

Peripheral/Accessory Connection

Peripheral/Accessory Connector Panel

Versana Essential peripherals and accessories can be properly connected using the rear connector panel.

⚠ CAUTION   For compatibility reasons, use only GE approved probes, peripherals or accessories.

DO NOT connect any probes, peripherals or accessories without approval by GE.

⚠ CAUTION   The connection of equipment or transmission networks other than as specified in these instructions can result in electric shock hazard. Alternate connections will require verification of compatibility and conformity to IEC/EN 60601-1 by the installer.

⚠ CAUTION   DO NOT touch the patient and any of the connectors on the ultrasound unit simultaneously, including ultrasound probe connectors.

DO NOT touch the conducting parts of the USB, Ethernet, Video, Audio cables when connecting equipment to the unit.

⚠ CAUTION   When using peripheral device, observe all warnings and cautions given in Peripheral manufacture's manuals.

Peripheral/Accessory Connector Panel (continued)

Figure 1-2.   Peripheral/Accessory Connector Panel

1.	S-Video	S-Video Out
2.	HDMI port	For video port
3.	VGA	VGA Video Out
4.	Ethernet	100MBase-T for net connectivity
5.	Dual USB port	USB for use
6.	Composite Out	Composited Video Out
7.	AC Inlet	100-240V
8.	Circuit breaker	Circuit breaker
9.	Diagnostic LED 1	For diagnostic
10.	Diagnostic LED 2	For diagnostic
11.	Diagnostic LED 3	For diagnostic

Wired Footswitch (Option)

You can attach the Footswitch to the system by connecting it to one of the USB port on the rear of the system.

⚠ **CAUTION**   To avoid damage of the cable, keep the cable away from the wheels. Disconnect the Footswitch before moving the system.

Figure 1-3.   Footswitch MKF 2-MED USB GP26

Figure 1-4.   1 Pedal Type Footswitch

You can configure the function of Footswitch from the *Utility-> Application-> Settings-> Footswitch*.

⚠ **CAUTION**   When using the Footswitch, DO NOT hold down the footswitch pedal. Press and release the Footswitch pedal. Pushing and holding down the pedal behaves the same way as pushing and holding down a key on the keyboard.

Control Panel Map

Controls are grouped together by function for ease of use. See the callout for this figure.

Figure 1-5.   Console panel map

1. Power On/Off
2. Menu keys
3. Up/Down keys
4. TGC
5. User Configurable keys
6. Patient key
7. Probe key
8. Report key
9. End Exam key
10. Whizz key (Auto Optimize)
11.   M Mode/M Mode Gain

12. CW (Option)
13. PW Mode/PW Gain
14. PDI
15. CF Mode/CF Gain
16. B Mode/B Mode Gain
17. Depth
18. Ellipse/Zoom key
19. Scan Coach
20. Left/Right key
21. Print key
22. Freeze key

23. Store key
24. Cursor key
25. Clear key
26. Measure key
27. Body Pattern key
28. Set key
29. Alphanumeric Keyboard
30. Trackball
31. CHI key
32. Comment key
33. Utility

NOTE: The factory default settings can be modified in Utility ->System -> User Configurable Key.

Alphanumeric Keyboard
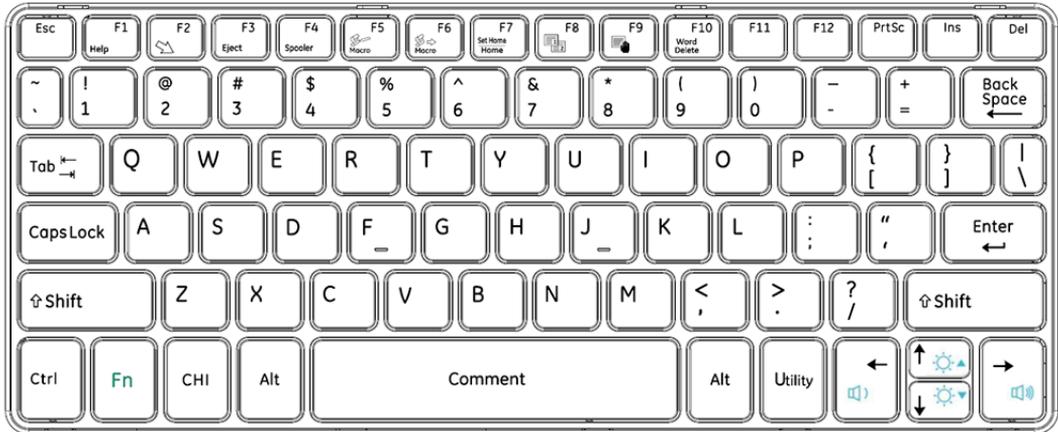
Figure 1-6.   Alphanumeric Keyboard

Alphanumeric Keyboard (continued)

The standard alpha-numeric keyboard has some special functions.

Esc	Exit current display screen.
Help (F1 Key)	Access Online help / user manual.
Arrow (F2 Key)	Annotation arrow.
Eject (F3 Key)	Eject media.
Spooler (F4 Key)	Activates DICOM Job Spooler screen.
Create a Fast Key (F5 Key)	Creates a Fast Key.
Play a Fast Key (F6 Key)	Plays a Fast Key.
Home/Set Home (F7 Key)	Move annotation cursor to home position; shift+key to set current annotation cursor position as the new home position.
Text1/Text2 (F8 Key)	Switch between user text annotation overlays.
Grab Last (F9 Key)	Activate the last selected data for edit.
Word Delete (F10 Key)	Erase word associated with comment cursor.
Fn + Left/Right Keys	Adjust audio volume.
Fn + Up/Down Arrow Keys	Adjust brightness.
Alt+1 or Alt+2	Place a marker in the log.
	If you encounter a problem and cannot collect the logs immediately:
Alt+D	Collect the logs.
	Once the logs are collected, the engineering team would be able to see the marker you added which will help engineering to troubleshoot the problem.

Top/Sub Menu

The Top/Sub Menu contains exam function and mode/function specific controls.

Figure 1-7.   Top/Sub Menu controls

The Top/Sub Menu contains adjustable knobs associated with it. The adjustable knobs are used to adjust the selected function. For example, to increase or decrease Frequency turn the knob clockwise or anticlockwise; the paddle switches are used to access and adjust the menu. The functionality of these controls change, depending upon the currently displayed menu.

The below figure displays five Primary menu functions at the bottom of the image. Per page only five primary menu functions are displayed. To navigate and view the 15 primary menu functions use the Up/Down key to move to the next/previous page.
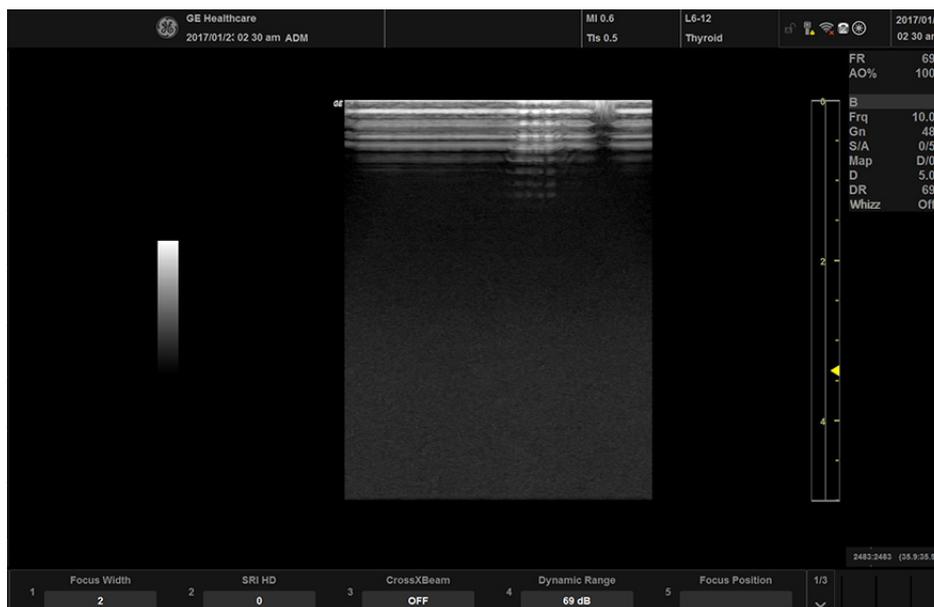
Figure 1-8.   Primary Menu

NOTE: *To perform functions on the primary menu when **Whizz** is on, only three functions on the primary menu are available for selection.*

Monitor Display
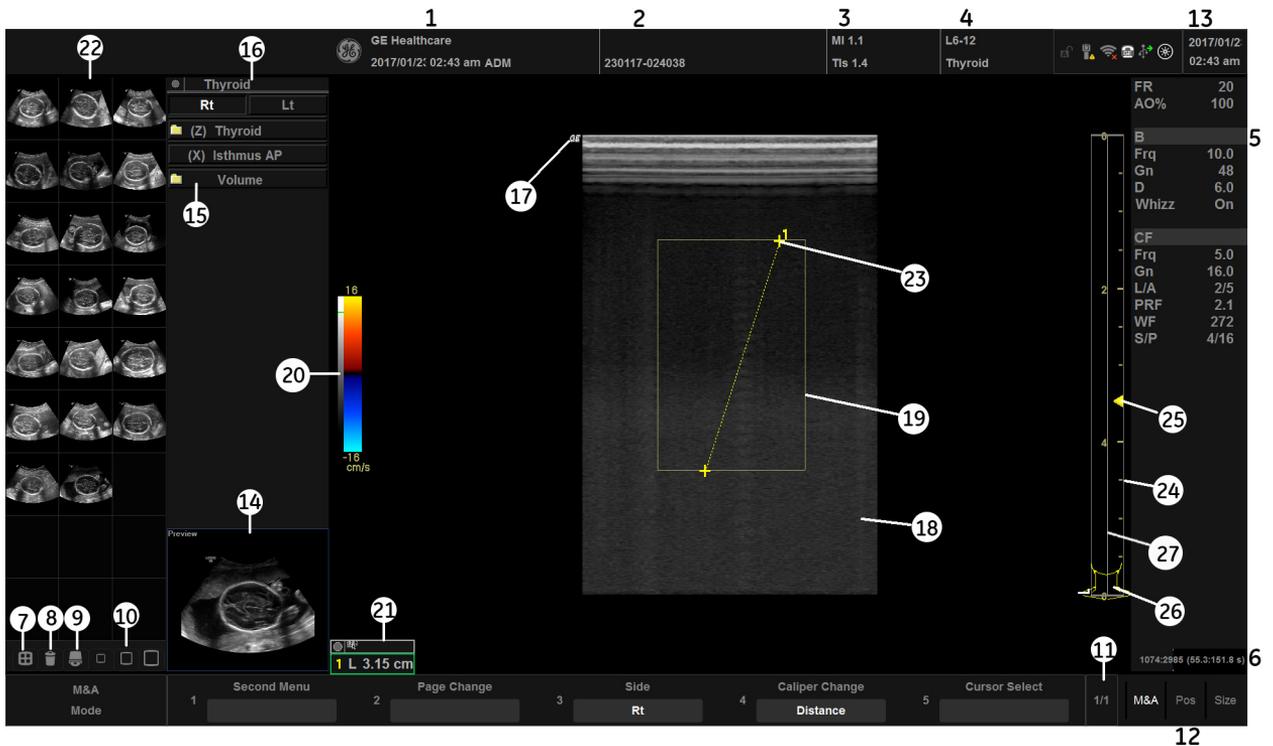
Figure 1-9.   Monitor Display Tour

1. Institution/Hospital Name, Date, Time, Operator Identification.
2. Patient Name, Patient Identification.
3. Power Output Readout.
4. Probe Identifier. Exam Preset.
5. Imaging Parameters by Mode.
6. Cine Gauge.
7. Active Images screen.
8. Delete Image.
9. Save As Menu.
10. Three types of Images Clipboard.
11. Primary Menu Page Indication.
12. Trackball Functionality Status.
13. Current date and time, Caps Lock: (lit when on), network connection indicator, system messages display, InSite status, InSite controls.
14. Image Preview.
15. Measurement Summary Window.
16. Exam Category.
17. Probe Orientation Marker.
18. Image.
19. Region of interest.
20. Gray/Color Bar.
21. Measurement Results Window.
22. Image Clipboard.
23. Measurement Calipers.
24. Depth Scale.
25. Focal Zone Indicator.
26. Body Pattern.
27. TGC.

To adjust the Monitor Position

The monitor can be swiveled and tilted.

Grab the bottom of the monitor when you adjust the position of the monitor.

Figure 1-10.   Grab the bottom of the monitor

⚠ CAUTION	When flipping up the monitor from the flip down status, you can grab the upper corner of the monitor.

⚠ CAUTION	To avoid injury or damage, make sure nothing is within the range of motion before moving the monitor. This includes both objects and people.

Adjust Monitor by Software

1. Press **Cursor** key on the control panel. Move the trackball to position the cursor over the adjustment icon, then press **Set** to display the setting menu.

Figure 1-11.   Setting Menu Icon

2. Follow the procedure below to adjust the Color Temperature, Contrast, Brightness and LCD:

   • To adjust the color temperature: press **Standard**, **Brown,** or **Blue** to choose the color temperature. The chosen color temperature displays in the **Color Temp** area.
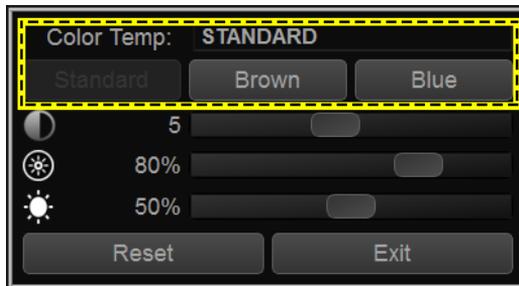
Figure 1-12.   Color Temperature

   • To adjust the Contrast: Press **Set** to choose the adjustment button, hold down the **Set** key and move the trackball to move the adjustment button. Move the adjustment button to the left to decrease the contrast or move the adjustment button to the right to increase the contrast.
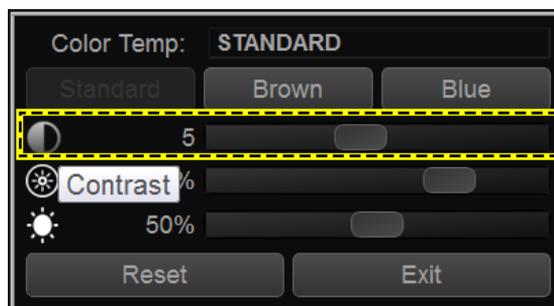
Figure 1-13.   Contrast

Adjust Monitor by Software (continued)

- To adjust the Brightness: Press **Set** to choose the adjustment button, hold down the **Set** key and move the trackball to move the adjustment button. Move the adjustment button to the left to decrease the brightness or move the adjustment button to the right to increase the brightness.
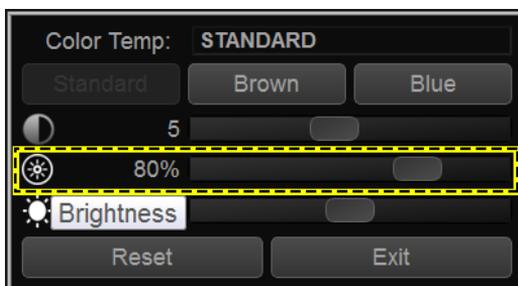
Figure 1-14. Brightness

- To adjust the LCD (at the bottom of the Monitor): Press **Set** to choose the adjustment button, hold down the **Set** key and move the trackball to move the adjustment button. Move the adjustment button to the left to decrease the LCD brightness or move the adjustment button to the right to increase the LCD brightness.
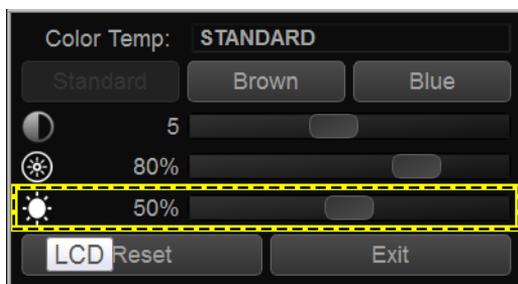
Figure 1-15. LCD Brightness

3. Press **Reset** to return to the default setting; Press Exit to exit the setting menu.

NOTE: *Press Reset button and the three color temperature settings will return to the default settings.*

Moving the system

Before moving the system

When moving or transporting the system, follow the precautions below to ensure the maximum safety for personnel, the system, and other equipment.

⚠ CAUTION When the system is not in use AND/OR before moving/transporting the system, make sure the monitor is flipped down to prevent system damage.

⚠ CAUTION **DO NOT** place probes or the footswitch into the side tray when moving/transporting the system. It is not storage space for probes, footswitch and any peripheral devices.

⚠ CAUTION This equipment is not to be used during transportation (e.g. ambulance cars, aircraft).

⚠ CAUTION Handle carefully. A drop of more than 5 cm can cause mechanical damages.

Before moving the system (continued)

1. Press the **Power On/Off** switch to power off the system. See 'Power Off' on *page 1-38 for more information.*

2. Unplug the power cord.

3. Wind the power cable around the rear handle.

NOTE: *To prevent damage to the Power Cord, **DO NOT** pull excessively on the cord or make sharp bends while wrapping.*

4. All cables from off-board peripheral devices and the ethernet connection must be disconnected from the console.

5. Ensure that no loose items are left on the console.

6. Connect all probes to be used while off site. Ensure that probe cables are out of the way from the wheels and not protruding beyond the console. Use the probe management hooks located below the Control Panel to further secure the probe cables.

7. Store all other probes in their original cases or in soft cloth or foam to prevent damage.

8. Store sufficient gel and other essential accessories in the provided space.

9. Flip down the monitor.

10. Disconnect the footswitch from the console.

11. Unlock the wheels.

Wheels

Examine the wheels frequently for any obvious defects that could cause them to break or bind.

All the four wheels have independent brake pedals.

Figure 1-16.   Wheel lock

1.   Locked: Press on the brakes to block the caster wheels.
2.   Unlocked: Release the brakes to unlock the caster wheels.

Moving Hazard
Never move the system with locked wheels.

Wheels (continued)

⚠ CAUTION   When two or more people are releasing the wheel controls with the front and rear wheels, take extra precaution to prevent unexpected movement which could result in possible toe injuries.

⚠ CAUTION   If you use/park the system on a slippery slope, you MUST use the brakes on the wheel.

Moving the System

1. Always use the handle to move the system.

    Moving the system, no incline   Moving the system on incline

2. Take extra care when moving the system long distances and on inclines. Ask for help if necessary.

    Avoid ramps that are steeper than ten degrees to avoid tipping over the system. Utilize additional care and personnel when moving on a steep incline (>5 degrees) or loading the system into a vehicle for transport.

NOTE: *Wheel chair ramps are usually less than five degrees.*

⚠ **CAUTION**   DO NOT attempt to move the console using any cables or fixtures, such as the probe connectors.

3. Use the foot brake (pedal), located on the bottom of the system in the front, when necessary.
4. Do not let the system strike walls or door frames.
5. Use extra care when crossing door or elevator thresholds.
6. Once the destination is reached, lock the wheels.

⚠ **CAUTION**   The system weighs less than 40 kg (88 lbs.), without any probes or peripherals. To avoid possible injury and equipment damage:

•   Be sure the pathway is clear.

•   Limit movement to a slow careful walk.

•   Use two or more persons to move the system on inclines or long distances.

Moving the system (continued)

 CAUTION   DO NOT attempt to move the system with the monitor by pulling cables or belts placed around the monitor and/or monitor arm.

   Do not put your whole body weight on the foot-rest holder.

Transporting the System

Use extra care when transporting the system using vehicles. See 'Before moving the system' on *page 1-24 for more information.* In addition to the instructions used when moving the system, also perform the following:

1. Before transporting, place the system in its special storage case.
2. Ensure that the system is firmly secured while inside the vehicle.
3. Secure the system with straps or as directed otherwise to prevent motion during transport.

⚠ CAUTION   Remove all peripherals from the console before transportation.

Load the system onto a vehicle

1. Only use vehicles that are designed for transport of Versana Essential system.
2. Load and unload the system to a vehicle parked on a level surface.
3. Ensure that the transporting vehicles can handle the weight of the system plus the passengers.
4. Ensure that the load capacity of the lift is capable of handling the weight of the system.
5. Ensure that the lift is in good working order.
6. Secure the system while it is on the lift so that it cannot roll. Use either wood chocks, restraining straps, or other similar types of constraints. Do not attempt to hold it in place by hand.
7. Employ two or three persons to load and unload safely from a vehicle.
8. Load the unit aboard the vehicle carefully and over its center of gravity. Keep the unit still and upright.

NOTE: *Do not lay the unit down on its side.*

9. Ensure that the system is firmly secured inside the vehicle.

NOTE: *DO NOT restrain the Versana Essential at the monitor or the monitor neck using a belt.*

10. Prevent vibration damage by driving cautiously. Avoid unpaved roads, excessive speeds, and erratic stops or starts.

System Start-Up

Connecting the System

To connect the system to the electrical supply:

1. Ensure that the wall outlet is of the appropriate type.
2. Ensure that the power switch is turned off.
3. Unwrap the power cable. Make sure to allow sufficient slack in the cable so that the plug is not pulled out of the wall if the system is moved slightly.

⚠ CAUTION   Use the appropriate power cord provided by or designated by GE.

4. Attach the power plug to the system, and then install the power cable bracket (a). Ensure the power plug is placed securely in power cable bracket.

Figure 1-17.   Circuit Breaker and Power Plug

5. Push the power plug securely into the wall outlet.

NOTE: *Do not use an extension cord or adapter plug.*

6. Switch ON the Circuit Breaker (b).The On/Off button on the control panel illuminates blue, indicating that the system is in standby mode.

Connecting the System (continued)

⚠ WARNING	To avoid risk of fire, the system power must be supplied from a separate, properly rated outlet. See 'Before moving the system' on *page 1-24 for more information.*

Under no circumstances should the AC power plug be altered, changed, or adapted to a configuration rated less than specified. Never use an extension cord or adapter plug.

To help assure grounding reliability, connect to a "hospital grade" or "hospital only" grounded power outlet. |
| ⚠ CAUTION | To ensure that the power cable does not disconnect during system use.

If the system is accidentally unplugged, data may be lost. |
| ⚠ WARNING | Failure to provide an adequate earth circuit can cause electrical shock, resulting in serious injury.

Connection of additional protective earth conductors or potential equalization conductors is not necessary in most cases and is only recommended for situations involving multiple equipment in a high-risk patient environment to provide assurance that all equipment is at the same potential and operates within acceptable leakage current limits. An example of a high-risk patient would be a special procedure where the patient has an accessible conductive path to the heart such as exposed cardiac pacing leads. |
| ⚠ CAUTION | Only connect Versana Essential and mains-operated accessories to the appropriate wall outlet. DO NOT connect them to a single or multiple socket outlets, an extension cord, power strip or an adapter plug. |
| ⚠ WARNING | To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth. |

Connecting the System (continued)
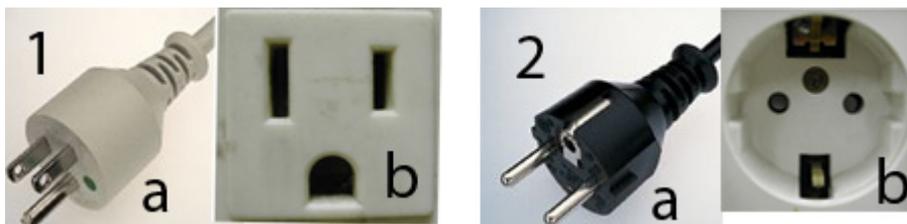
Figure 1-18.   Example Plug and Outlet Configurations

1. 100-120 VAC, 10A

    Plug and Outlet Configuration

2. 220-240 VAC, 10A

    Plug and Outlet Configuration

NOTE: *Country-specific power cords are currently available for China, India, Argentina, Europe, Japan, Switzerland, the United Kingdom, the United States, Israel and Australia.*

Voltage level check

Check the rating label on the rear side of the system. Check the voltage range indicated on the label.

Connecting to the electrical outlet

WARNING   POWER OUTAGE MAY OCCUR. The ultrasound unit requires a dedicated single branch circuit. To avoid circuit overload and possible loss of critical care equipment, make sure you DO NOT have other equipment operating on the same circuit.

CAUTION   Disconnect the plug from the wall outlet in case an emergency should occur. Ensure easy access to the power outlet.

Circuit breaker

The Circuit Breaker is located at the rear panel of the system. On supplies main power to all internal systems. Off removes main power from all internal systems. The circuit breaker automatically shuts off power to the system in case of a power overload.

If a power overload occurs:

1. Turn off all peripheral devices.
2. Reactivate the Circuit Breaker switch.
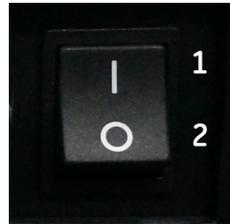
Figure 1-19.   Circuit Breaker (located on the rear panel)

The Circuit Breaker switch should stay in the **On** position; **DO NOT** hold the switch in the **On** position. If the Circuit Breaker switch remains **On**, follow the Power On procedure.

1. On position
2. Off position

NOTE: *If the Circuit Breaker switch does **not** remain in the **On** position or trips again:*

1. Disconnect the Power Cable.
2. Call Service immediately.

DO NOT attempt to use the system.

Power On

ᶜ ⚠ CAUTION	Press the ***Power On/Off*** switch to turn the power on. The circuit breaker must also be in the on position. For circuit breaker location, See 'Circuit breaker' on *page 1-35 for more information.*

After the circuit breaker is on, the LED light at the bottom of the monitor is lit and the Power On/Off switch illumination turns to blue.

After a successful boot-up process, the Power On/Off switch illumination turns from blue to green, the keyboard backlight is lit.

Login

Personal IDs and associated passwords can be preset on the Versana Essential.

If the User Auto Logon preset is blank, you are prompted to login.
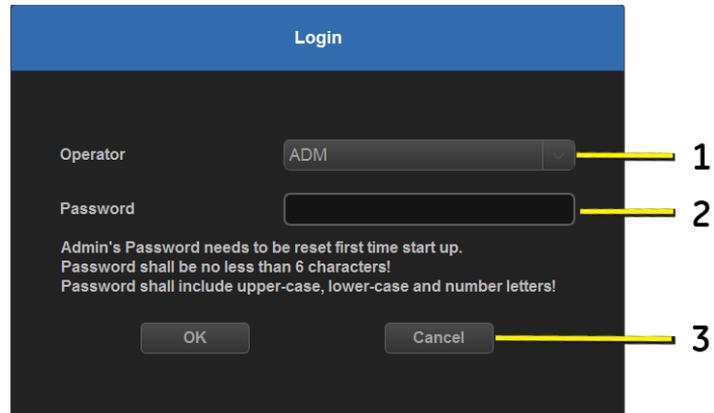
Figure 1-20. Operator Login Window

1. **Operator**: Select the Operator.
2. **Password**: Enter Operator's password (optional).
3. Select type of Logon or Cancel.

    • **OK**: Standard logon
    • **Cancel**: Cancel logon.

NOTE: *When you login as administrator for the first time you are prompted to set a password.*

NOTE: *A valid password must be at least 6 characters. A password must contain at least 1 upper-case, 1 lower-case and 1 number.*

Power Off

To power off the system:

1. When you shutdown the system, enter the scan screen and lightly press the **Power On/Off** switch at the front of the system once. The System-Exit window is displayed.

NOTE: *DO NOT press and hold down the Power On/Off switch to shutdown the system.*

2. Using the Trackball, select Shutdown.

   The shutdown process takes a few seconds and is completed when the Power On/Off switch illumination turns from green to blue.

NOTE: *DO NOT select Exit for Shutdown. Exit is only available to Service representative.*

NOTE: *If the system has not fully shut down in 60 seconds in the power-off sequence, press and hold down the On/Off switch until the system shuts down.*

3. Disconnect the probes.

   Clean or disinfect all probes as necessary. Store them in their shipping cases or another appropriate probe storage system to avoid damage.

⚠ CAUTION   **DO NOT** turn off the circuit breaker before the monitor display turns off.

Data may be lost or system software damaged if the circuit breaker is turned off before the system shuts down.

4. Disconnect the power plug from the power outlet.

Crash Recovery Instructions

In cases where the system detects an internal error, the system may reboot on its own. If this happens, the system automatically returns to the start-up screens. All images and measurements, except for generic reports, are preserved in the system.

The system automatically ends the current exam and permanently store all the images and measurements. When the system reboots, check that all images and measurements have been preserved in the system. Then, simply hold down the power switch to initiate a normal power down sequence.

NOTE: *If the image is not updated properly when the system is up, shut down the system again.*

NOTE: *Generic reports are not saved if the system crashes before you save it.*

WARNING   The system crash may cause the internal HDD corruption. Avoid using the internal HDD as a permanent storage device. Backup data on a regular basis.

Probes

Connecting the Probe

Only use approved probes.

⚠ CAUTION   Inspect the probe before and after each use for damage or degradation to the housing, strain relief, lens, seal, cable and connector. DO NOT use a transducer which appears damaged until functional and safe performance is verified. A thorough inspection should be conducted during the cleaning process.

⚠ CAUTION   Remove any dust or foam rests from the probe pins.

⚠ CAUTION   Fault conditions can result in electric shock hazard. Do not touch the surface of probe connectors which are exposed when the probe is removed. DO NOT touch the patient when connecting or disconnecting a probe.

Connecting the Probe (continued)

Probes can be connected at any time, regardless of whether the console is powered on or off.

To connect a probe:

1. Place the probe's carrying case on a stable surface and open the case.
2. Carefully remove the probe and unwrap the probe cord.
3. Put the probe in the probe holder.

CAUTION

DO NOT allow the probe head to hang free. Impact to the probe head could result in irreparable damage.

4. Hold the probe connector horizontally with the cable pointing upward.
5. Slide the connector lock to the left (unlocked position).
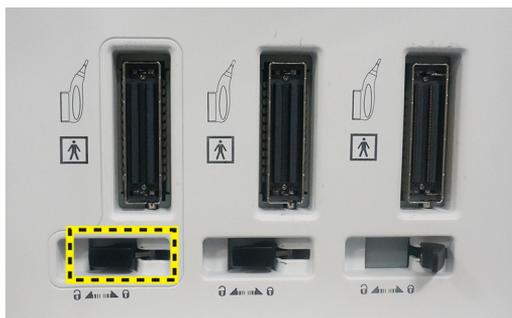
Figure 1-21.   Unlocked position

Connecting the Probe (continued)

6. Insert the connector into the probe port and slide the connector lock to the right position to lock the probe connector.
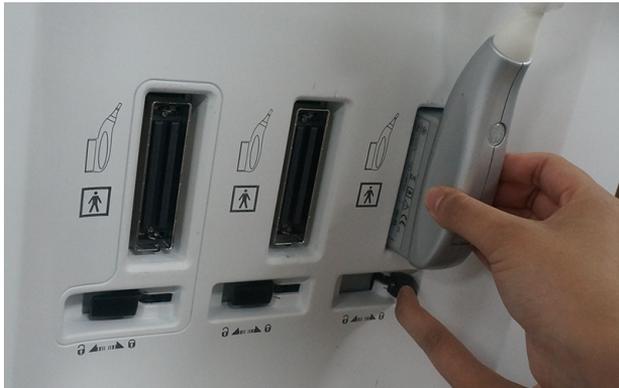
Figure 1-22.   Lock the probe connection

7. Wrap the probe cables around the probe cable hooks under the control panel. Ensure the probe cables are wrapped properly, not extended beyond sides of console.

Figure 1-23.   Handle probe cable

Cable Handling

Take the following precautions with probe cables:

- Keep free from wheels.
- Do not bend the cable acutely.
- Avoid crossing cables between probes.

Activating/Deactivating the Probe

To activate the probe, select the appropriate probe from the probe indicators in Probe/Preset screen.

To deactivate the probe, select another probe or press **Freeze** key to enter into freeze mode.

The probe's default settings for the mode and selected exam are used automatically.

⚠ CAUTION   Make sure that the probe and application names displayed on the screen correspond to the actual probe and application selection.

Disconnecting the Probe

Probes can be disconnected at any time. However, the probe should not be active when disconnecting the probe.

1. Deactivate the probe.
2. Slide the connector lock to the left position to unlock the probe.
3. Pull the probe connector straight out of the probe port carefully.
4. Ensure the cable is free.
5. Be sure that the probe head is clean before placing the probe in its storage box.

Beginning an Exam

Patient Screen
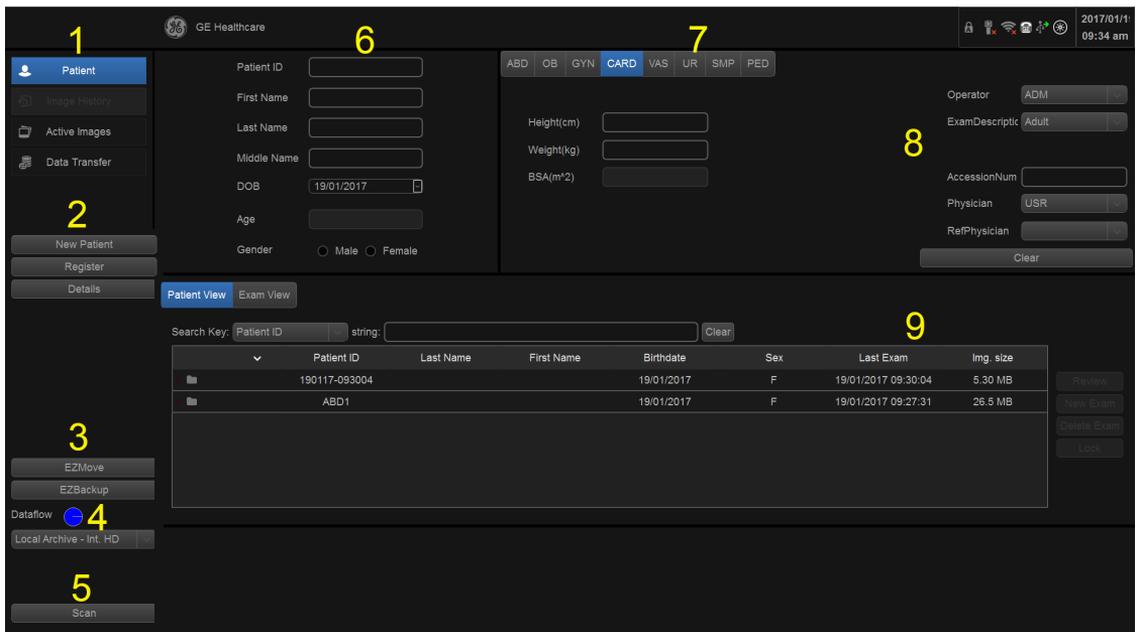
Figure 1-24.   Patient Screen

1.   Image Management
2.   Function Selection
3.   EZBackup/EZMove
4.   Dataflow Selection
5.   Scan
6.   Patient Information
7.   Category Selection
8.   Exam Information
9.   Patient View/Exam View

Scanning a New Patient

| ⚠ WARNING | Imaging functions may be lost without warning. Develop emergency procedures to prepare for such an occurrence. |

| ⚠ WARNING | Ensure you have selected a workflow. If No Archive is selected, no patient data is saved. The Workflow will display as below: |

Workflow 🚫

No Archive
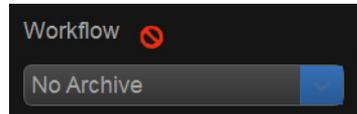
| ⚠ CAUTION | To avoid patient identification errors, always verify the identification with the patient. Make sure the correct patient identification appears on all screens and hard copy prints. |

| ⚠ WARNING | Always use the minimum power required to obtain acceptable images in accordance with applicable guidelines and policies. |

| ⚠ WARNING | Always use the system on a flat surface in the patient environment. |

| ⚠ WARNING | Ensure that the hands of the patient are away from the system during the exam.

The position of the operator and the patient vary by scan region.

In most cases, the operator sits/stands straight in front of the operator console and the patient lies on the bed on the right (or left) side of the system. |

Scanning a New Patient (continued)

When starting a new patient's exam, ensure you do the following:

1. Select **Patient** on the control panel.
2. Select **New Patient** on the patient menu.

   If there are images on the clipboard, a pop-up menu appears. Specify whether you want to store images, delete images, or go to active images.
3. Choose the exam category.
4. Verify the dataflow.

NOTE: *DO NOT use the removable media Dataflows on the New patient menu.*

NOTE: *The system will display a warning dialog when the patient is registered to "No Archive". If the "Warn register to No Archive" preset is selected in the Utility -> Connectivity -> Miscellaneous menu, a warning displays. Please select a different dataflow for permanent storage of patient data.*

5. Fill in patient information.

NOTE: *You can also select a patient from the patient database at the bottom of the Patient menu if the patient has a patient ID.*

NOTE: *Columns drive the ordering of the patients displayed. The columns that you select drive the order of the displayed patient database.*

NOTE: *Do not use the following characters when filling in patient information:*

   *" ' / : ; . , * < > | + = [ ] & !, @, #, $, %, ^, &, *, (,), ?, /, ~ , [,], {, }*

6. Select *Register*. Enter Past OB Exam information, if desired.
7. Select the probe to start scanning (or select Esc, Scan, or Freeze).
8. Perform the exam.

Scanning a New Patient (continued)

9. Store the images/loops to the clipboard.

    To store the still image, press **Freeze** and run the cineloop using the **Trackball**. Select the frame and press **Store**.

    To store the cineloop, press **Freeze** and run the cineloop using the **Trackball**. Select the start/end frame and run the selected loop. Press **Store**.

10. When you have completed the study, press *End Exam*. The Active Images screen displays. Select the images (still frame or cineloop) you want to store or simply select *Permanent Store* to store the images permanently.

⚠ CAUTION

After completing the measurement, verify that the measurement result window is updated before you send or save the image.

Entering a Patient List

All patient information can be entered before starting an exam.

1. Press **Patient** to display the Patient Screen.
2. Press *New Patient* to erase the current patient data.
3. Select **Store All** if data from previous patient was not saved.
4. Enter the Patient ID.
5. Enter the patient and exam information.
6. Press *Register*.
7. Repeat above steps as required.

Select the patient from the Patient List. Select **Resume Exam** to continue the last exam that was performed on the selected patient.

Select **New Exam** to start a new exam on the selected patient.

Starting a new exam on an existing patient

1. Select **Patient** on the control panel.
2. Select the patient from the Patient List.
3. Select **New Exam**.
4. A new exam is created. Enter the data and begin the scan.

Scanning without entering any patient data

To scan a patient without entering any patient data until the end of the exam:

1. Scan the patient and save images to clipboard without the patient information, the system displays a Warning message, "A patient must be selected for permanent storage of images." Select **OK**, a warning message is also displayed at the bottom of the image monitor in red.

2. When the scanning is finished, press **Patient** to display the Patient Search screen.

3. Enter the Patient ID, patient data and exam information as necessary, select *Register*.

4. If images or measurements have been stored to the clipboard, the system will display the following message:

   "Unsaved images, measurements or fetus number will be linked to the current patient information, continue?" Press **OK** if you want to permanently store the images/measurements that were just taken.

5. Enter the Active Images Screen, select *Permanent Store*.

6. Return to patient page, select **New Patient**.

Ending a Patient

To end a patient:

Press *Patient* -> *New Patient*, then select **Store All** in the pop-up menus to store exam data.

Changing Current Patient to Existing Patient (with Patient ID)

To change the current patient (with patient ID) to an existing patient, when there are some unsaved images on the clipboard for the current patient:

Select the existing patient from the patient list, the following dialog displays.
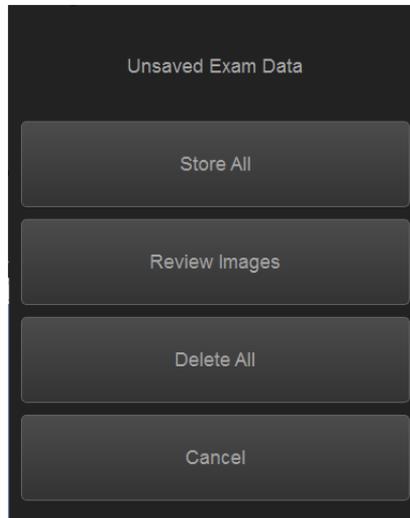
Figure 1-25.   Unsaved Exam Data

1. **Store All.** All the unsaved images will be saved to the current patient.
2. **Review Images.** Review the unsaved images in **Active Images** page and select to permanent store or delete.
3. **Delete All.** Delete all the unsaved images.

   The system will display a dialog: "Do you really want to delete all temporary images?" Select OK to delete the unsave images, select Cancel not to delete the images.
4. **Cancel.** Do nothing with the unsaved data, and return to **Patient** page.

Changing Current Patient to Existing Patient (without Patient ID)

To change the current patient (without patient ID) to an existing patient, when there are some unsaved images on the clipboard for the current patient:

Select the existing patient from the patient list, the following dialog displays.
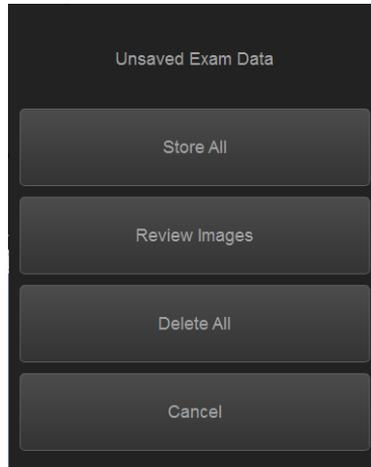
Figure 1-26.   Unsaved Exam Data

1. **Store All** All the unsaved images will be saved. The current patient doesn't have Patient ID, the system will indicate to enter patient ID.
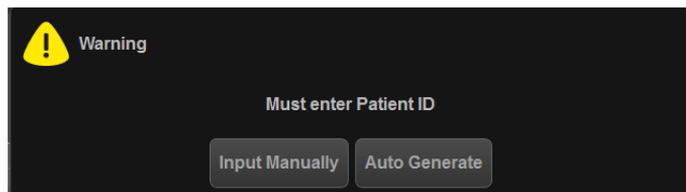
Figure 1-27.   Enter Patient ID

- **Input manually** Input the Patient ID and other information manually, and then select **Register** to register the new patient. And the system will display:

   "Unsaved images, measurements or fetus number will be linked to the current patient information, continue?" Select OK to save the images.

- **Auto Generate** The system will generate a new patient ID and the unsaved images will be saved to this new patient automatically.

Changing Current Patient to Existing Patient (without Patient ID) (continued)

2. **Review Images.** Review the unsaved images in **Active Images** page and select to permanent store or delete.

3. **Delete All.** Delete all the unsaved images.

    The system will display a dialog: "Do you really want to delete all temporary images?" Select OK to delete the unsave iamges, select Cancel not to delete the images.

4. **Cancel.** Do nothing with the unsaved data, and return to **Patient** page.

Delete the existing patient/exam/image

⚠ CAUTION   Before deleting a patient or image from the Patient Screen, make sure you have already saved the data with EZBackup/EZMove, Backup, or Export. Verify the media before deletion.

Delete the existing patient

1. Search and select the patient in the patient list.
2. Select *Delete*. The confirmation dialog box displays.

   OR

   Press the **Cursor** key. A pop-up menu displays. Select *Delete*. The confirmation dialog box displays.
3. Select **OK** to delete or **Cancel**.

Delete multiple patients from the patient list

1. Select the multiple patients to be deleted from the patient list by holding down the Control key and selecting patients one by one or holding down the Shift key to select a group of patients.
2. Select *Delete*. The confirmation dialog box displays.

   OR

   Press the **Cursor** key. A pop-up menu displays. Select *Delete*. The confirmation dialog box displays.
3. Select **OK** to delete or **Cancel**.

Delete the existing exam

1. Search and select the patient in the patient list under patient screen.
2. Select *Exam View* to display patient exam screen.
3. Select the exam to be deleted.
4. Select *Delete Exam*. The confirmation dialog box displays.
5. Select OK to delete or Cancel.

Delete the existing image

1. Search and select the patient in the patient list under patient screen.
2. Select *Exam View*. The patient exam screen displays.
3. Select the exam which contains the image to be deleted.
4. Select *Active Images* to display the image list.
5. Select the image to delete and select *Delete*. The confirmation dialog box displays.
6. Select **Yes** to delete or **No** to cancel.

Chapter 2

Performing an Exam

Optimizing the Image, Measurement and Analysis

Optimizing the Image

B-Mode Controls

B-Mode is intended to provide two-dimensional images and measurement capabilities concerning the anatomical structure of soft tissue.

Table 2-1: B-Mode Controls

Control	Bioeffect	Description/Benefit
Depth	Yes	Depth controls the distance over which the B-Mode images anatomy, and the field of view. To visualize deeper structures, increase the depth. To visualize the flatter structures, decrease the depth.
Gain	No	B-Mode Gain increases or decreases the amount of echo information displayed in an image. It may have the effect of brightening or darkening the image if sufficient echo information is generated.
Focus	Yes	Increases the number of focal zones, moves the focal zone(s) and change the zone width so that you can tighten up the beam for a specific area. A graphic caret corresponding to the focal zone position(s) appears on the right edge of the image.
Whizz	No	Whizz will continuously optimize the brightness, contrast and uniformity of B mode images when scanning on different tissues. Whizz in PW/CW Doppler Mode (ASO: Auto Spectral Optimization) optimizes the spectral data. Auto adjusts the Velocity Scale/PRF (live imaging only), baseline shift, and invert (if preset). Upon deactivation, the spectrum is still optimized.
Mode Cursor	Yes	Display the M/D cursor on the B-Mode images.
CrossXBeam	Yes	CrossXBeam is the process of combining three or more frames from different steering angles into a single frame. CrossXBeam is available on Convex and Linear probes. CrossXBeam combines multiple co-planar images from different view angles into a single image at real-time frame rates, using bi-cubic interpolation.
Coded Harmonic Imaging (Phase Inversion Harmonic) (CHI)	Yes	Harmonic imaging utilizes Digitally Encoded Ultrasound (DEU). Coded Harmonics enhances near field resolution for improved small parts imaging as well as far field penetration.
Frequency	Yes	Switch the frequency.

Table 2-1:   B-Mode Controls (continued)

Control	Bioeffect	Description/Benefit
Steer	Yes	You can slant the B-Mode or Color Flow acoustic beam without moving the probe. The steer function only applies to linear probes. NOTE: Steer is not available while using CrossXBeam.
Virtual Convex	Yes	On Linear and Sector probes, Virtual Convex provides a larger field of view in the far field.
TGC	No	TGC amplifies returning signals to correct for the attenuation caused by tissues at increasing depths. TGC slide pots are spaced proportionally to the depth. The area each pot amplifies varies as well. A TGC curve may appear on the display (if preset), matching the controls that you have set (except during zoom). You can choose to deactivate the TGC curve on the image.
Width	Yes	You can widen or narrow the size of the sector/convex angle to maximize the image's region of interest (ROI).
Tilt	Yes	You can steer the sector angle to get more information without moving the probe while in B-Mode, M-Mode, Doppler Mode, and Color Flow Mode. NOTE: Tilt is not available on linear probe. NOTE: Tilt is available when CrossXBeam is off.
Reverse	No	Flips the image 180 degrees left/right.
Dynamic Range	No	Dynamic Range controls how echo intensities are converted to shades of gray, thereby increasing the adjustable range of contrast.
Line Density	Yes	Optimizes B-Mode frame rate or spatial resolution for the best possible image.
Gray Map	No	The system supplies B, M, and Doppler Mode system maps.
Frame Average	No	Temporal filter that averages frames together, thereby using more pixels to make up one image. This has the effect of presenting a smoother, softer image.
Colorize	No	Colorize is the colorization of a conventional B-Mode image or Doppler Spectrum to enhance the user's ability to discern B, M, and Doppler Mode intensity valuations. Colorize is NOT a Doppler Mode. *NOTE: You can colorize real-time or CINE images or Timeline CINE.* Colorizes the gray scale image to enhance the eye's discrimination capability. Spectrum Colorize colorizes the spectrum as a function of power using the inverse of the Colorize map for the signal intensity in each Doppler line. Colorize enhances the visibility of the spectrum's characteristics and enhances your ability to identify spectral broadening and the edge contours of the spectrum used to define the peak frequency/velocity. The colorize bar displays while Colorize is activated.
Edge Enhance	No	Edge Enhance brings out subtle tissue differences and boundaries by enhancing the gray scale differences corresponding to the edges of structures.

Table 2-1: B-Mode Controls (continued)

Control	Bioeffect	Description/Benefit
Rotation	No	You can flip the image up/down. **CAUTION:** When reading an rotated image, be careful to observe the probe orientation to avoid possible confusion over scan direction or left/right image reversal.
Rejection	No	Selects a level below which echoes will not be amplified (an echo must have a certain minimum amplitude before it will be processed).
Suppression	No	Suppresses the noise in the image.
SRI-HD	No	SRI-HD (Speckle Reduction Imaging High Definition) is an adaptive algorithm to reduce the speckle in the ultrasound image.
LOGIQ View (Option)	No	LOGIQ View provides the ability to construct and view a static 2D image which is wider than the field of view of a given transducer. This feature allows viewing and measurements of anatomy that is larger than what would fit in a single image. Examples include scanning of vascular structures and connective tissues in the arms and legs. LOGIQ View constructs the extended image from individual image frames as the operator slides the transducer along the surface of the skin in the direction of the scan plane. The quality of the resulting image is somewhat user-dependent and requires some additional skill and practice to develop proper technique and become fully proficient. LOGIQ View is only available in B mode.

M-Mode Controls

M-Mode is intended to provide a display format and measurement capability that represents tissue displacement (motion) occurring over time along a single vector.

Table 2-2:   M-Mode Controls

Control	Bioeffect	Description/Benefit
Sweep Speed	No	Changes the speed at which the timeline is swept. Available in M-Mode, Doppler Mode and M Color Flow Mode.
Anatomical M-Mode (option)	Yes	Anatomical M-Mode gives you the ability to manipulate the cursor at different angles and positions. The M-Mode display changes according to a motion of the M cursor.

Color Flow Mode Controls

Color Flow Mode and Color M-Mode are Doppler Modes intended to add color-coded qualitative information concerning the relative velocity and direction of fluid motion within the B-Mode or M-Mode image.

Table 2-3:   Color Flow Mode Controls

Control	Bioeffect	Description/Benefit
Flow Selection	Yes	In the Lower Extremity Vein (LEV) and Abdominal applications, you can quickly select the flow state via a shortcut on the Color Flow Mode menu.
Gain	No	Gain amplifies the overall strength of echoes processed in the Color Flow window or spectral Doppler timeline.
Scale (Velocity Scale)	Yes	Increases/decreases the Scale on the color bar.
Wall Filter	No	Filters out low flow velocity signals. It helps get rid of motion artifacts caused from breathing and other patient motion.
Size/Position	Yes	Adjust size and position of the color window.
Invert (Color Invert)	No	Lets you view blood flow from a different perspective, e.g., red away (negative velocities) and blue toward (positive velocities). You can invert a real-time or frozen image. *NOTE: Invert reverses the color map, NOT the color PRF.*
Baseline	No	Changes the Color Flow or Doppler spectrum baseline to accommodate higher velocity blood flow. Minimizes aliasing by displaying a greater range of forward flow with respect to reverse flow, or vice versa. Baseline adjusts the alias point. The default baseline is at the midpoint of the color display and at the midpoint of the color bar reference display.
Angle Steer	Yes	You can slant the ROI of the Color Flow linear image left or right to get more information without moving the probe. The Angle Steer function only applies to linear probes.
Accumulation	No	Time Accumulation of Color Flow.
Color Flow Line Density	Yes	Optimizes the Color Flow frame rate or spatial resolution for the best possible color image.
Map	No	Allows you to select a specific color map. After you have made your selection, the color bar displays the resultant map.
Map Compress	No	Change the gradation of color map.
Threshold	No	Limits color flow overlay to low level echoes inside vessel walls. Helps minimize color `bleeding' outside vessel walls.
Frame Average	No	Averages color frames.
Transparency Map	No	Brings out the tissue behind the color map.

Table 2-3: Color Flow Mode Controls (continued)

Control	Bioeffect	Description/Benefit
Spatial Filter	No	Smooths out the color, makes it look less pixely.
Flash Suppression	No	Activates/deactivates Flash Suppression, a motion artifact elimination process.
Packet Size	Yes	Controls the number of samples gathered for a single color flow vector.
Sample Volume	Yes	Adjusts the size of the color flow doppler transmit wave (or pulse) and size (or length). Lower setting gives better flow resolution and a higher setting increases sensitivity.
CF/PDI Auto Sample Volume	Yes	Set the default value at Utility -> Imaging -> CF Mode.
CF/PDI Focus Depth	Yes	
CF/PDI Frequency	Yes	
CF/PDI Auto Frequency	Yes	
CF/PDI Center Depth	Yes	
PDI	Yes	Power Doppler Imaging (PDI) is a color flow mapping technique used to map the strength of the Doppler signal coming from the tissue rather than the frequency shift of the signal. Using this technique, the ultrasound system plots color flow based on the number of reflectors that are moving, regardless of their velocity. PDI does not map velocity, therefore it is not subject to aliasing.
TVI (Option)	Yes	Tissue Velocity Imaging (TVI) calculates and color-codes the velocities in tissue. The tissue velocity information is acquired by sampling of tissue Doppler velocity values at discrete points.The information is stored in a combined format with gray scale imaging during one or several cardiac cycles with high temporal resolution.
TVD (Option)	Yes	TVD: Tissue Velocity Doppler: basing on TVI mode, activate a sample volume of PW ventricular wall to get the spectral information of the sample section.
QAnalysis (Option)	No	QAnalysis is available for the image loop acquired in the following modes: TVI, CF and PDI. All of the QAnalysis modes operate similarly, with some variation.

M Color Flow Mode

M Color Flow is used for cardiac applications. Color Flow overlays color on the M-Mode image using velocity and variance color maps. The Color Flow wedge overlays the B-Mode image and M-Mode time line.

See 'Color Flow Mode Controls' on *page 2-6 for more information.*

Doppler Mode Controls

Doppler is intended to provide measurement data concerning the velocity of moving tissues and fluids. PW Doppler lets you examine blood flow data selectively from a small region called the sample volume.

Table 2-4:   Doppler Mode Controls

Control	Bioeffect	Description/Benefit
Auto Spectral Optimize [ASO] (Auto)	Yes	Auto in Doppler Mode optimizes the spectral data. Auto adjusts the Velocity Scale/PRF (on live images only), baseline shift and invert (if preset). The benefit of Auto can be found in reduced optimization time and a more consistent and accurate optimization process.
Set/ B Pause	Yes	Toggles between simultaneous and update presentation while viewing the timeline.
Doppler sample volume gate position	Yes	Moves the sample volume gate on the B-Mode's Doppler Mode cursor. The gate is positioned over a specific position within the vessel.
Doppler sample volume length	Yes	Sizes the sample volume gate.
Scale (Velocity Scale)	Yes	Adjusts the velocity scale to accommodate faster/slower blood flow velocities. Velocity scale determines pulse repetition frequency. If the sample volume gate range exceeds single gate Scale capability, the system automatically switches to high PRF mode. Multiple gates appear, and HPRF is indicated on the display.
Angle Correct	No	Estimates the flow velocity in a direction at an angle to the Doppler vector by computing the angle between the Doppler vector and the flow to be measured. *NOTE: When the Doppler Mode Cursor and angle correct indicator are aligned (the angle is 0), you cannot see the angle correct indicator.*
Quick Angle	No	Quickly adjusts the angle by 60 degrees.
Wall Filter	No	Insulates the Doppler signal from excessive noise caused from vessel movement.
Baseline	No	Adjusts the baseline to accommodate faster or slower blood flows to eliminate aliasing.
Mode Cursor	No	Displays the Doppler Mode cursor on the B-Mode image.
Steer and Fine Steer	Yes	You can slant the ROI of the Color Flow linear image left or right to get more information without moving the probe. The angle steer function only applies to linear probes.
Volume	No	Controls audio output.
Invert	No	Vertically inverts the spectral trace without affecting the baseline position.

Table 2-4:   Doppler Mode Controls (continued)

Control	Bioeffect	Description/Benefit
Compression	No	Dynamic range controls how echo intensities are converted to shades of gray, thereby increasing the range of contrast you can adjust.
Trace Method	No	Traces the average mean and peak velocities in real-time or frozen images.
Cycles to Average	No	The average value over a number of cycles (from 1-5).
Trace Sensitivity	No	Adjust the trace to follow the waveform for signal strength.
Trace Direction	No	Specifies trace direction.
Display Format	No	Changes the horizontal/vertical layout between B-Mode and Doppler-Mode, or timeline only.
Modify Auto Calcs	No	Activates the menu to select which calculations are automatically calculated.
Auto Calcs	No	Activates the calculation automatically which you select in the Modify Auto Calculation when the system is in a state of freeze or live.
Simultaneous (Duplex/Triplex)	Yes	When you select Simultaneous, everything is live. Simultaneous includes duplex and triplex. For example, it is duplex if both B-Mode and PW Doppler Modes are active; it is triplex if B-Mode, PW Doppler Mode, and CF Modes are active. If Simultaneous is not selected, use Set/ B Pause to toggle between modes.
Continuous Wave Doppler (CWD) (option)	Yes	Allows examination of blood flow data all along the Doppler Mode cursor rather than from any specific depth. Gather samples along the entire Doppler beam for rapid scanning of the heart. Range gated CW allows information to be gathered at higher velocities.

Easy 3D Mode (Option)

Table 2-5:   3D Package Options

3D Type	Description	Sensor/No Sensor	Available Tabs
Easy 3D Mode	Designed for rendering B Mode images, e.g., fetal face scans.	No sensor	3D Acquisition, Easy Mode, Movie

Acquiring a 3D Scan

1. Optimize the B-Mode image. Ensure even gel coverage.
2. Press the User Defined key configured for 3D functionality. Two screens appear.

NOTE: *Before scanning, set appropriate values for Acq Mode, Scan Plane and the Scan distance.*

3. To start acquiring the image, press L (the left split screen key).
4. To perform a parallel scan, scan evenly. To perform a sweep (fan) scan, rock the probe once. Note the distance of the scan.
5. The 3D volume of interest (VOI) is dynamically assembled on the right side of the screen.

NOTE: *If the image stops before you're done scanning, start acquiring the 3D volume of interest again.*

6. To complete the 3D scan, press R (the right split screen key).

NOTE: *You can also press Freeze, but then you need to also press the 3D key to obtain the final rendering images.*

Other Controls

Zoom

To zoom an image, rotate **Zoom** clockwise. A reference image appears in the down, left-hand section of the display.

To exit zoom, press B-Mode or rotate Zoom counterclockwise until the reference zoom image is removed.

Reference Image is the small un-zoomed image displayed next to the zoomed image.

Read Zoom

To activate Read Zoom, turn the **Zoom** knob.

Read Zoom magnifies the display of the data without making any changes to the ultrasound image data that is acquired.

Available in a live, frozen, cine or recalled raw data image.

Write Zoom

Zooming an image changes the frame rate which tends to change thermal indices. The position of the focal zones may also change which may cause the peak intensity to occur at a different location in the acoustic field. As a result, the MI (TI) may change.

Acoustic Output Hazard

Observe the output display for possible effects.

NOTE: *Write Zoom is available only when CrossXBeam is off.*

To activate Write Zoom, press the **Zoom** knob.

With Write Zoom, the Ultrasound line density and/or sampling frequency increases, giving a better resolution.

Available only in pre-processing.

You can preset the write zoom window size (height and width) on Utility -> Imaging -> B-Mode.

NOTE: *The difference between Read Zoom and Write Zoom can be described in relation to photography. With a photograph, Read Zoom manipulates the negative and enlarges the picture; whereas Write Zoom uses a telephoto lens to bring the image closer before taking the picture.*

HINTS

First use the Read Zoom (turn knob) to get to the area of interest, then use Write Zoom (press knob).

Split Screen

To activate a dual split screen, press *L* or *R*.To activate a quad display, press and hold down *L*.

To switch between active images, press *L*/*R*.

To deactivate, press *R* until the screen changes.

NOTE: *To put a copy of the image on the opposite side when entering dual split screen, use the "When Entering Dual Image" preset found on Utility --> Application --> Settings preset page.*

Simultaneous mode

While using CFM or PDI, press the L and R keys simultaneously to display B and B+CFM, or B and B+PDI in real-time on the left and right side.

It is useful to observe the ROI in B-Mode.

Freezing an image

To freeze an image,

- Press **Freeze**. The Freeze key backlight turns green. Image is on freeze mode (Frozen image).

    If you are in a mixed mode, both images freeze immediately. Deactivating Freeze restarts both modes.

To reactivate the image,

- Press **Freeze** again. The Freeze key backlight becomes blue (unfreeze). Image is on real time scan mode (Live image).

NOTE: *Deactivating Freeze erases all measurements and calculations from the display (but not from the report).*

Use the Trackball to start CINE after pressing Freeze.

Activating CINE

To activate CINE,

1. Press Freeze.
2. Move the Trackball.

Body Patterns

Press the **Body Pattern** key on the control panel to enter into body pattern mode.

Select the desired body pattern and the selected body pattern is displayed on the monitor.

- Select the **Move Pattern** control to reposition the body pattern with the **Trackball** and **Set** controls.
- Move the body pattern to the desired location.

NOTE: *Home Position is independent between the display format.*

NOTE: *Body Pattern Position is updated when the display format is changed.*

NOTE: *Body Pattern Position is reset to factory default when patient is changed (e.g. End Exam).*

- A probe mark is associated with the body patterns and illustrates the probe position on the body pattern. This marker can be placed with the **Trackball** and rotated with the **Body Pattern** button.
- The probe mark type is selectable by rotating the **Probe Type** control. There are different choices available with one being a blank selection.
- To select the active side in dual B-Mode, use the **Active Side** rotary control on the Primary Menu.
- To clear the body pattern, press the ***Body Pattern*** control to activate body patterns and then press the ***Clear*** key.
- Press ***Set*** on the keyboard to exit without erasing the body pattern.

Annotating an Image

Pressing the **Comment** key or any keys on the alphanumeric keyboard initiates the comment mode. This assigns the trackball function to controlling the cursor and displays the comment library on the menu area.

In comment mode, text can be added by using the comment library or by typing from the alphanumeric keyboard.

After activating the comment mode, a vertical bar type cursor appears on the screen. Use the *Trackball* to move the cursor.

To delete comments by character, press the *Backspace* key.

To delete all comments and arrow marks, press the *Clear* key after entering the comment mode.

To move by words or by text group, press the *Tab* key.

Arrow pointers can be used by activating the *Arrow* key on the keyboard. **Comment** key can be activated either by pressing the Annotate key or Arrow key on the control panel. When the pointer comes up, it is a GREEN color, indicating it is active and can be moved.

Scan Coach (Option)

Before performing Scan Coach function on the system, please read and accept the Statement, Disclaimer and Limitation of liability described as below:

Statement

- Scan Coach IS NOT MEANT TO REPLACE TRAINING, OR TUTORIALS/HANDS-ON. IT IS MERELY A REFRESHER TOOL OF ALREADY RECEIVED EDUCATION AND TRAINING.
- Scan Coach IS AN ON -DEMAND REFRESHER AND REMINDER TOOL WHICH DISPLAYS INFORMATION IN THE FORM OF DICOM IMAGES AND ANIMATIONS; THE PROVIDED REFERENCE MATERIAL MAY HELP USER IN ACQUIRING ULTRASOUND IMAGES.
- Scan Coach DOES NOT PROVIDE A DIAGNOSIS, BUT DOES PROVIDE REFERENCE MATERIAL FOR SOME TYPES OF ACQUISITIONS.
- Scan Coach IS MEANT TO PROVIDE REFERENCE MATERIAL FOR ACQUISITION, BUT IT IS NOT INTENDED TO IDENTIFY DIAGNOSTIC IMAGE QUALITY. ACTUAL IMAGES, INCLUDING IMAGE QUALITY, OF THE DEVICE MAY VARY VERSUS THE PROVIDED REFERENCE MATERIAL.

Disclaimer

Scan Coach AND THE CONTENT AVAILABLE THROUGH IT ARE PROVIDED ON AN "AS IS" AND "AS AVAILABLE" BASIS. YOU EXPRESSLY AGREE THAT USE OF Scan Coach AND/ OR ITS CONTENT IS AT YOUR SOLE RISK. TO THE FULLEST EXTENT PERMISSIBLE PURSUANT TO APPLICABLE LAW, GE AND ITS AFFILIATES DISCLAIM ALL WARRANTIES OF ANY KIND, WHETHER EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT. YOU EXPRESSLY AGREE THAT USE OF Scan Coach, INCLUDING ALL CONTENT, IS AT YOUR SOLE RISK.

ANY RESPONSIBILTY FOR IMAGE ACQUISITION, IMAGE INTERPRETATION, IDENTIFICATION OF ANATOMICAL PARTS, ANATOMICAL MEASUREMENTS AND CLINICAL DIAGNOSIS LIES WITH YOU, THE ULTRASOUND USER.

TO THE FULLEST EXTENT PERMISSIBLE PURSUANT TO APPLICABLE LAW, GE AND ITS AFFILIATES DISCLAIM ALL LIABILTY AND RESPONSIBILITY FOR ANY DAMAGES SUFFERED BY A USER, OR PATIENT OF A USER INCLUDING, BUT NOT LIMITED TO, DAMAGES ARISING OUT OF LOSS OR INACCURACY OF CONTENT OF Scan Coach.

IT IS THE RESPONSIBILTY OF YOU, THE ULTRASOUND USER, TO UNDERTAKE ALL NECESSARY AND CUSTOMARY TRAINING, AND TO MEET ALL OTHER REQUIREMENTS OF APPLICABLE LAWS AND REGULATIONS, BEFORE USING THE ULTRASOUND DEVICE.

Limitation of Liability

UNDER NO CIRCUMSTANCES, INCLUDING, WITHOUT LIMITATION, NEGLIGENCE, SHALL GE OR ITS PARENTS, SUBSIDIARIES, AFFILIATES, OFFICERS, DIRECTORS, EMPLOYEES, AGENTS, OR SUPPLIERS BE LIABLE FOR ANY DIRECT, INDIRECT, INCIDENTAL, SPECIAL OR CONSEQUENTIAL DAMAGES ARISING FROM OR IN CONNECTION WITH THE USE OF OR THE INABILITY TO USE Scan Coach.

Introduction

Scan Assistant provides an automated exam script that moves you through an exam step-by-step. This allows you to focus on performing the exam rather than on controlling the system and can help you to increase consistency while reducing keystrokes. The system automatically invokes the correct mode and imaging parameters, advances to the next step in an exam, annotates the image, initiates measurements, and assigns the measurements to the report.

Scan Coach is based on Scan Assistant, it displays information which helps user acquire the right scan plane. The reference image indicates how the scan plane image for a given step should look like. The probe/beam anime image shows the corresponding probe placement, or beam formation for getting the correct scan plane. The schema anime shows the key anatomical structures to be visualized in two dimensional mode.

Scan Coach can be used as an on-demand refresher/reminder tool in live scanning.

Scan Coach Description
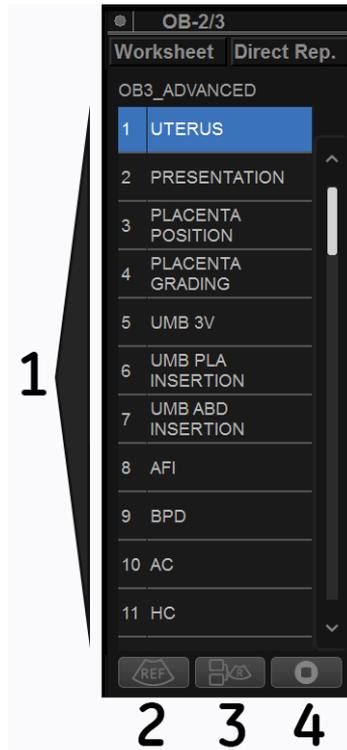

Figure 2-1.   Scan Coach Display Description

1.   Program step number and step name

NOTE: *The user is also able to select the program step by pressing the Up/Down key on the AN keyboard.*

2.   Select this icon to activate Reference image.

3.   Select this icon to activate Animation and Reference image.

4.   Select to Restart, Exit or Edit Scan Coach.

Setting up Scan Coach

Go to Utility -> Scan Coach -> Scan Coach Manager to create, import/export and manage the Scan Coach programs.
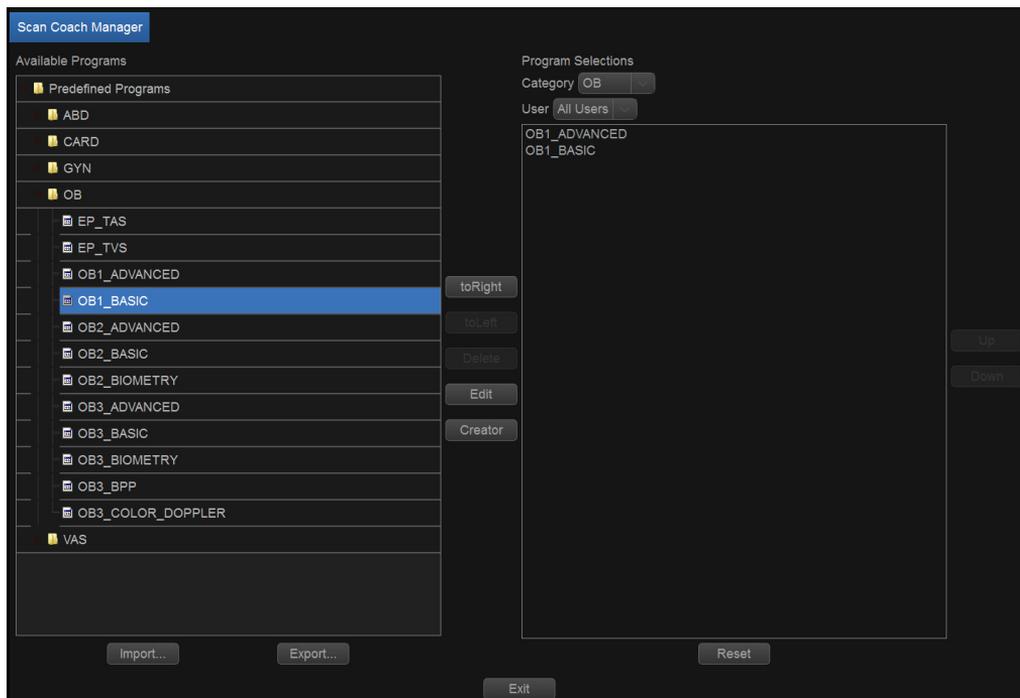

Figure 2-2. Setting up scan coach

Using Scan Coach

1. Go to Utility -> Scan Coach -> Scan Coach Manager, select the protocol from the left column, move it to the **Program Selections** column. Then select **Exit** to the Scanning page.
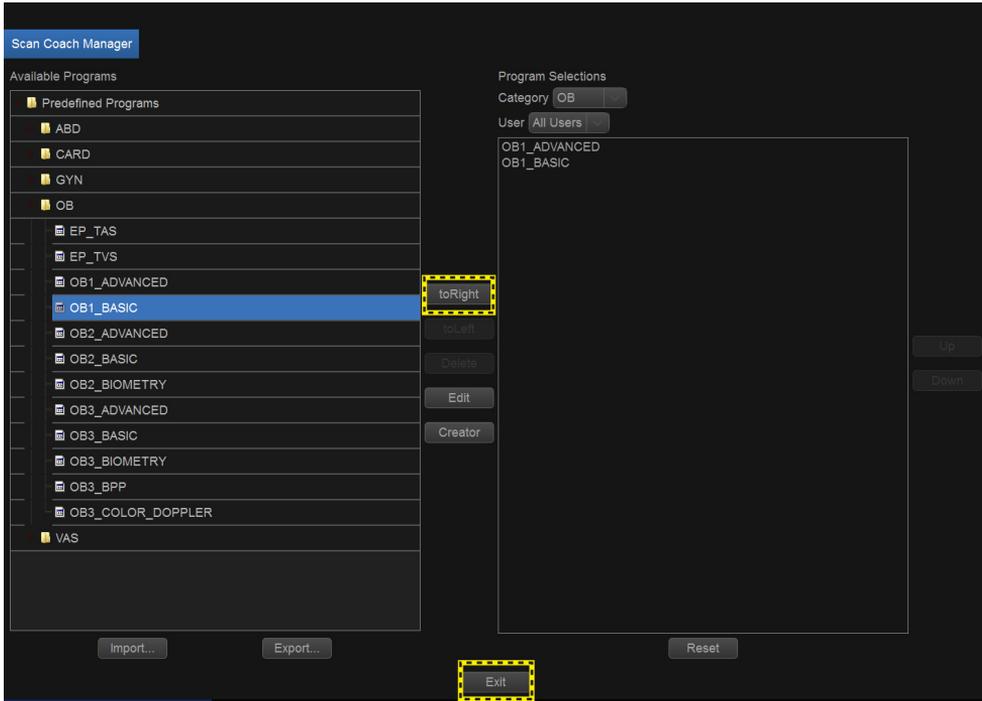

Figure 2-3.   Select Scan Coach Protocol

Using Scan Coach (continued)

2. Press **Scan Coach** key on the control panel to activate the Scan Coach function. The Scan Coach addendum displays, refer to 'Scan Coach (Option)' on *page 2-18* for detailed information. Select **Acknowledge** to continue.
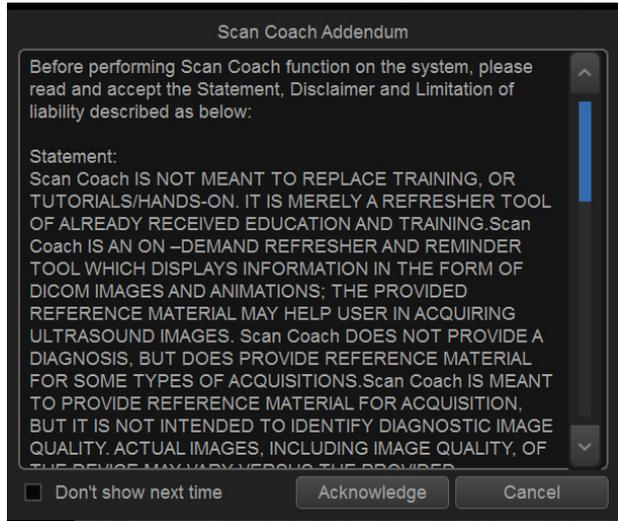
Figure 2-4.   Scan Coach Addendum

Or select **Cancel** not to start Scan Coach.

Check the box before **Don't show next time** and the Scan Coach addendum won't display next time.

3. Select the protocol from the pull-down menu, and then select **Start**.

NOTE: *If there is only one program in the current application, the system will display the Scan Coach screen directly. This step is only available when there are two or more programs.*
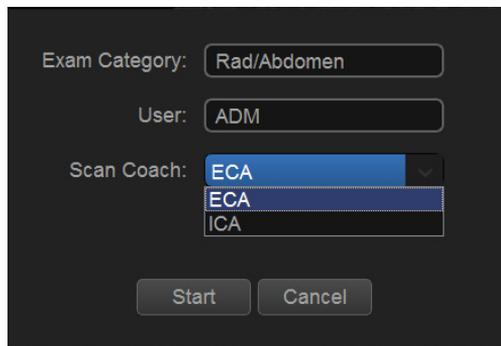
Figure 2-5.   Scan Coach Start

Using Scan Coach (continued)

4. If **Always Use Protocol Preview** is selected in **Utility** ->
    System -> **General**, the system will display a demo for the
    programs. It helps the user understand the workflow of Scan
    Coach.

NOTE: *Uncheck **Always Use Protocol Preview** and the system
will not show the program preview.*
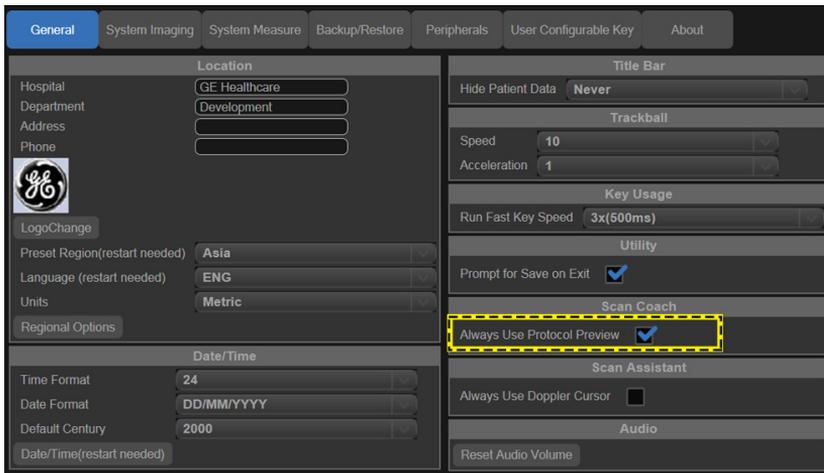
Figure 2-6.   Utility->System->General
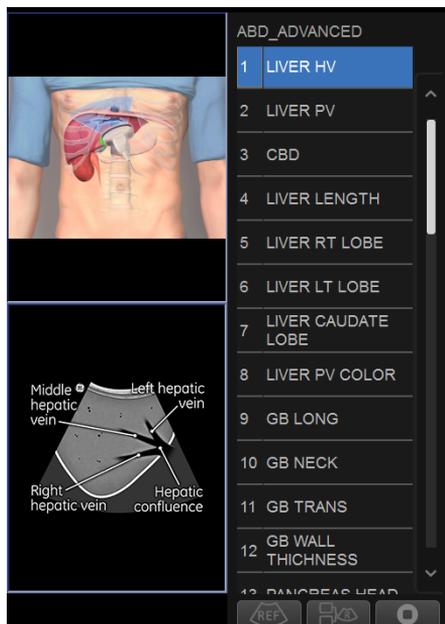
Figure 2-7.   Scan Coach Preview

Using Scan Coach (continued)

5. Select program, for example, LIVER LENGTH, then select the button **1** to review the reference image.
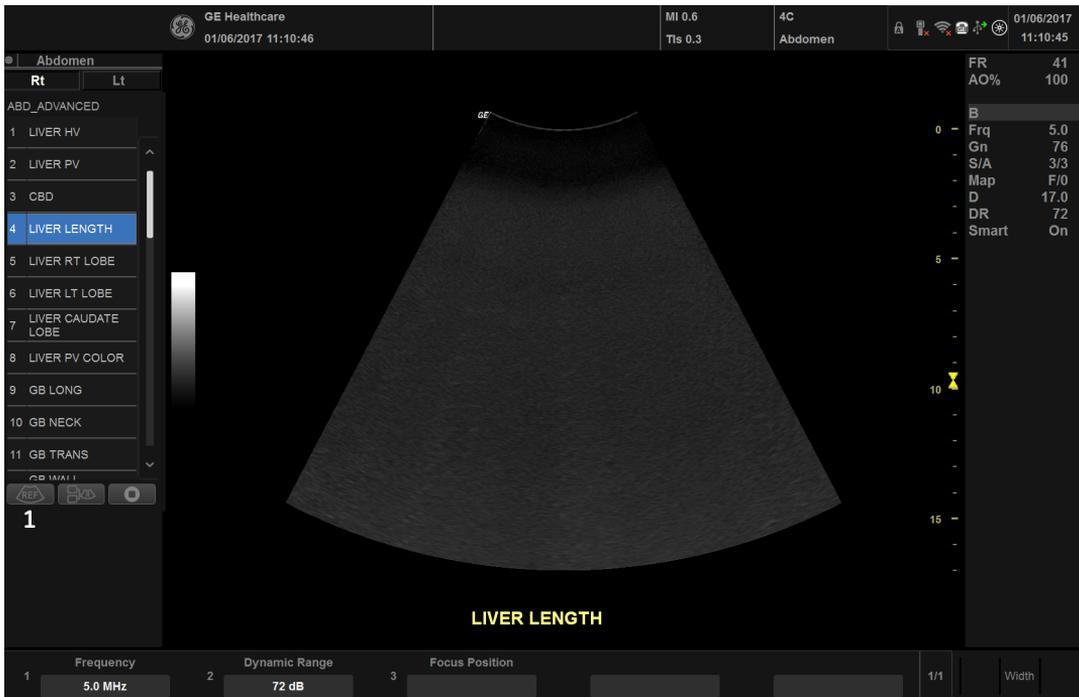
Figure 2-8.   Using Scan Coach

Using Scan Coach (continued)

6. The reference image is displayed. Then select the button **2** to view the probe position and schema also.

    You can also press the button 1 to return to the program step list.

Figure 2-9.   Using Scan Coach L1

Using Scan Coach (continued)

7. It displays reference image, probe position and schema to guide the user acquire the right scan plane.

    Select the button marked as 1 to stop/restart the video that demonstrates the probe position.
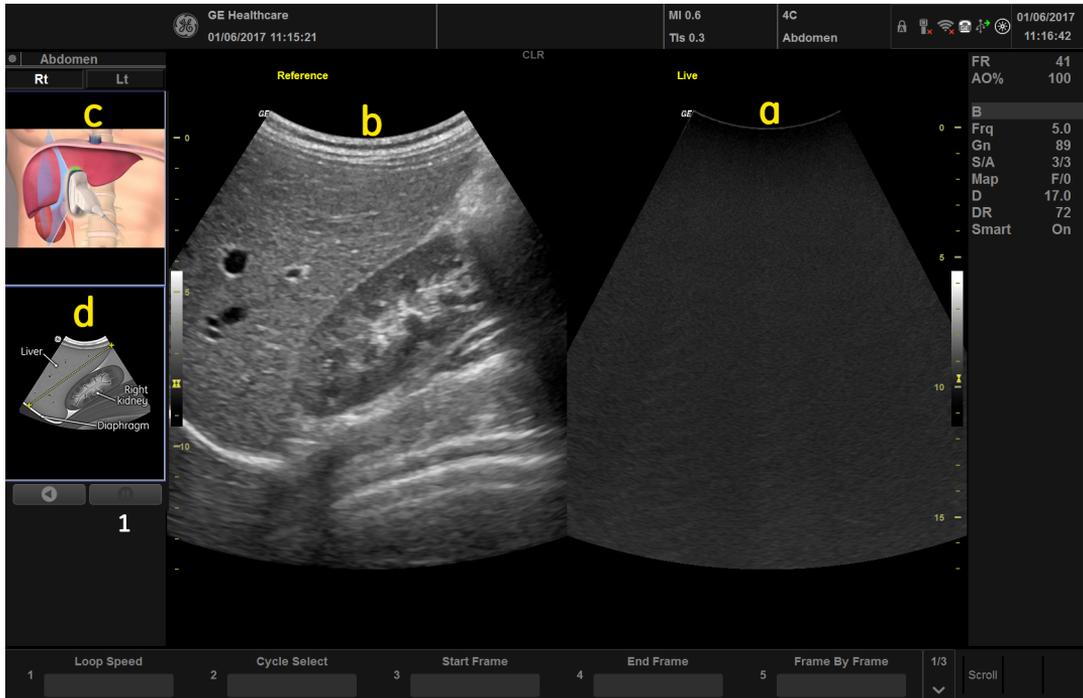
Figure 2-10.   Using Scan Coach L2

a. live scan image
b. reference image
c. probe position
d. two dimensional schema of the current scan plane

Edit Scan Coach Protocol

1. To edit Scan Coach protocols, go to Utility -> Scan Coach -> Scan Coach Manager and select **Creator**.
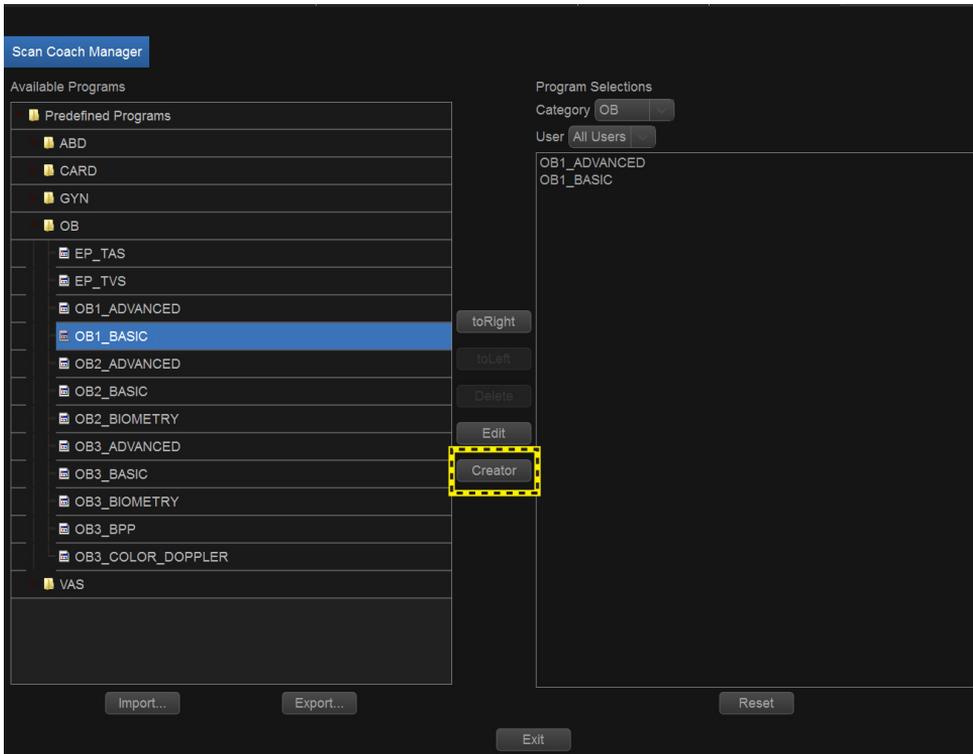
Figure 2-11.   Scan Coach Manager

Edit Scan Coach Protocol (continued)

Or Select the button marked as 4 in the program list.
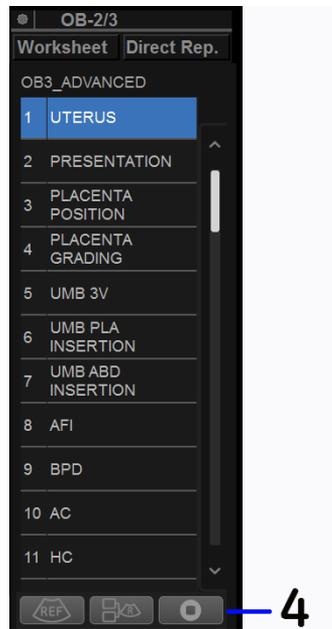
Figure 2-12.   Program List

Then select [pencil icon] and the system will lead to the Scan Coach Edit page.
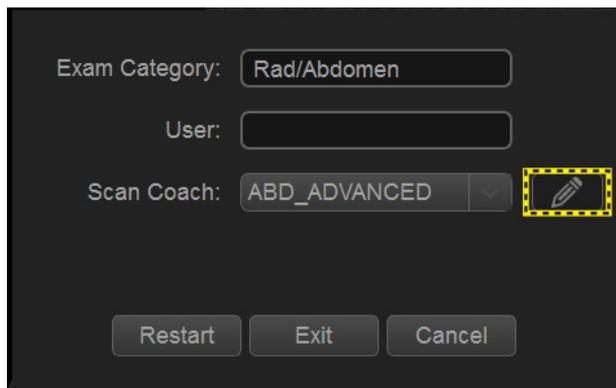
Figure 2-13.   Edit the Protocol

Edit Scan Coach Protocol (continued)

2. The Scan Coach Creator is used to build customized programs that can be imported onto the Versana Essential. Select **Scan Coach** on the tool bar to display the Scan Coach edit page.
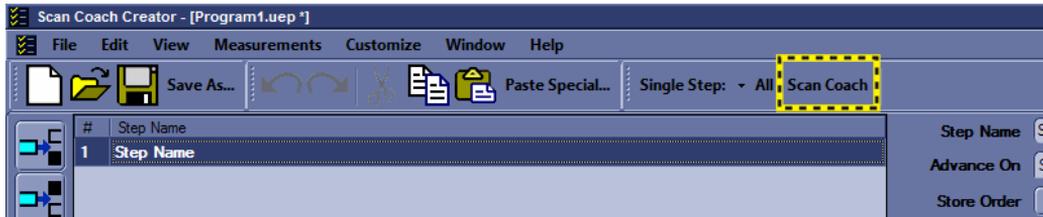
Figure 2-14.   Scan Coach Creator

3. Select the Scan Plane. Select **Browse** to upload the reference image.

Figure 2-15.   Select Scan Plane

Edit Scan Coach Protocol (continued)

4. Select **Upload** to Upload the reference image from the folder called "Reference Images" of the corresponding application. Then select **Close** after the upload is complete.

NOTE: *The reference image only supports *.dcm file.*
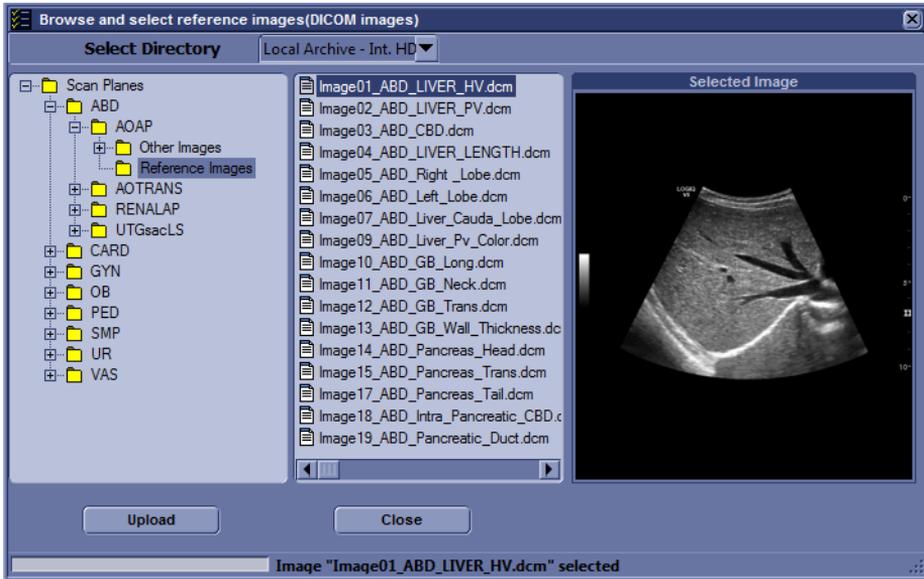
Figure 2-16.   Upload Reference Image 1

Edit Scan Coach Protocol (continued)

The reference image can also be uploaded from external
USB stick/HDD/CD/DVD. Select the correct directory from
the pull-down menu, and then select the appropriate image
to upload.
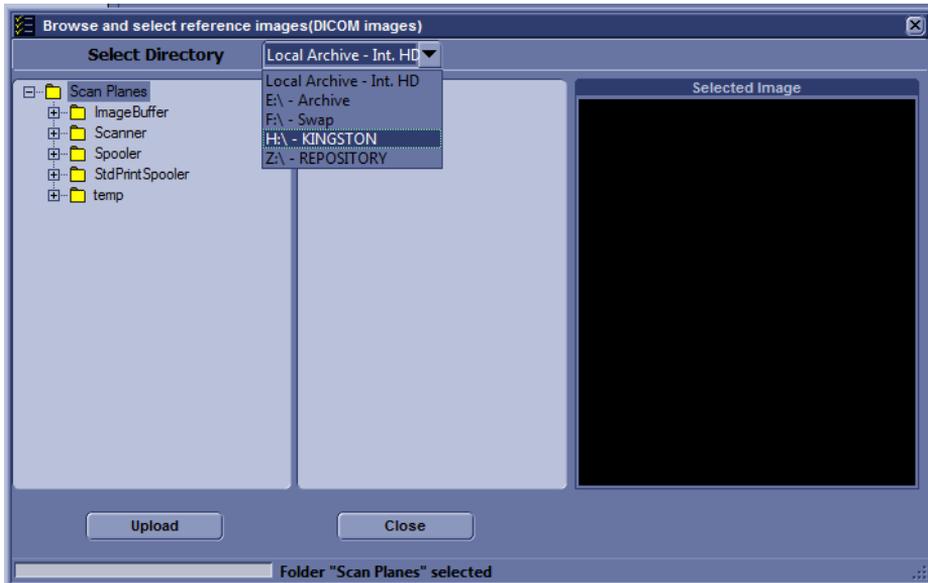
Figure 2-17.   Upload Reference Image 2

5.   Upload Probe Position Image and Schema Image from the
folder called "Other Images" of the corresponding
application, or from the external devices.

NOTE: *A protocol can be created without uploading the reference*
image, but the protocol without reference image do not display
*in **Utility** ->**Scan Coach** ->**Scan Coach Manager**. It can be*
*found via **Utility** ->**Scan Assistant** ->**Scan Assistant Manager***
*-> **Custom Programs**.*

Scan Assistant

Introduction

Scan Assistant provides an automated exam script that moves you through an exam step-by-step. This allows you to focus on performing the exam rather than on controlling the system and can help you to increase consistency while reducing keystrokes. The system automatically invokes the correct mode and imaging parameters, advances to the next step in an exam, annotates the image, initiates measurements, and assigns the measurements to the report.

Availability

The following additional imaging parameters and preferences are available for use in a Scan Assistant program: CW Doppler, Dual on Freeze, Depth, Color Scale, PW Doppler Scale, PW Sample Volume size, and Flow Model Selection.

You can initiate one or more manual Doppler measurements/ calculations.

Body Patterns are available for use during a Scan Assistant program. You can turn a Body Pattern on/off, select a particular Body Pattern graphic, and specify the position of the probe mark on the Body Pattern graphic.

The footswitch can be used with Scan Assistant. You can map Pause/Resume, Previous Step, and Next Step to the footswitch.

The "Always Use Doppler Cursor" preset, available on the Utility --> System --> General page, allows all PW Doppler steps to start with full screen 2D image plus mode cursor. You can specify the Store Order in Scan Assistant to set the Reading Order for the radiologist. The Learn Probe attribute can be set to learn and change the probe for the user in the middle of the exam.

Scan Assistant Definitions

Scan Assistant definitions:

- **Scan Assistant Manager**. Available via the Utility -> Scan Assistant page to import/export Programs created via the Scan Assistant Creator and to assign Programs to a user/ exam category.
- **Import**. Used to load Programs created via the Scan Assistant Creator on to the Versana Essential.
- **Export**. Used to move Programs from one Versana Essential system to another Versana Essential.
- **Scan Assistant Creator**. Used to create Scan Assistant Programs.

Scan Assistant Description
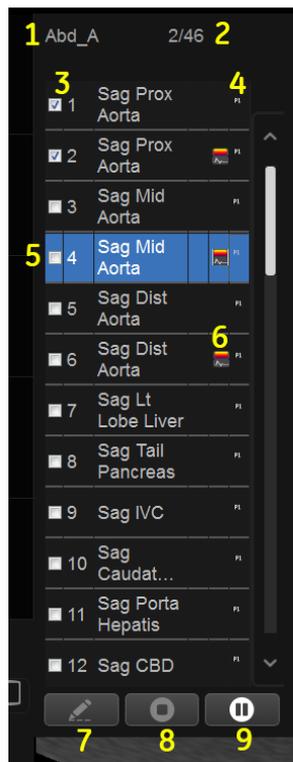
Figure 2-18.   Scan Assistant Display Description

1. Program name.
2. Completed steps/out of total number of steps, and step description area.
3. Program step status (Complete/Incomplete), step number, step name. A checkmark indicates that this step has been completed. You can also manually check the box to bypass this step.
4. This column indicates that the action moves the Program to the next step.
5. Active step.
6. This column indicates the mode or when a measurement needs to be made.
7. Edit (Pencil Icon).
8. Stop. Stop also allows the program to be stopped, restarted, or a new program selected.
9. Pause/Resume.

Setting up Scan Assistant

To set up Scan Assistant,

1. Import the Scan Assistant Program created using the Scan Assistant Creator or exported from another Versana Essential program.

    a. Insert the media with the saved Program from the Scan Assistant Creator or exported program from another Versana Essential.

    b. Press Utility -> Scan Assistant.

    c. Select Import from the Scan Assistant Manager page.
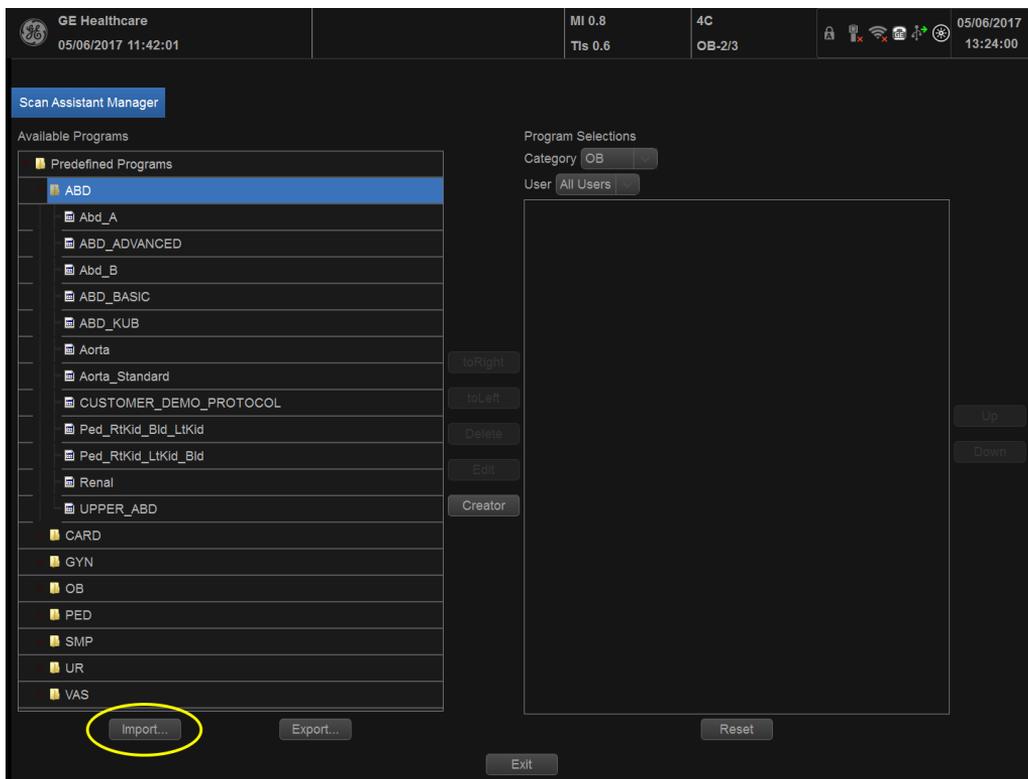
Figure 2-19.   Import Programs

d. In the Source field at the top of the Import Programs pop-up, select the media that the Program is stored on.

Setting up Scan Assistant (continued)

e. Select the Program(s) to be imported. If a folder is selected, all programs in the folder will be imported.
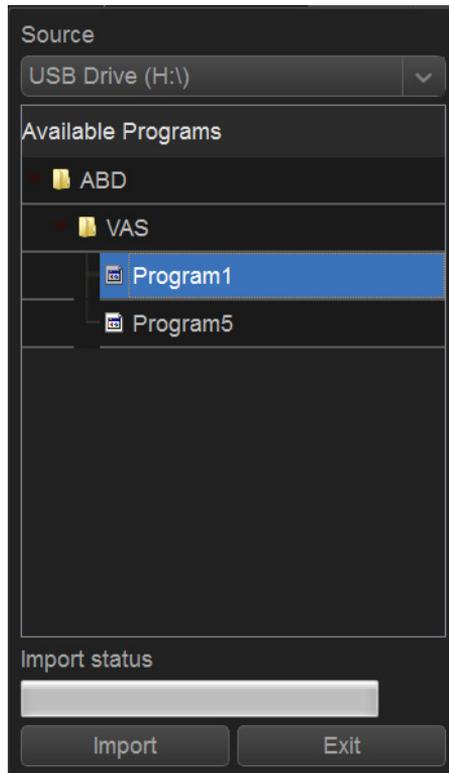
Figure 2-20.   Import Programs

Setting up Scan Assistant (continued)

f. Select Import. The Program(s) you selected are stored to the Versana Essential. Select **Exit**. Then you can add it to the exam category and user.
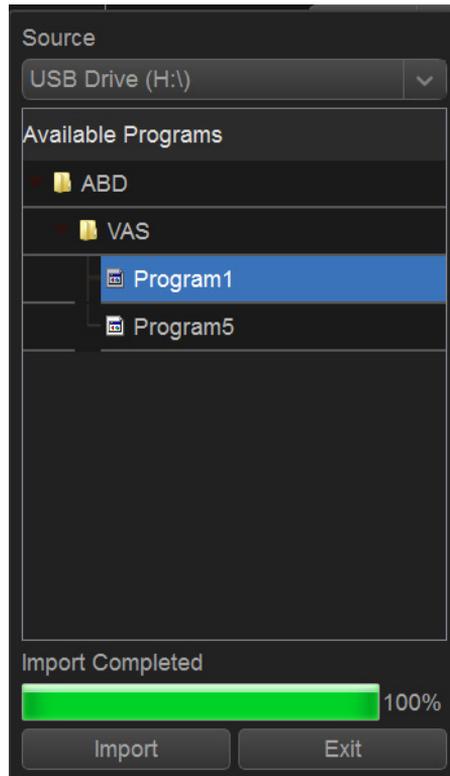
Figure 2-21.   Import Completed

Setting up Scan Assistant (continued)

2. Assign the imported Program to the exam category and user. Under Program Selections on the right-hand side of the Scan Assistant Manager page, specify the Exam Category and User for this Program. You can select All Users, or a specific user. If you specify All Users, all users will have the ability to use this Program while in the specified exam category, unless the user has his/her own list defined.

3. Select the imported Program from Available Programs -> Custom Programs on the left-hand side of the page. Then press the right arrow button to move the imported Program to the exam category and user selected above.
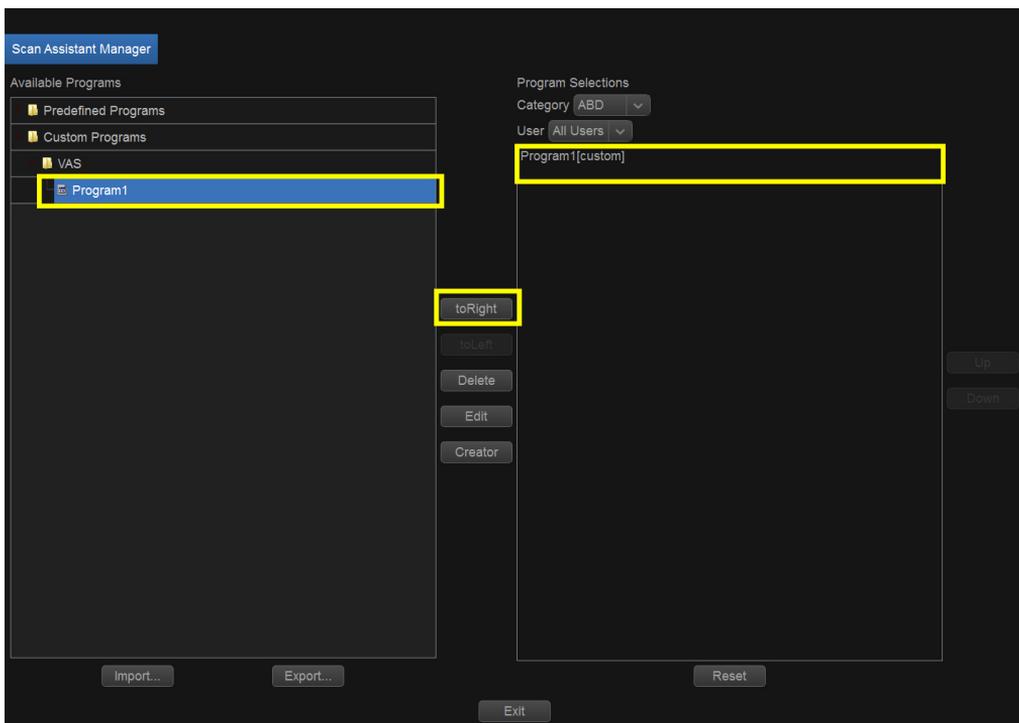
Figure 2-22.   Add Program

Setting up Scan Assistant (continued)

You can access the Scan Assistant Creator to edit the exam's program from the imaging display via the Creator Icon located at the bottom of the Scan Assistant Program monitor on the display. You can activate the Scan Assistant Creator from the image screen, make edits, and then run Scan Assistant to test your changes.

NOTE: *If you edit the program after you have already stored several images, and your edits change the number of program steps, you are prompted to Restart or Continue the Scan Assistant program.*

NOTE: *If you edit the program after you have already completed several steps, checkmarked steps remain checkmarked, even if you insert a new step between checkmarked steps. If this is not correct, you can edit the checkmarks or restart the program.*

Using Scan Assistant

After you have set up Scan Assistant, the Program is active when you exit the Patient menu. The Program is located on the left-hand side of the display and as you can see in the example below, the annotation for the first step has been automatically noted on the image, ready for you to scan the specified anatomy.
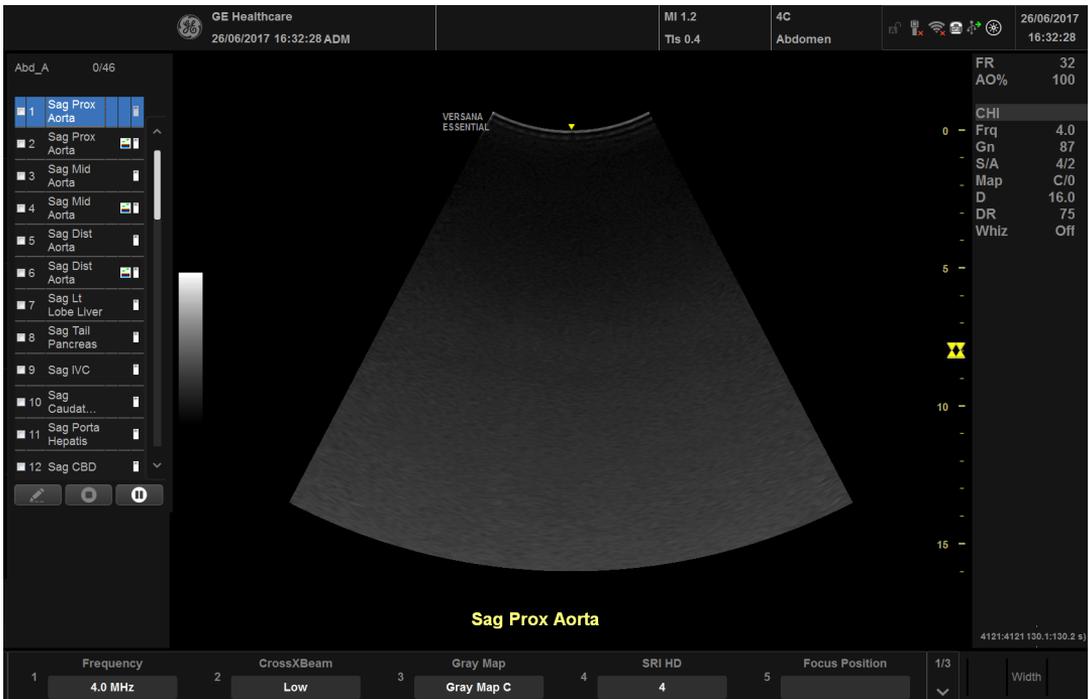
Figure 2-23.   Scan Assistant Display

Using Scan Assistant (continued)

1. Follow the steps indicated in the Program: image/measure the appropriate anatomy.

2. Perform the indicated trigger to move to the next step in the Program.

NOTE: *The footswitch can be used with Scan Assistant. You can map Pause/Resume, Previous Step, and Next Step to the footswitch.*

3. To pause or unpause Scan Assistant, press the pause button on the display.

4. To stop or restart a Program, press the Stop icon at the bottom of the Scan Assistant Program. A dialog pops up. This dialog lets you restart the current Program, start another Program, or stop Scan Assistant.

5. To skip a step or move to a certain step, press the up/down arrows on the keyboard or select the step you want to move to using the Trackball and Set keys.

Exporting Scan Assistant Programs

Exporting Scan Assistant Programs allows them to be imported to another Versana Essential or to be edited offline with the Scan Assistant Creator tool. To export a Program,

1. Insert the media to save the Program.
2. Press Utility -> Scan Assistant.
3. Select Export from the Scan Assistant Manager page.
4. In the Source field at the top of the Export Programs pop-up, select the media that the Program is to be stored on.
5. Specify the Program Directory using the drop-down menu if the desired Program Directory already exists on the media. If not, or if you want to export the Program to a new Program Directory, type a new Program Directory name in the field.
6. Select the Program(s) to be exported. If a folder is selected, all programs in the folder will be exported.
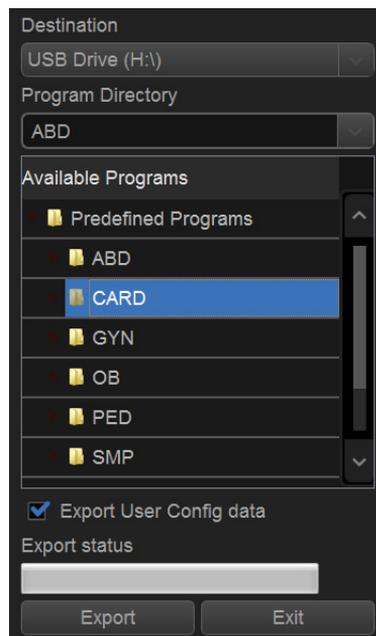
Figure 2-24.   Export Programs

7. Select Export. The Program(s) you selected are stored to the media. You can now import it to a new Versana Essential.

My Trainer

Overview

My Trainer provides a quick guide to operate the system.

To access My Trainer,

1. Press Alt + H to enter My Trainer.

    Or,

    Press Utility -> System -> User Configurable Key. Check Enable Numeric Key, then set **My Trainer** in the Keyboard Key or User Defined Key.
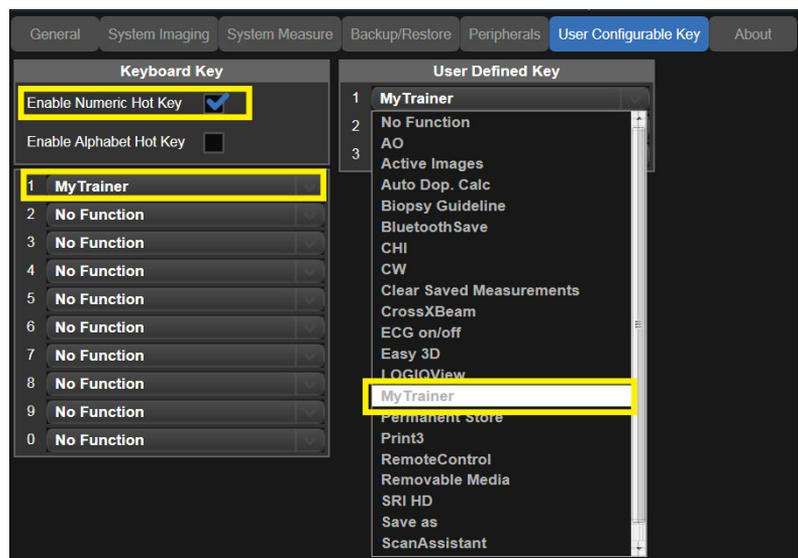
Figure 2-25.   Set My Trainer

2. Press defined key to access My Trainer.

Overview (continued)

There are five sections in My Trainer. The five sections are displayed on the left side of the My Trainer interface.
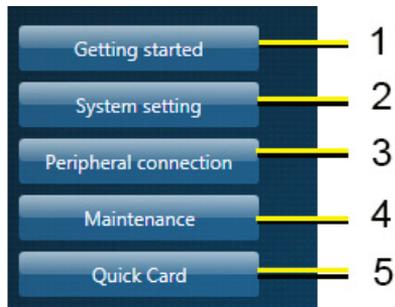
Figure 2-26.   Sections Display

1. Getting Started: Circuit breaker, Probe Connection.
2. System Setting: Facility name set up, Date time set up, Enable options check, Language setting, User conf, User preset.
3. Peripheral Connection: Back panel ports, Network Connectivity, Connect to a printer, DICOM setting, Back-up/ restore the patient information, software version.
4. Maintenance: Trackball, Contact GE service, Connect to Insite, Log export, Air Filter Replacement.
5. Quick Card: Control Panel Overview, Entering Patient Data, Selecting a Probe/Application, Measurements, Annotating an Image, Adjust Color ROI, Pulsed Wave Doppler, Split Screen, End Exam, About GE Healthcare.

Overview (continued)
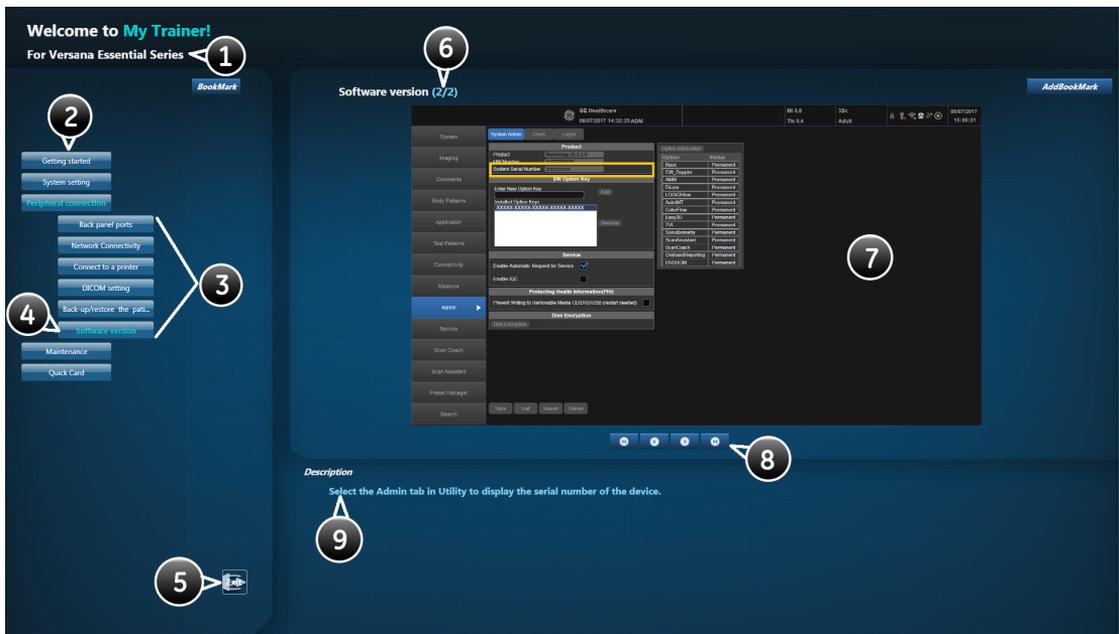
Figure 2-27.   Interface Illustration

The interface of the My Trainer includes below information:

1.   The product name of the system.

2.   Sections. Select the button to expand the section to show the list of subsections.

3.   Subsections.

4.   The highlighted subsection shows this subsection is currently opened and displayed on the right side.

5.   Exit. Press this button to exit this interface.

6.   The left number shows the current page of the subsection. The right number shows the total pages of the subsection.

7.   Illustration with graphic.

8.   Text instruction about how to operate.

Table 2-6:   Page turning

	Select the arrow to go to the previous page

Table 2-6:   Page turning

	Select the arrow to move to the next page.
	Select the arrow to go to the home page .
	Select the arrow to go to the end page.

SonoBiometry (AFB)

SonoBiometry (AFB)

SonoBiometry (AFB) is an alternative to the common fetal biometry measurements. It provides system suggested measurements for AC, BPD, FL and HC which need to be confirmed by the user or can be changed manually.

Table 2-7:   List of Abbreviations

Abbreviation	Full Form	Definition
AC	Abdominal Circumference	Abdominal Circumference of the baby's abdomen
BPD	Biparietal Diameter	Transverse distance between the protuberances of the two parietal bones of the skull
FL	Femur Length	The length in centimeters of the developing baby's femur (the femur is the long bone in the human thigh)
HC	Head Circumference	Head Circumference of the baby's head

SonoBiometry (AFB) (continued)

Using SonoBiometry (AFB)

1. Press *Utility* and then select System.

2. Select System Measure.

3. Check the desired boxes under SonoBiometry (AFB) Option Selection to enable system suggested measurements.
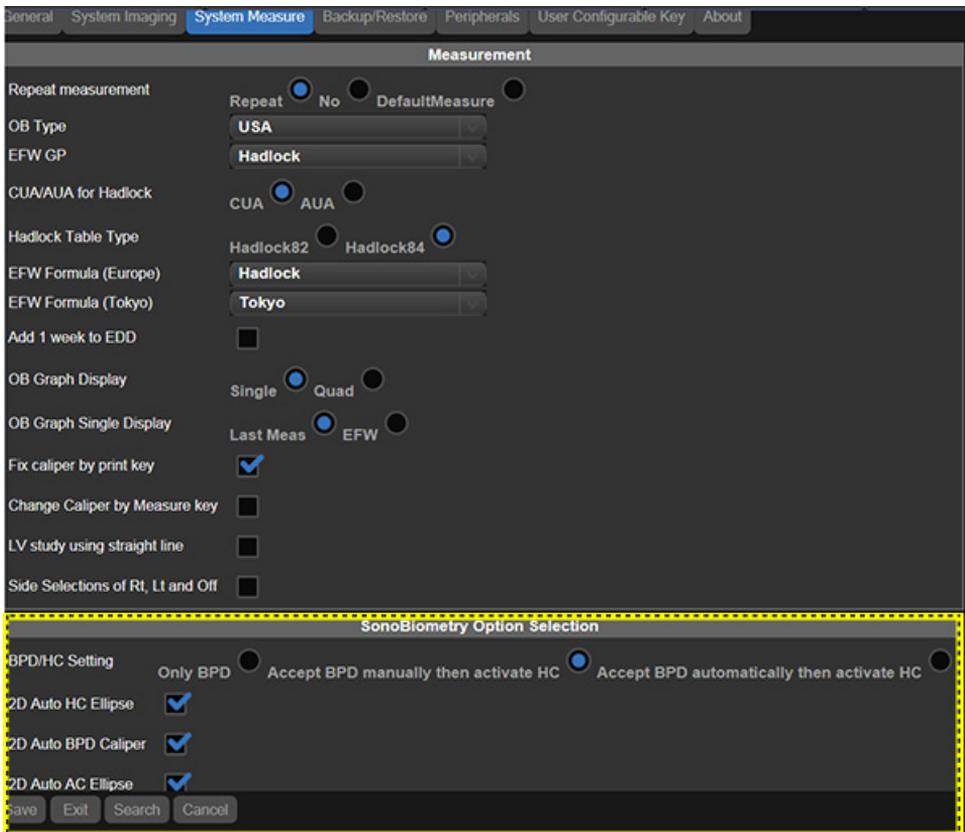
Figure 2-28.   SonoBiometry (AFB) checkboxes

Using SonoBiometry (AFB)

- Select OB.
- Press **Measure**.
- Select BPD/HC/AC/FL.

Figure 2-29.   SonoBiometry (AFB) option

NOTE: *SonoBiometry (AFB) measurements are supported on only recalled raw DICOM images and frozen images.*

Using SonoBiometry (AFB) (continued)

You can not use SonoBiometry (AFB) measurements on the following images:

- Images displayed in Dual/Quad view. In these views, an SonoBiometry (AFB) measurement will change to manual measurement automatically.
- Zoomed image.
- Rotated image.

NOTE: *If a particular scanned image does not have valid fetus data, a warning message appears: "Auto measurement failure. Adjust calipers manually ...".*

NOTE: *If a particular image is not supported for SonoBiometry (AFB) measurement, a warning message appears: "Auto measurements do not operate on DICOM images. Using manual measurement ...".*

Measurement and Analysis

Introduction

Measurements and calculations derived from ultrasound images are intended to supplement other clinical procedures available to the attending physician. The accuracy of measurements is not only determined by system accuracy, but also by the use of proper medical protocols by the user. When appropriate, be sure to note any protocols associated with a particular measurement or calculation. Formulas and databases used within the system software that are associated with specific investigators are so noted. Be sure to refer to the original article describing the investigator's recommended clinical procedures.

⚠ WARNING

The system provides calculations (e.g estimated fetal weight) and charts based on published scientific literature. The selection of the appropriate chart and clinical interpretation of calculations and charts is the sole responsibility of the user. The user should consider contraindications for the use of a calculation or chart as described in the scientific literature. The diagnosis, decision for further examination, and medical treatment must be performed by qualified personnel following good clinical practice.

Location of Measurement Controls

Figure 2-30.   Locating Measurement Controls

1. **Clear**. During a measurement sequence, erases the measuring caliper and measurement data from the display. When not performing a measurement sequence, clears all calipers and measurements from the display.

2. **Measure**. Activates a measurement caliper and the calculation package associated with the currently selected preset.

3. **Zoom/Ellipse**. To Zoom an image, rotate **Zoom** clockwise. After the first caliper for a distance measurement has been set and the second caliper positioned, **Ellipse** activates the area/ellipse measurement function. During the ellipse adjustment, use the **Trackball** to increase or decrease the size of the ellipse. Select *Cursor Select* to adjust the measurement calipers.

4. **Set**. Fixes the caliper for measurements and completes the measurement sequence.

5. **Trackball**. Moves the measurement calipers, selects the measurement on the Summary Window.

B-Mode Measurements

Two basic measurements can be made in B-Mode.

- Distance
- Circumference and Area

    - Ellipse Method
    - Trace Method
    - Spline Method
    - Intensity (Echo level) Method

NOTE: *The following instructions assume that you first scan the patient and then press **Freeze**.*

Distance measurement

To make a distance measurement:

1. Press **Measure**.
2. To position the active caliper at the start point, move the **Trackball**.
3. To fix the start point, press **Set**.

    The system fixes the first caliper and displays a second active caliper.
4. To position the second active caliper at the end point, move the **Trackball**.

    A dotted line connects the measurement points, if preset accordingly.
5. To complete the measurement, press **Set**.

    The system displays the distance value in the Results Window.

HINTS

• **Before** you complete a measurement:
  • To toggle between active calipers, adjust **Cursor Select**.
  • To erase the second caliper and the current data measured and start the measurement again, press **Clear** once.

• **After** you complete the measurement:
  • To rotate through and activate previously fixed calipers, adjust **Cursor Select**.
  • To erase all data that has been measured to this point, but not data entered onto reports, press **Clear**.

Circumference and area (ellipse) measurement

You can use an ellipse to measure circumference and area. To measure with an ellipse:

1. Press **Measure**.
2. To position the active caliper, move the **Trackball**.
3. To fix the start point, press **Set**. The system fixes the first caliper and displays a second active caliper.
4. To position the second caliper, move the **Trackball**.
5. Use the Gain control on the Trackball to adjust the **Ellipse** control; an ellipse with an initial circle shape displays.
6. To position the ellipse and to size the measured axes (move the calipers), move the **Trackball**.
7. To increase or decrease the **Ellipse** adjust the Gain control on the Trackball.
8. To toggle between active calipers, adjust **Cursor Select**.
9. To complete the measurement, press **Set**. The system displays the circumference and area in the Results Window.

HINTS

Before you complete the ellipse measurement:

- To erase the ellipse and the current data measured, press **Clear** once. The original caliper is displayed to restart the measurement.
- To exit the measurement function without completing the measurement, press **Clear** a second time.

Circumference and area (trace) measurement

Trace

To trace the circumference of a portion of the anatomy and calculate its area:

1. Press the **Measure** key in Measure mode to select **Trace**.
2. To position the caliper at the start point, move the **Trackball**.
3. To fix the trace start point, press **Set**. The caliper changes to an active caliper.
4. To trace the measurement area, move the **Trackball** around the anatomy. A dotted line shows the traced area.
5. To complete the measurement, press **Set**. The system displays the circumference and the area in the Results Window.

Open Trace

To trace the circumference of a portion of the anatomy and calculate its length:

1. Press the **Measure** key in Measure mode to select **Trace**, an active caliper displays.
2. To position the caliper at the start point, move the **Trackball**.
3. To fix the trace start point, press **Set**. The caliper changes to an active caliper.
4. To trace the measurement area, move the **Trackball** around the anatomy. A dotted line shows the traced area.
5. To complete the measurement, press **Set**. The system displays the circumference in the Results Window.

HINTS

Before you complete the trace measurement:

- To erase the line (bit by bit) back from its current point, move the **Trackball** or adjust the **Ellipse** control counterclockwise.
- To erase the dotted line but not the caliper, press **Clear** once.
- To clear the caliper and the current data measured, press **Clear** twice.

Circumference and area (spline trace) measurement

To trace the circumference of a portion of the anatomy and calculate its area:

1. Press the **Measure** key in Measure mode to select *Spline Trace*.

2. To position the first caliper at the start point, move the **Trackball**.

3. To fix the trace start point, press **Set**. The first caliper turns yellow. The second caliper appears at the same position as the first caliper and is green.

NOTE: *When pressing the **Clear** key once, the second caliper disappears and the first caliper is activated.*

*If **Clear** is pressed again, the first caliper disappears and the Spline trace is cancelled.*

4. To position the second caliper, move the **Trackball** and press **Set**. The third caliper appears at the same position.

NOTE: *The **Clear** key functionality is the same as noted in the previous step.*

The spline trace requires at least three points to draw the trace. Continue setting the points of the trace until the desired points are set.

5. Press **Set** again after the last caliper is fixed to finalize the spline trace. All points are removed from the line and the spline trace turns yellow.

NOTE: *Pressing **Set** twice finishes the trace measurement.*

If **Clear** is pressed twice when more than 3 points exist on the trace, all points are removed and the first caliper again displays.

Circumference and area (spline trace) measurement (continued)

Edit the spline trace

1. Select *Cursor Select*. The spline trace changes to green and all points appear on the trace as yellow.

   A pick-caliper appears on the center of the image and the message "Edit spline trace" displays at the bottom of the screen.

NOTE: *The pick-caliper is used to select and move the trace points.*
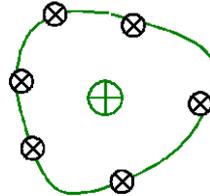
Figure 2-31.   Edit spline trace

Select Cursor Select again. The trace is deactivated (changes to yellow) and all points, including the pick-caliper, are removed.

If the previous/next fixed caliper exists on the image, it is activated.

NOTE: *Pressing **Clear** at this time removes all points and the trace graphic.*

2. Move the pick-caliper to the desired point and press **Set**. The point is activated and turns green.

3. Move the point to the desired position and press **Set**. The point is fixed and turns yellow. The pick-caliper appears on the center of the image.

NOTE: *The spline trace is updated at run time.*

NOTE: *To remove a point, press **Clear** while moving the point. The trace turns green and the remaining points continue to be shown as yellow. If there are less than three points, the spline trace is removed.*

4. Press **Set** again. All points are removed from the trace and the trace is shown as yellow.

Intensity (Echo level) measurement

To make an echo level measurement:

1. Press **the Measure** key in Measure mode to select **Intensity**.
2. To position the first caliper at the start point, move the **Trackball**.
3. To fix the trace start point, press **Set**. The caliper changes to an active caliper.
4. To trace the measurement area, move the **Trackball** around the anatomy. A dotted line shows the traced area.
5. To complete the measurement, press **Set**. The system displays the echo level, as EL __ dB, in the Results Window.

NOTE: *The echo level measurement is only available on a frozen image, not on a B-paused image.*

NOTE: *Echo Level is not available through the factory default. To enable echo level, modify the Measure Key Sequence preset, found in the Utility -> Measure -> Advanced preset.*

Doppler Mode Measurements

Basic measurements below can be made in Doppler Mode.

• Velocity

• TAMAX and TAMEAN (Manual or Auto Trace)

• Two Velocities with the Time Interval and Acceleration between them

• Time Interval

• Volume Flow

NOTE: *The following instructions assume that you do the following:*

1. In the B-Mode part of the display, scan the anatomy you want to measure.
2. Go to the Doppler Mode part of the display.
3. Press **Freeze**.

Velocity

To measure velocity:

1. Press **Measure**; an active caliper with a vertical dotted line displays.
2. To position the caliper at the desired measurement point, move the **Trackball**.
3. To complete the measurement, press **Set**. The system displays the velocity measurement in the Results Window.

TAMAX and TAMEAN

Manual Trace

The value measured depends upon the Vol Flow Method preset. The two selections available are: Peak (TAMAX) and Mean (TAMEAN).

To do a manual trace of TAMAX or TAMEAN:

1. Press **Measure** key in Measure mode to select *Trace*.

   Select **Manual** or in the Utility -> Measure - Advanced preset menu set **Trace** preset to **Manual**.

2. To position the caliper at the trace start point, move the **Trackball**.

3. To fix the start point, press **Set**.

4. To trace the maximum values of the desired portion of the spectrum, move the **Trackball**.

   NOTE: To edit the trace line, move the **Trackball**.

5. To complete the measurement, press **Set**. The system displays the measurement values in the Results Window.

TAMAX and TAMEAN (continued)

Auto Trace

The value measured depends upon the Vol Flow Method preset. The two selections available are: Peak (TAMAX) and Mean (TAMEAN).

To auto trace TAMAX:

1. Press **Measure** key in Measure mode to select *Trace*.

   Select **Auto** or in the Utility -> Measure - Advanced preset menu set **Trace** preset to **Auto**.

2. To position the caliper at the trace start point in the Doppler spectrum, move the **Trackball**.

3. To fix the start point, press **Set**.

4. To position the vertical caliper at the end point, move the **Trackball**.

5. To complete the measurement, press **Set**. The system automatically fixes both calipers and traces the maximum value between the two points. The system displays this value in the Results Window.

NOTE: *When you set the Auto Trace for Both (above and below), the system picks up the maximum power of the signal, NOT the maximum velocity. If the maximum velocity is not the maximum power, the system may not trace accurately. If you want to use maximum velocity, select either Above or Below.*

Slope (Velocity, Time Interval and Acceleration)

To measure two velocity values, the time interval (ms), and acceleration (m/s^2):

1. Press **Measure** to select *Slope*. An active caliper with vertical and horizontal dotted lines displays.
2. To position the caliper at the start point, move the Trackball.
3. To fix the start point, press **Set**. The system fixes the first caliper and displays a second active caliper.
4. To position the second caliper at the end point, move the Trackball.
5. To complete the measurement, press **Set**. The system displays the two peak end point velocities, the time interval, and the acceleration in the Results Window.

Time interval

To measure a horizontal time interval:

1. Press **Measure** to select *Time interval*. An active caliper with vertical and horizontal dotted lines displays.
2. To position the active caliper at the start point, move the **Trackball**.
3. To fix the start point, press **Set**. The system fixes the first caliper and displays a second active caliper.
4. To position the second caliper at the end point, move the **Trackball**.
5. To complete the measurement, press **Set**. The system displays the time interval between the two calipers in the Results Window.

M-Mode Measurements

Basic measurements that can be taken in the M-Mode portion of the display are:

• Tissue Depth (Distance)
• Time Interval
• Time Interval and Velocity

NOTE: *The following instructions assume that you do the following:*

1. In the B-Mode part of the display, scan the anatomy you want to measure.
2. Activate M-Mode.
3. Press **Freeze**.

Tissue depth

Tissue depth measurement in M-Mode functions the same as distance measurement in B-Mode. It measures the vertical distance between calipers.

1. Press **Measure** once; an active caliper with a vertical and horizontal dotted line displays.
2. To position the active caliper at the most anterior point you want to measure, move the Trackball.
3. To fix the start point, press **Set**.

   The system fixes the first caliper and displays a second active caliper.
4. To position the second caliper at the most posterior point you want to measure, move the Trackball.
5. To complete the measurement, press **Set**.

   The system displays the vertical distance between the two points in the Results Window.

Time interval

To measure a horizontal time interval and velocity:

1. Press **Measure** to select Time; an active caliper with vertical and horizontal dotted lines displays.
2. To position the caliper at the start point, move the **Trackball**.
3. To fix the first caliper, press **Set**. The system fixes the first caliper and displays a second active caliper.
4. To position the second caliper at the end point, move the **Trackball**.
5. To complete the measurement, press **Set**. The system displays the time interval between the two calipers in the Results Window.

Slope (Time interval and Velocity)

To measure time and velocity between two points:

1. Press **Measure** to select *Time interval*. An active caliper with vertical and horizontal dotted lines displays.
2. To position the active caliper at the start point, move the Trackball.
3. To fix the start point, press **Set**.

   The system fixes the first caliper and displays a second active caliper.
4. To position the second caliper at the end point, move the Trackball.
5. To complete the measurement, press **Set**.

   The system displays time(s) and slope between the two points in the Results Window.

Wide Dual Screen Measurements

To preform measurements in wide dual screen, select measurement item from primary menu.

1. Press **L** and **R** key on the control panel simultaneously to enter wide dual screen.

NOTE: *Ensure that the "Dual Screen" has been selected in the Automitic Wide Screen... portion of the Utility -> System -> System Imaging.*

2. Press **Measure** on the control panel, the Result window displays at the left bottom of the screen. To perform measurement, select measurement item from left measurement list or select measurement item from primary menu at the bottom of screen. To switch from different mode measurement package, press Left/right arrow keys on the Alphanumeric keyboard.

NOTE: *The location of Result Window and measurement item in wide dual screen is different from single screen and dual screen.*
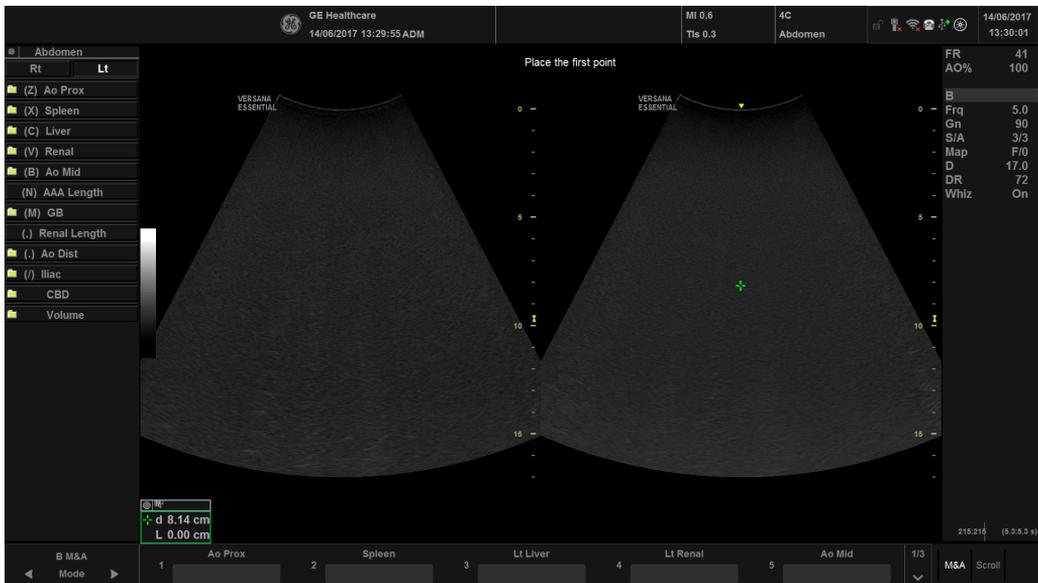
Figure 2-32.   Wide Dual screen measurements

Viewing and Editing Reports

NOTE: *Reports are not saved if the system crashes.*

As you complete measurements, the system puts measurement data in the appropriate reports.

To view a report

To view a report, select *Report* on the control panel.

The system displays the report for the current study.
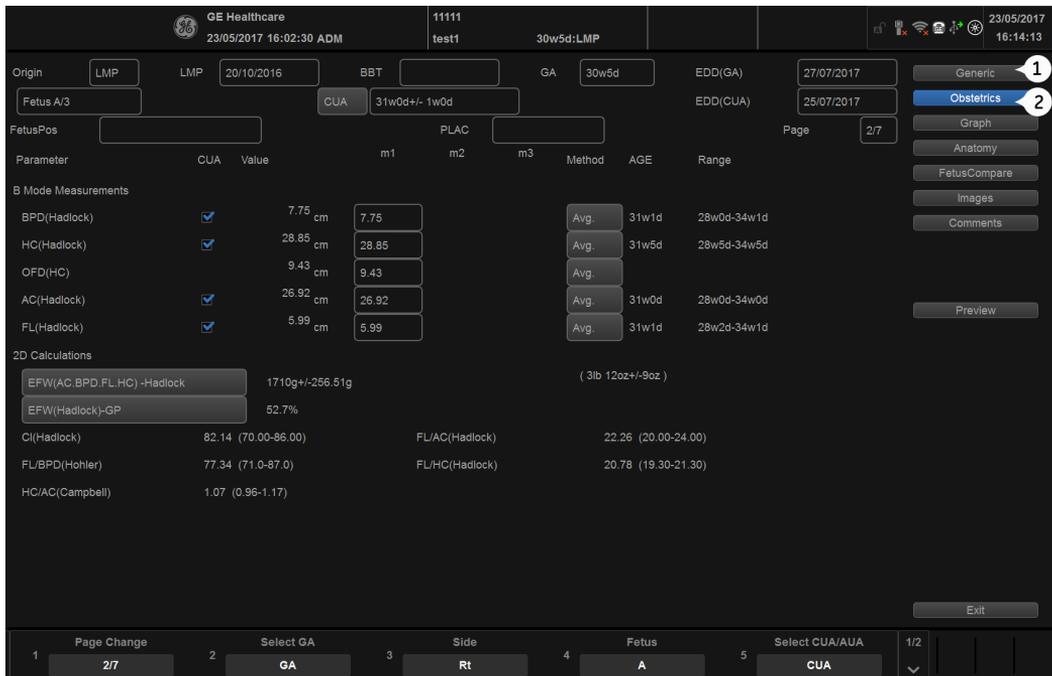
Figure 2-33.   OB B-Mode Report

1. **Generic**: Select to view the generic report.
2. **Obstetrics**: Select to view a particular exam report.

If a report has more data on a second page, to view the next page, adjust the **Page Change** control on the **System Menu**.

To return to scanning, do one of the following:

- Select *Report*.
- Press *Esc*.
- Select the *Exit* button.

To edit a report

To change data on a report:

1. Move the **Trackball** to the field you want to change.
2. Press **Set**.
3. Type the new data in the field. The new data is displayed in blue to indicate that it was manually entered.

To delete or exclude data on a report:

1. Move the **Trackball** to the field you want to delete or exclude, press the **Cursor**. The field is highlighted.
2. Do one of the following:

   • To delete the field, select *Delete Value*.
   • To exclude the field, select *Exclude Value*.

      The data in the field is not visible and is not included in report calculations.

   • To include a value that you previously excluded, select *Exclude Value*.

To type a comment on a report:

1. Select *Comments*. The Comments window opens.
2. Type comments about the exam.
3. To close the Comments window, select other Menu.

To turn the volume measurement value off:

• Select the method type *Off*.

HINTS

Some fields on the report are view only, and others you can change or select. To easily see which fields you can change or select, move the **Trackball**. As the cursor moves over a field that you can change or select, the field is highlighted.

Delete All report Values

You can delete all report values on a report.

1. When the Report is displayed on the monitor, press the **Clear** key.
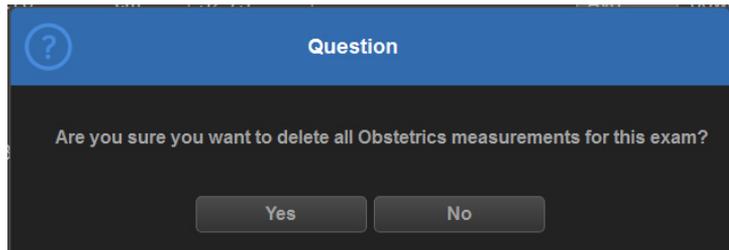
Figure 2-34.   Delete Warning Message

2. Select *OK* to delete all.

   Select *Cancel* to cancel the deletion.

Clinical Measurement Accuracy

Basic Measurements

The following information is intended to provide guidance to the user in determining the amount of variation or measurement error that should be considered when performing clinical measurements with this equipment. Error can be contributed by equipment limitations and improper user technique. Be sure to follow all measurement instructions and develop uniform measurement techniques among all users to minimize the potential operator error. Also, in order to detect possible equipment malfunctions that could affect measurement accuracy, a quality assurance (QA) plan should be established for the equipment that includes routine accuracy checks with tissue mimicking phantoms.

Please be advised that all distance and Doppler related measurements through tissue are dependent upon the propagation velocity of sound within the tissue. The propagation velocity usually varies with the type of tissue, but an average velocity for soft tissue is assumed. This equipment is designed for, and the accuracy statements listed on are based on, an assumed average velocity of 1540 m/s. The percent accuracy when stated applies to the measurement obtained (not the full scale range). Where the accuracy is stated as a percent with a fixed value, the expected inaccuracy is the greater of the two.

Basic Measurements (continued)

Table 2-8:   System Measurements and Accuracies

Measurement	Units	Useful Range	Accuracy	Limitations or Conditions
Depth	mm	Full Screen	<=10%	
Angle	degree	Full Screen	<=5%	
Distance:				
Axial	mm	Full Screen	<5%	
Lateral	mm	Full Screen	<5%	Linear Probes
Lateral	mm	Full Screen	<5%	Convex Probes
Lateral	mm	Full Screen	<5%	Sector Probes
Circumference:				
Trace	mm	Full Screen	<=10%	Linear Probes, Convex Probes, Sector Probes
Ellipse	mm	Full Screen	<=5%	Linear Probes, Convex Probes, Sector Probes
Area:				
Trace	mm^2	Full Screen	<=5%	Linear Probes, Convex Probes, Sector Probes
Ellipse	mm^2	Full Screen	<=5%	Linear Probes, Convex Probes, Sector Probes
Time	s	Timeline Display	<5%	M mode, AM mode, CM mode, PWD mode, CWD mode
Slope	mm/s	Timeline Display	<=10%	M mode, AM mode, CM mode,
Doppler SV Position	mm	Full Screen	<=2 mm	PWD mode
Doppler Velocity	cm/s	Form 0 to 100 cm/s	<15%	PWD mode, CWD mode
		From 100 to 130 cm/s	<10%	
Doppler Angle Correction	cm/s	From 0-80°	<=5%	PWD mode

Setting up the Off-Line Paper Printer

You can connect an off-line paper printer via the USB connection.

⚠	**CAUTION**	ONLY plug in devices to the USB ports of the system WHILE the Versana Essential is NOT powered up. If you plug in a device while the Versana Essential is powered on, your system may become unusable.

⚠	**CAUTION**	DO NOT place an off-line paper printer inside the patient environment. This assures compliance to leakage current.

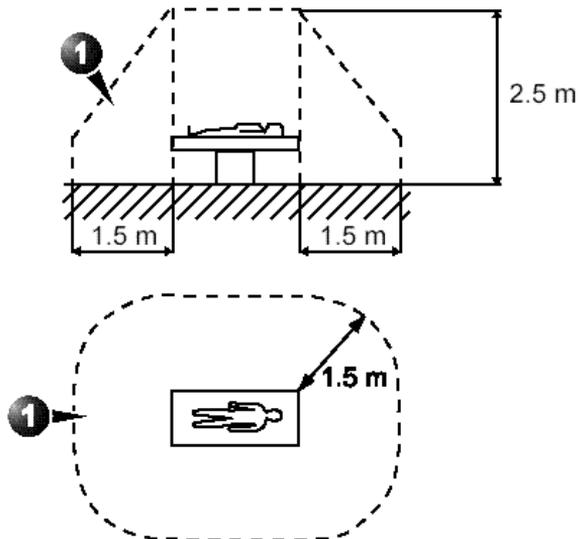|		
⚠	**CAUTION**	**DO NOT** place an off-line paper printer inside the patient environment (within the dotted line area noted by "1" in Figure 2-35). Refer to the off-board printer's manufacture manual for details.

Figure 2-35. Patient Environment

Chapter 3

After The Exam Is Over

System Presets, Data Backup, Configuring Connectivity, Electronic Documentation, Assistance Information, and System Care and Maintenance.

Preset

Overview

Preset Menus provides the following functionality:

- **System presets**. View and update general system configuration settings, measurement settings, backup and restore data and configuration files.
- **Imaging presets**. View and update exam and imaging parameters.
- **Comments presets**. Set up comment libraries by application.
- **Body / Patterns presets**. Set up body pattern libraries by application.
- **Application presets**. Configure application- and user-specific settings.
- **Test Patterns presets**. Helps configure system settings.
- **Connectivity Setup**. Define connection and communication setup, including exam dataflow information.
- **Measure presets**. Customize exam studies, create measurements, set up manual sequencing, and create OB Tables.
- **Reports Presets**. Allows you to edit the report template, diagnosis codes, and report comments.
- **Admin presets**. Perform system administrator activities such as setting up user IDs and logon formats.
- **Service**. Activates the Service Browser.
- **Scan Coach**. Create, import/export, and manage Scan Coach programs.
- **Scan Assistant**. Create, import/export, and manage Scan Assistant programs.
- **Search**. You can search for a parameter on the Utility pages (Measure, Reports, and Service pages cannot be searched.)

To access these functions, select the *Utility* on the keyboard, then select the appropriate menu key.

System Presets

Language Keyboard Setup

NOTE: *You must apply the changes on each setup page before moving to the next page.*

1. In **Utility** -> **System** -> **General**, select Regional Options.

Figure 3-1.   Region Option

Language Keyboard Setup (continued)

2.   Under Formats select desired language.
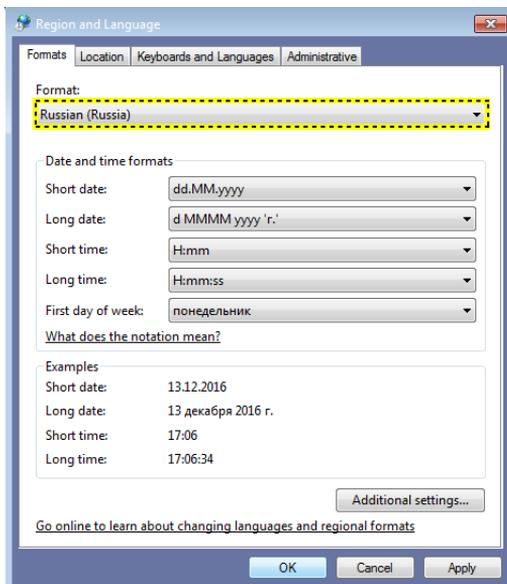
Figure 3-2.   Formats selection

3.   Under Location select desired location.
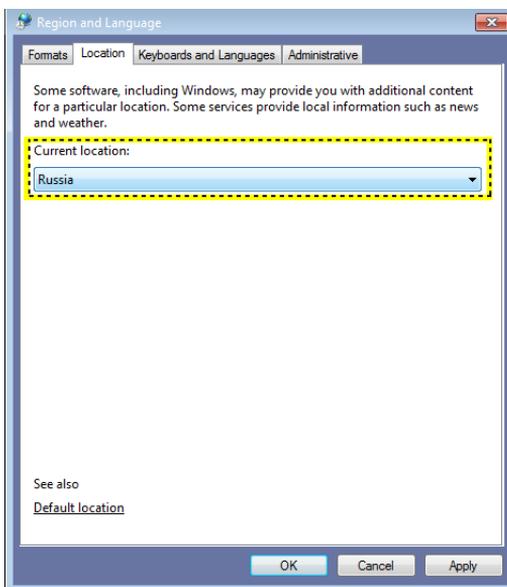
Figure 3-3.   Regional Options

Language Keyboard Setup (continued)

4. Under **Administrative**, select **Change system locale...**.
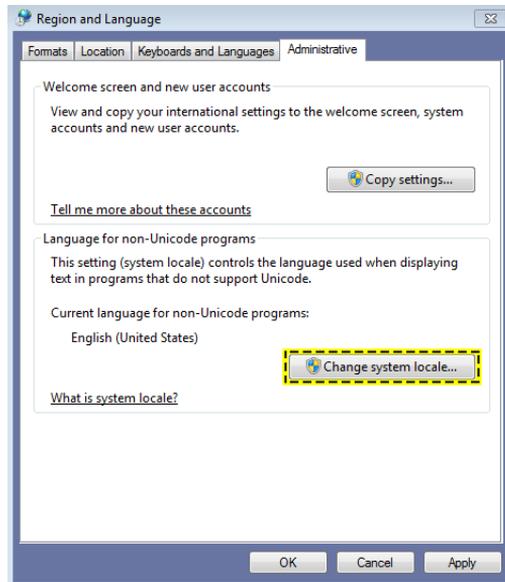
Figure 3-4. Administrative

5. Select **Apply** when below message displays.
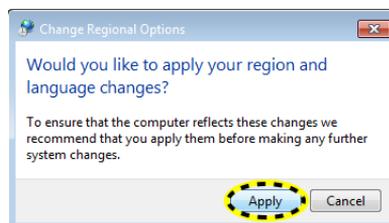
Figure 3-5. Change Regional Options

Language Keyboard Setup (continued)

6. Select the language under **Current system locale**, then select **OK**.
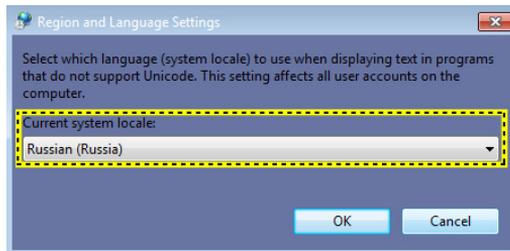
Figure 3-6.   Set Language

7. Select **Cancel** not to restart the system.
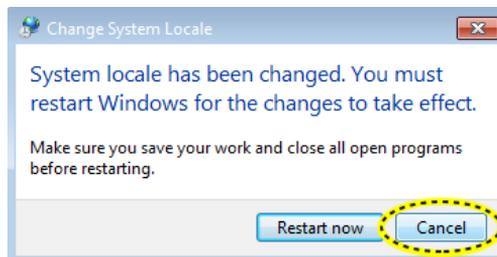
Figure 3-7.   Restart Request

Language Keyboard Setup (continued)

8. In the **Keyboards and Languages** tab, then select **Change keyboards...**.
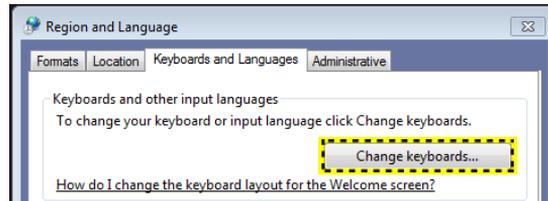
Figure 3-8.   Change Keyboard

9. Select **Add** to add the installed services.
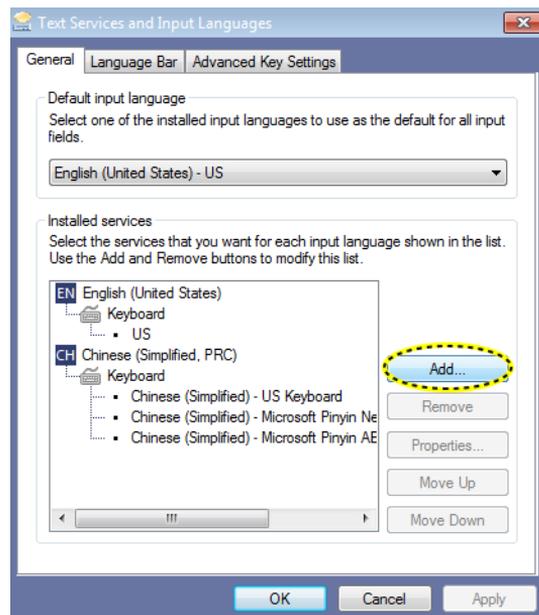
Figure 3-9.   Add Service

Language Keyboard Setup (continued)

10. Select the language using the checkbox before the language and then select **OK**.

    Or select **Preview...** to review the keyboard layout.
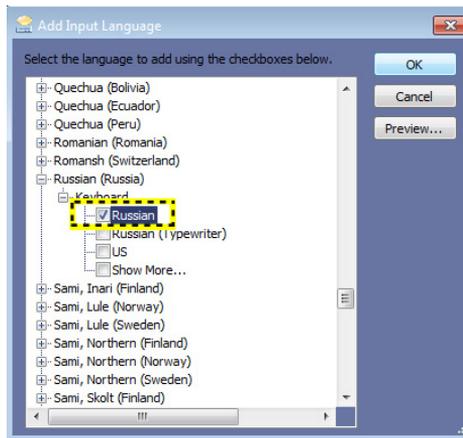
Figure 3-10.   Add Input Language

11. Select the language under Default input language. Select **OK**.
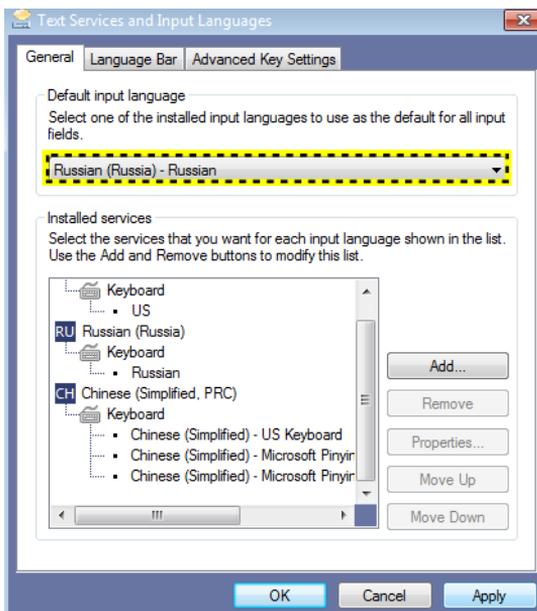
Figure 3-11.   Change the System Language

Language Keyboard Setup (continued)

12. Select **Close** to close the window.
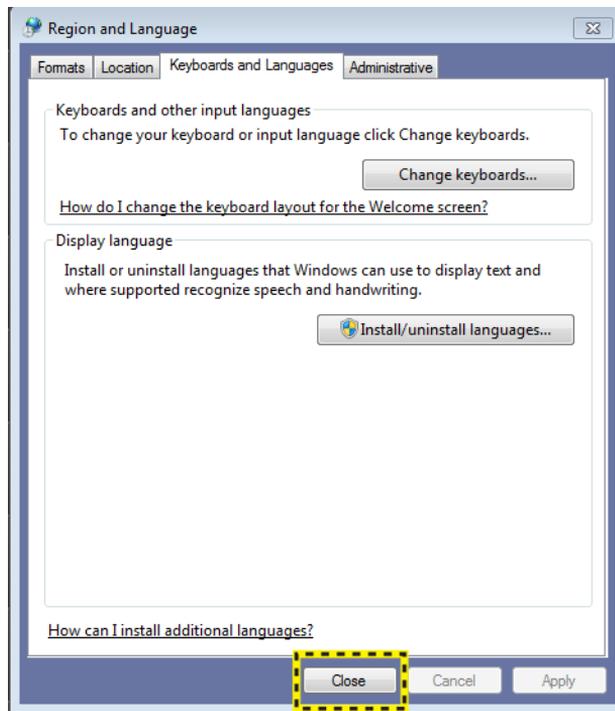
Figure 3-12.   Close Window

13. Select **Cancel** not to restart the system.
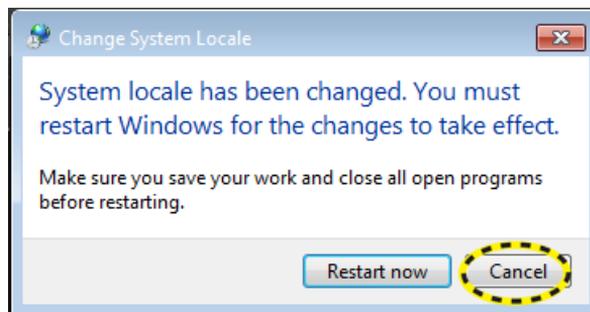
Figure 3-13.   Restart Request

Language Keyboard Setup (continued)

14. In **Utility** -> **System** -> **General**, select the language as desired, and then select **Save**.
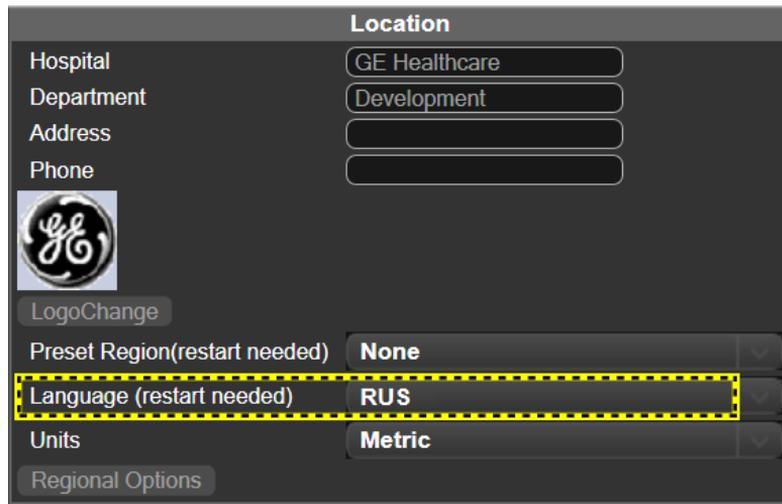
Figure 3-14.   Change the System Language

15. The system will indicate to restart the system, select **OK** to continue.
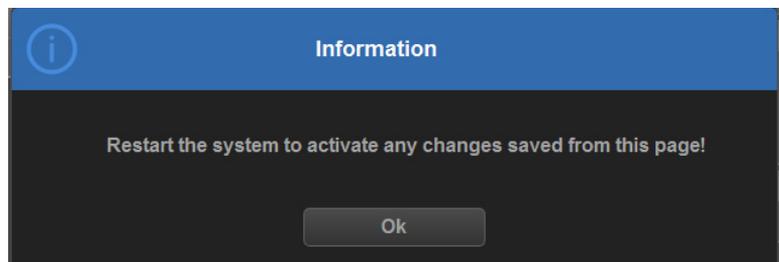
Figure 3-15.   Information Window

16. When the system boots up, the system appears in the selected language.

NOTE: *To have the settings take effect, you **MUST** restart the system.*

NOTE: *Press Ctrl+Shift to change the input method, press Alt+Shift to change the input language.*

Data Backup

The backup and restore procedures described in this section are divided into two parts. The first part describes procedures to backup and restore patient data. The second part describes procedures to backup and restore system and user-defined configurations.

The Backup/Restore function enables the user to:

• Copy/Restore the patient archive.
• Copy/Restore the system configuration. The Copy/Restore system configuration feature enables the user to configure several units with identical presets, providing that the units have the same software version.

Depending on the system, you can use either a CD-R, DVD-R, USB Flash Drive, or USB Hard Disk for system backup/restore. For the sake of simplicity, we have used the CD-R in the following examples.

NOTE: *The system ONLY supports CD-R / DVD-R and DOES NOT support CD-RW / DVD+R.*

⚠ WARNING GE is not responsible for lost data if the suggested backup procedures are not followed and will not aid in the recovery of lost data.

⚠ WARNING The Versana Essential is not intended to be used as a storage device; backup of the Patient and Image Database is your institution's responsibility. GE is NOT responsible for any lost patient information or for lost images.

⚠ WARNING The system crash can cause the HDD corruption.The HDD is not considered a permanent storage device. Backup data on a regular basis.

Data Backup (continued)

> ⚠ CAUTION   To minimize accidental loss of data, perform EZBackup and Backup on a regular basis.
>
> 1. First, perform EZBackup to save the images.
> 2. Next, perform Backup at ***Utility -> System -> Backup/ Restore***. Enable the following checkboxes under Backup:
>
>   •   Patient Archive
>   •   Report Archive
>   •   User defined configuration
>   •   Service

> ⚠ CAUTION   Archived data is managed at the individual sites. Performing data backup (to any device) is recommended.

> ⚠ CAUTION   Make sure to verify the media after writing of data, such as EZBackup, SaveAs or Export.
>
> Verifying media requires additional time, which varies depending on the amount of data backed up or exported.

> ⚠ CAUTION   Before deleting a patient or image from the patient screen, make sure you have saved the data by EZBackup/Backup or Export and verify that the media transfer of data was successful.

EZBackup and EZMove

EZBackup or EZMove allows you to manage hard disk space (move images off the hard drive) while maintaining the patient database on the scanner, as well as to back up the patient database and images.

- **EZBackup**: Copy the data from the local HDD to the removable media.
- **EZMove**: Copy the data from the local HDD to the removable media. After copying the image file to the media, EZMove deletes the image file from the Local HD.

HINTS   PLEASE READ THIS

Ensure that you have established a data management protocol for your office/institution. You MUST manage the backup media by keeping a log and by creating a media filing system.

For example, if you need to back up 500 MB/day, or 2.5 GB/week, then you need to back up 5 CDs/week, or ~250CDs/year.

Generally speaking, you should back up the system when you have 10 GB of images to back up.

You should assign the person who is in charge of performing the backups. Backups will vary by the volume of your work. You need to track how long it takes your office/institution to get to 10 GB, and set the back-up parameters accordingly.

Your office/institution needs to determine your backup strategy, for instance, backup weekly and move monthly. It should be an easy strategy to perform and to remember. And follow this same strategy/schedule consistently.

It's also useful to keep your more recent information on the hard drive since it's easier to recall that way.

EZBackup and EZMove (continued)

⚠ CAUTION   You can still do a backup/move daily; but ALWAYS do a patient
               archive backup after each move.

⚠ CAUTION   Only cancel the backup/move in case of an emergency. The
               system completes backing up the current media and then
               cancels the operation.

⚠ CAUTION   When EZBackup requires more than one disk (CD-R or
               DVD-R) for backup, a message appears when the first disk is
               full. If you select "Cancel" to stop the backup procedure and
               later try EZBackup again, all the data may not be backed up.

               Select "Full Backup" on the first EZBackup wizard screen if the
               last time you were performing EZBackup you selected
               "Cancel".

⚠ CAUTION   If you use EZBackup or EZMove as a "true" patient archive,
               you must maintain a separate backup of the patient database
               (Patient Archive and Report Archive). If for any reason the
               Local Archive - Int HD gets corrupted or the base system
               software has to be reloaded, then the patient archive is the
               ONLY way to rebuild the EZBackup and EZMove patient
               archive.

⚠ CAUTION   DO NOT turn off the power while EZBackup is running. The
               data may be lost. It may take several hours for EZBackup to
               finish, depending on the amount of data being backed up.

               The following may give the impression of a lockup, but
               EZBackup is continuing in the background.

               •   The progress bar does not move.
               •   The screen may become white.
               •   The hourglass icon keep turning.

EZBackup and EZMove (continued)

⚠ CAUTION   NEVER restore the patient archive from media made previous to the last move.

NOTE: *EZBackup/EZMove saves data as RAW data. If you import data to the system, you can modify the image data.*

NOTE: *To display exported Raw DICOM images on a PC, you need the dedicated viewer.*

NOTE: *When backing up or moving reports, do not use EZBackup or EZMove, EZBackup or EZMove cannot back up or move reports.*

NOTE: *"Archived" information is saved to each exam during EZBackup. When you perform EZBackup, the system backs up the exams except for the archived exam.*

NOTE: *EZBackup/EZMove cannot span a single image across two (2) or more media. Therefore, if EZBackup/EZMove encounters an image that is greater than the capacity of the media, it skips the oversized image.*

NOTE: *EZBackup/EZMove does not store images to media in sequential order. Instead it maximizes the most amount of images per media.*

NOTE: *If the system locks up during the media auto format process, shutdown the system by holding down the power button and reboot the system. After the system is up, replace the media to a new one and execute EZBackup or EZMove again. To avoid trouble such as data loss, do not reuse the failed media for any other function.*

NOTE: *If you try exporting a previously backed-up exam, the message "Can't Find Source file" displays. The image data had already been removed from the hard disk drive with EZBackup/EZMove.*

EZBackup and EZMove (continued)

Basically, when you perform the EZBackup or EZMove procedure, you insert the media (or connect USB HDD if applicable), the system backs up/moves the images, and creates a reference between the patient database and the media's volume.

EZBackup/EZMove can take up to 20 minutes (or longer, depending on the size of the backup). Make sure to schedule this at the same time daily, when no patients are scheduled.

1. Prepare unformatted media or the USB HDD before starting EZBackup/EZMove.
2. Specify the EZBackup/EZMove setup on the Utility --> System --> Backup/Restore page.
3. To start the EZBackup/EZMove procedure, go to the **Patient** menu and select EZBackup/EZMove. The EZBackup/ EZMove Wizard starts.

NOTE: *If you use the USB HDD, some wizards and the pop-up messages DO NOT appear.*

EZBackup and EZMove (continued)

4. Verify the information on the first page of the EZBackup/ EZMove Wizard, then press *Next*.

   Full backup options display on the first page of the EZBackup wizard. If you want to backup all of the exams in the range (even if the exam was previously backed up, check this option). If you uncheck this option, the system only backs up exams which have not yet been backed up.

   EZBackup does not back up the exams which were previously backed up once by EZBackup or Export.

NOTE: *You can set the range in Utility --> System --> Backup/ Restore --> Move files older than in days for EZMove.*

NOTE: *If you update an exam which is already backed up, the exam is also backed up.*
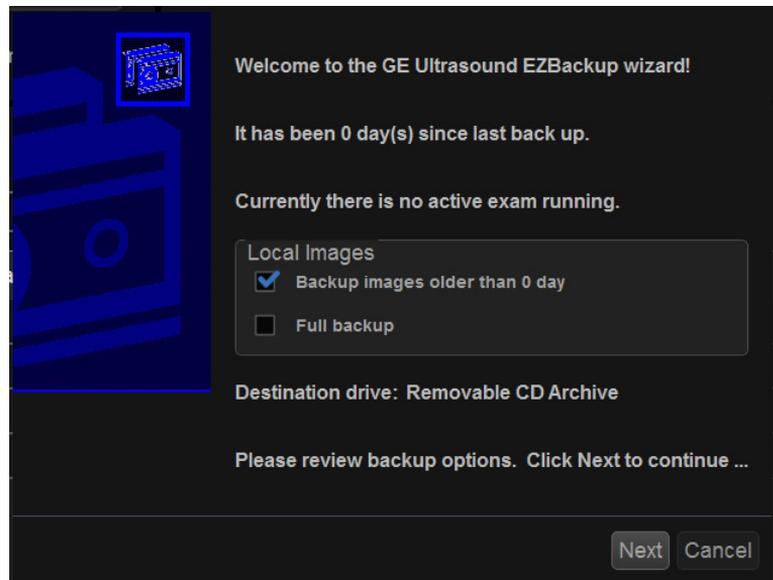
Figure 3-16.   EZBackup/EZMove Wizard, Page 1

EZBackup and EZMove (continued)

5. Verify the information on the EZBackup/EZMove Wizard, Page 2. The backup may span multiple media. This page tells you how many media you need to do this backup. After you have gathered the media (allow for one extra media, just in case), you are ready to begin the backup. Press *Next*.

    Free Space/Total Size: tells you the size of the data you have selected to store/and the total size of the USB Hard Drive storage media. If the storage capacity of the USB HD is insufficient, you will see the message, "Selected Location does not have enough free space."

NOTE: *The calculation for the number of backup CD is only an estimate. Allow for one additional CD when performing an EZBackup/EZMove.*

NOTE: *This message appears if you press Next without inserting the backup media: "Please insert a blank media...". Insert the media and continue.*
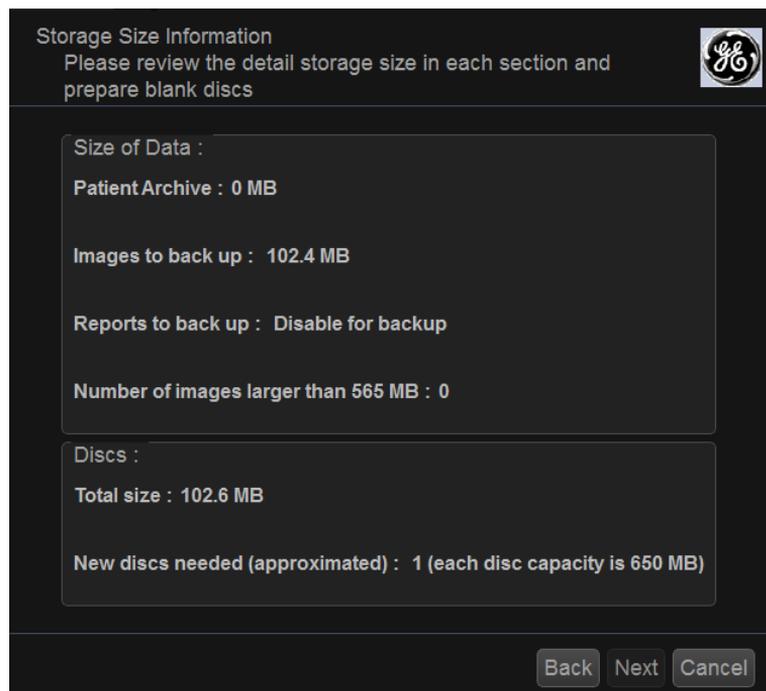
Figure 3-17.   EZBackup/EZMove Wizard, Page 2

EZBackup and EZMove (continued)

6. A pop-up message appears that provides you with the media label. Label the media, then insert the media. Press *OK*.

Please insert a blank media (it will be labeled as 20170615_01) in CDRW drive.

ALL DATA IN THE MEDIA WILL BE ERASED.

Click OK to continue and CANCEL to quit backup.

Ok   Cancel
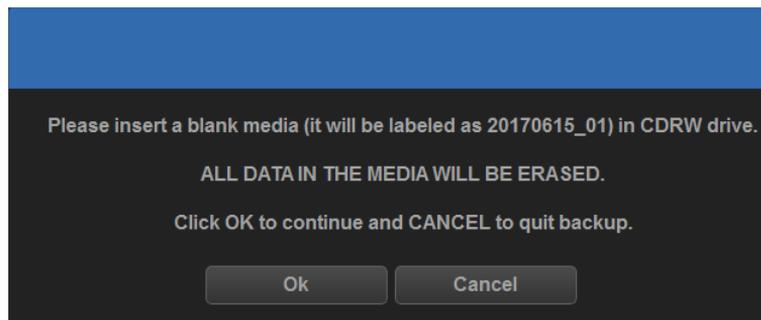
Figure 3-18.   Insert Media Message

a. Ensure that you label the media with not only the volume name indicated on the Insert Media Message, but with the name of the Versana Essential system where this backup/move procedure was done.

b. Update the EZBackup/EZMove log with this information the volume information and the location of the media.

c. After the backup/move has been completed, file the media.

Table 3-1:   Typical EZBackup/EZMove Log

Date	Scanner ID Name	Backup Images Y/N	Older than __ Days	Move Images Y/N	Media Label (and Scanner ID)

EZBackup and EZMove (continued)

7. A pop-up window shows the system is checking whether the media is inside the drive.
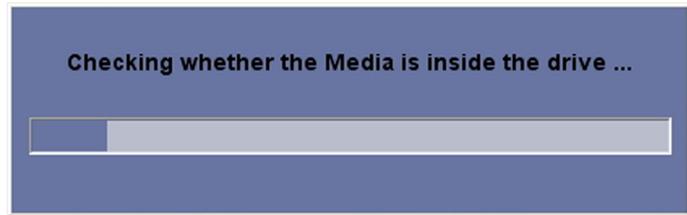
Figure 3-19.   Check Media

-   If the media is in the drive, the window automatically disappears when the checking is completed. The EZBackup progress then begins.
-   If the media is not in the drive, a pop-up message appears notifying that there is no media in the drive. Press OK.
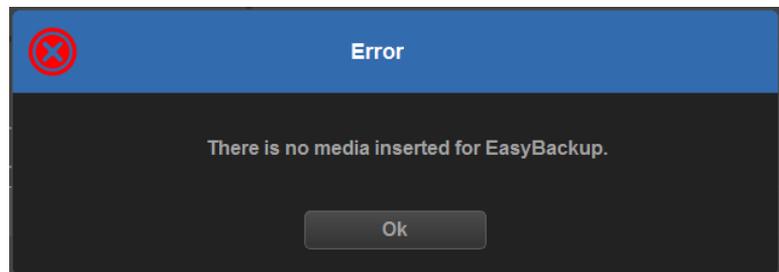
Figure 3-20.   Insert Disc Error

A pop-up message appears that provides you with the media label. Label the media, then insert the media. Press *OK*.

EZBackup and EZMove (continued)

8. The status menu appears. When the backup/move has been completed, press **Next**.
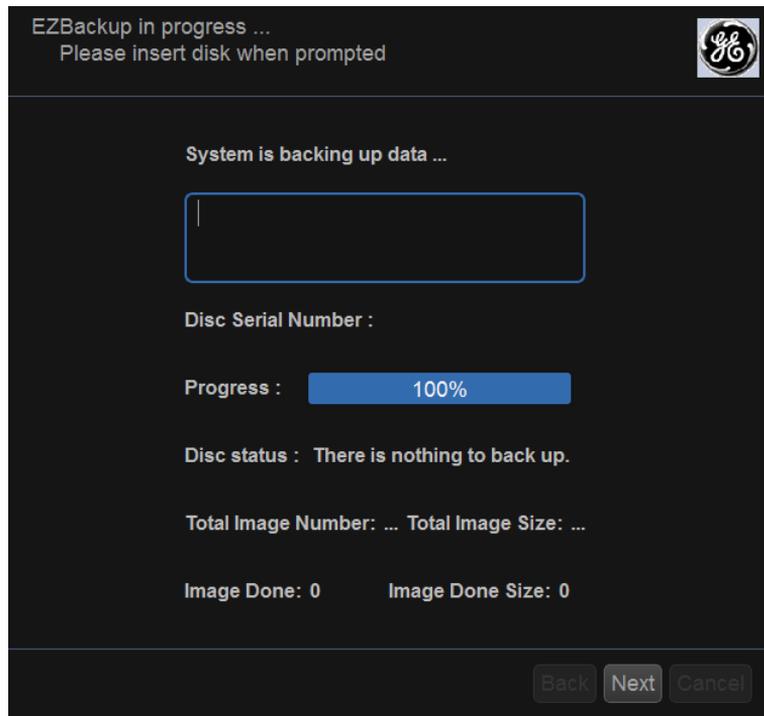
Figure 3-21.   EZBackup Wizard Page 3

NOTE: *When/if you need to insert the next media, a message appears providing you with the media label. Label the media, then insert the next media and press OK.*

EZBackup and EZMove (continued)

9. When the backup is complete, the completed wizard page appears. Press ***Finish***.
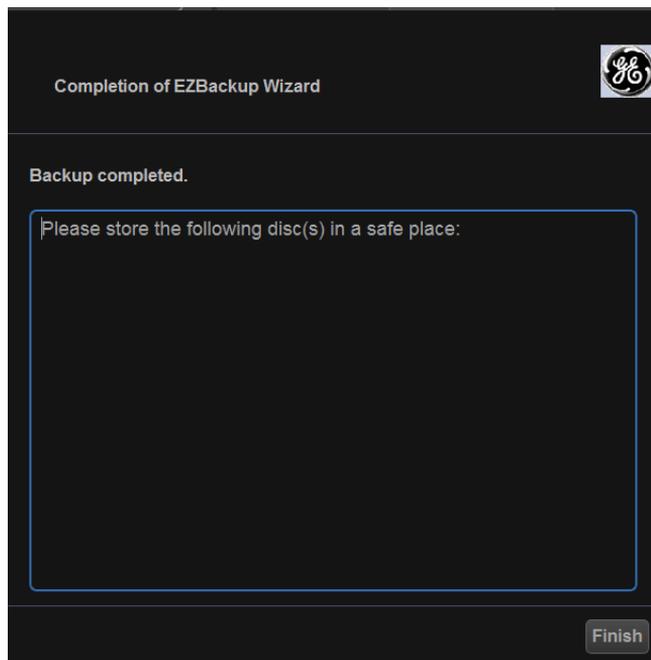
Figure 3-22.   EZBackup/EZMove Wizard, Page 4

10. Do a patient archive after each EZBackup/EZMove.

We recommend attaching the patient list to the EZBackup/ EZMove media.

NOTE: *Use Import to restore EZBackup images.*

To Review EZBackup/EZMove and Export Images

You can review backed up media via the Patient Menu, Import, and the DICOM Read dataflow.

If you review EZMoved image,

1. Select the patient on the Patient Menu (on the same system where the EZMove was performed).
2. Insert the media volume indicated on the Patient Menu.
3. View the exam from the media.

NOTE: *You may need to insert a media volume prior to or after the recommended media.*

NOTE: *If the patient is split over multiple media, images on the previous or next media are displayed as triangles.*

NOTE: *To view the whole patient on the system, use Import, from as many media as you have for that patient. However, take care not to import studies over existing studies; duplicate or missing images may result. Delete the existing exam first.*

Backup and Restore

To minimize accidental loss of data, perform backup of the patient archives stored on the local hard drive **DAILY** as described in this section. Use a formatted Backup/Restore disk to back up patient archives from the hard drive, using the backup procedure described in this section. Data from the Backup/Restore disk may be restored to the local hard drive using the restore procedure.

NOTE: *To perform backup and restore procedures, you must login with administrator privileges.*

Backup procedure

Back up patient data AFTER you've archived (via EZBackup/EZMove) images so that the pointers to the patient's images reflect that the images have been moved to removable media and are no longer on the hard drive.

1. Insert a media into the drive or USB device into a USB port.
2. On the Archive screen under dataflow, select Local Archive - Int. HD.
3. Go to Utility --> System --> Backup/Restore.
4. In the Backup list,

    •   Select **Patient Archive** and **Report Archive** to backup the patient records.
    •   Select **User Defined Configuration** to copy system settings and user presets.
    •   Select **Service** to backup service presets.

NOTE: *The detailed section of this menu decouples the user defined configuration above. This allows you to selectively restore what you want to restore across multiple machines.*

5. Specify where to save data in the media field.
6. Select *Backup*.

    The system performs the backup. As it proceeds, status information is displayed on the Backup/Restore screen.

7. At the end of the process, the Backup completed message is displayed on the monitor.

    Press Eject (F3) for eject media/disconnect USB device.

8. Make sure to physically label the media. An identification of the system should also be noted on the media and a backup log should be kept.

    File the media in a safe place.

Restore procedure

⚠ CAUTION   The restore procedure overwrites the existing database on the local hard drive. Make sure to insert the correct media.

You cannot restore the data between systems with different software versions.

⚠ CAUTION   To avoid the risk of overwriting the local patient and report archives, DO NOT check Patient Archive when restoring user-defined configurations.

1. Go to Utility --> System --> Backup/Restore.
2. In the Restore list,
   • Select **Patient Archive** and **Report Archive** to restore the patient archive.
   • Select **User Defined Configuration** to restore all system settings and user presets.

     or

     One or several system configuration items to restore parts of the Detailed Restore of User Defined.
   • Select **Service** to restore Service Settings.
3. In the Media field, select the appropriate Source device.
4. Select *Restore*.

   The system performs the restore. As it proceeds, status information is displayed on the Backup/Restore screen.
5. The Versana Essential restarts automatically when Restore is done.

Backup and restore strategy: user-defined configurations

In addition to generating a safety copy, the backup/restore function of the user-defined configuration (presets) can be used to configure several Versana Essential systems with identical presets (preset synchronization).

Preset synchronization

The procedure for preset synchronization of several scanners is as follow:

1. Make a backup of the user-defined configurations on a removable media from a fully configured Versana Essential system.

2. Restore user-defined configurations from the removable media to another Versana Essential system (you can restore all the user-defined presets or select specific presets to restore via Detailed Restore).

Configuring Connectivity

Overview

You use Connectivity functionality to set up the connection and communication protocols for the ultrasound system. This section gives an overview of each of the Connectivity functions.

Connectivity Functions

To set up your institution's connectivity, you must login with administrator privileges.

1. **TCPIP**: allows you to configure the Internet Protocol.
2. **Device**. allows you to set up devices.
3. **Service**: allows you to configure a service (for example, DICOM services such as printers, worklist, and other services such as standard print) from the list of supported services. This means that the user can configure a device with the DICOM service(s) that particular device supports.
4. **Dataflow**: allows you to adjust the settings of the selected dataflow and associated services. Selecting a dataflow customizes the ultrasound system to work according to the services associated with the selected dataflow.
5. **Button**: allows you to assign a pre-configured output service (or a set of output services) to the Print keys on the control panel.
6. **Removable Media**: enables formatting (DICOM, database, or blank formatting) and DICOM verification of removable media.
7. **Miscellaneous**: allows you to set up the patient/exam menu options, print and store options, patient/exam Message options, Other ID Options and columns in the examination listing.

Configure these screens from left to right, starting with the Tcpip tab first.

NOTE: *The ultrasound system is pre-configured for many services, with default settings selected. You can change these services and settings as needed.*

CAUTION   You must restart the Versana Essential after making any changes to connectivity settings in the Utility menus. This includes any changes on the TCPIP or dataflow setup screens.

Anti-Virus Software Note

Anti-virus software IS NOT present on the Versana Essential system. Since the Versana Essential is already protected against attack by the measures listed below, no Anti-virus software is deemed necessary.

- Only communication ports required for system operation are enabled.
- Only operating system services required by system application software are enabled.
- Software programs CANNOT be loaded onto the Versana Essential (e.g., e-mail, web browser, etc.).
- An auto-executable file CANNOT be run automatically on the Versana Essential.
- The Versana Essential software includes the latest MS Windows security protection.

We have worked diligently to develop a combination of the safety measures noted above and the security standards of Windows Embedded Standard 7 to provide a degree of safety against Viruses, Worms, Trojan Horses, etc., especially for a system used in a professional hospital grade networking environment that also typically features its own sufficient safety measures.

Electronic Documentation

Accessing Documentation Via a PC

To view user documentation on a PC,

1. Insert the media into the media drive.
2. Open the media drive on your desktop.
3. Select and open the item you want to view.

To close the window, press the 'X' in the upper, right-hand corner of the window.

NOTE: *If your PC does not have Adobe Reader, a free download is available on the Adobe web site at http://www.adobe.com.*

System Care and Maintenance

Expected Service Life Description

The expected service life for the Versana Essential system and probes is identified in this table:

Table 3-2:   Expected Service Life

Equipment/Accessory	Expected Service Life
Versana Essential system	The expected service life for the Versana Essential is at least seven (7) years from the manufacturing date under the provision of regular maintenance by authorized service personnel.
Versana Essential probes	The expected service life for the Versana Essential probes meets or exceeds five (5) years from the date the probe is placed in service, under the provision that the customer follows the care instructions provided on the Probe Care Card that accompanies the Versana Essential instructions for Use.

Inspecting the System

⚠ CAUTION   To avoid electrical shock hazard, do not remove panels or covers from console. This servicing must be performed by qualified service personnel. Failure to do so could cause serious injury.

Monthly Maintenance

Examine the following on a monthly basis (or whenever there is a reason to assume that any issue may have occurred):

- Connectors on cables for any mechanical defects.
- Entire length of electrical and power cables for cuts or abrasions.
- Equipment for loose or missing hardware.
- Control panel and keyboard for defects.
- Casters for proper locking operation.

WARNING — Do not perform system care and maintenance in the patient environment.

Weekly Maintenance

The system requires weekly care and maintenance to function safely and properly. Clean the following:

- System Cabinet
- Monitor
- Operator control panel
- Probe holder and Gel holder
- Footswitch

NOTE: *Frequency of the cleaning is dependent on the environment.*

Failure to perform required maintenance may result in unnecessary service calls.

Cleaning the system

Prior to cleaning any part of the system:

1. Turn off the system power. Disconnect the power cord. See 'Power Off' on *page 1-38 for more information.*

 WARNING   Ensure that you follow the cleaning procedure and use the cleaning agents provided in this manual.

System Cabinet

To clean the system cabinet:

1. Moisten a soft, non-abrasive folded cloth with a mild, general purpose, non-abrasive soap and water solution.
2. Wipe down the top, front, back, and both sides of the system cabinet.

NOTE: *Do not spray any liquid directly into the unit.*

Operator Control Panel

To clean the operator control panel:

1. Moisten a soft, non-abrasive folded cloth with a mild, general purpose, non-abrasive soap and water solution.
2. Wipe down operator control panel.
3. Use a cotton swab to clean around keys or controls. Use a toothpick to remove solids from between keys and controls.

NOTE: *When cleaning the operator control panel, make sure not to spill or spray any liquid on the controls, into the system cabinet, or in the probe connection receptacle.*

NOTE: *In case of SARS, use bleach, alcohol, or Cidex in a normal diluted form for cleaning/disinfecting the operator panel.*

NOTE: *DO NOT use T-spray or Sani Wipes on the control panel.*

Monitor

To clean the monitor face:

Use a soft, folded cloth. Gently wipe the monitor face.

Do NOT use a glass cleaner that has a hydrocarbon base (such as Benzene, Methyl Alcohol or Methyl Ethyl Ketone) on monitors with the filter (anti-glare shield). Hard rubbing will also damage the filter.

NOTE: *When cleaning the screen, make sure not to scratch the monitor.*

Footswitch

To clean the footswitch:

1. Moisten a soft, non-abrasive folded cloth with a mild, general purpose, non-abrasive soap and water solution.
2. Wipe the external surfaces of the unit then dry with a soft, clean, cloth.

Trackball

1. Power off the system.
2. Rotate the retainer counterclockwise until it can be removed from the keyboard.
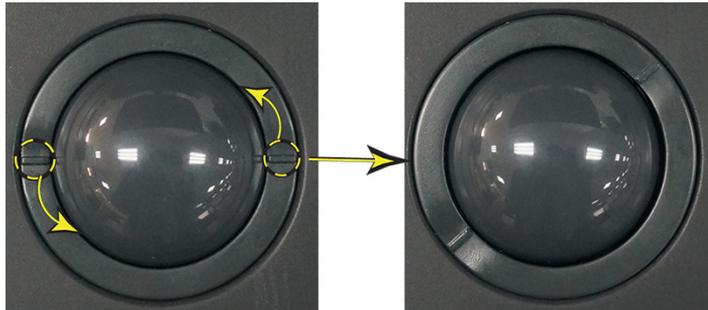
Figure 3-23.   Rotate the retainer

3. Separate the trackball and the retainer. Wipe off any oil or dust from the trackball, retainer and the trackball housing using a cleaner or cotton swab.
4. Assemble the trackball and retainer, then put it into the housing and rotate it clockwise until its notches are set in position.

CAUTION   When cleaning, make sure not to spill or spray any liquid into the trackball housing (keyboard or system). DO NOT use Windex, Screen-Clean, etc. as these contain ammonia, which will remove the anti-glare coating on the Trackball.

Cleaning the air filters

Clean the system's air filters to ensure that a clogged filter does not cause the system to overheat and reduce system performance and reliability. It is recommended the filters be cleaned every two weeks, but the requirements will vary due to your system use.

⚠ CAUTION   Be sure to lock the wheels before cleaning the air filters to avoid injury by any unexpected movement of the system.

DO NOT operate the unit without the air filters in place.

Allow the air filters to dry thoroughly before re-installing them on the unit.

Cleaning

1. Power off the system.
2. Remove the body left and right cover on both sides.

Figure 3-24.   Remove the body left cover

Cleaning the air filters (continued)

3. Remove the air filters on body left and right cover.
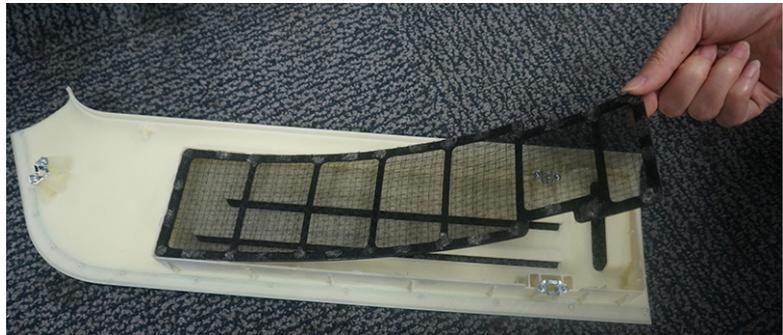
Figure 3-25.   Remove the Filters

4. Dust the filters with a vacuum cleaner and/or wash it with a mild soapy solution.

    If washed, rinse and dry the filters before re-installation.

5. Put back the air filters.

Prevention of static electricity interference

Interference from static electricity can damage electronic components in the system. The following measures help to reduce the likelihood of electrostatic discharge:

- Wipe the alphanumeric keyboard and monitor with lint-free tissue or a soft cloth dampened with anti-static spray on a monthly basis.
- Spray carpets with anti-static spray because constant walking on carpets in or near the scanning room may be a source of static electricity.

Disposal

Table 3-3: WEEE symbol

	Rear of the system and Probe connector

This symbol indicates that waste electrical and electronic equipment must not be disposed of as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.

Troubleshooting

Please refer to Service Manual if other messages appear on the monitor display.

Table 3-4:   Error messages

	The system has detected the lower air filter requires cleaning. Please clean the lower air filter.
Warning The system has detected the lower air filter requires cleaning. Please clean the lower air filter. Ok	1. Shutdown the system. Disconnected the power cord. Then clear the air filter according to 'Cleaning the air filters' on *page 3-35*.
Warning System temperature is too high. System will shut down. Ok Cancel	System temperature is too high. System will shut down. 1. Shutdown the system. 2. Clean the air filter according to 'Cleaning the air filters' on *page 3-35*.
Warning System voltage fault. System will shut down. Ok Cancel	System voltage fault. System will shut down. 1. Select *OK* and reboot the system. 2. If the same message appears after reboot, shut down the system and turn off the breaker. Then turn on the system according to 'Power On' on *page 1-36*.
Error System Error. Please Restart the system. Ok	System Error. Please reboot the system. 1. Select *OK* and reboot the system. 2. If the same message appears after reboot, shut down the system and turn off the breaker. Then turn on the system according to 'Power On' on *page 1-36*.
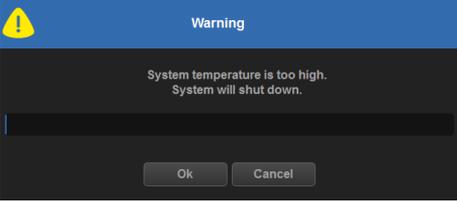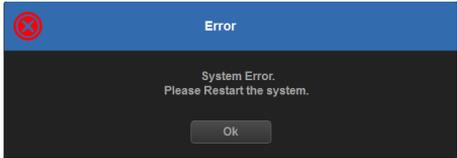
Assistance

Supplies/Accessories

| | CAUTION | **DO NOT** connect any probes or accessories without approval by GE. |

| | CAUTION | Use only GE approved internal equipment when replacing an internal peripheral. |

The user or the operator should never install/replace the internal peripheral. Service representatives authorized by GE will install/replace the internal peripheral.

Not all features, products, probes or peripherals described in this document may be available or cleared for sale in all markets. Please contact your local GE Ultrasound representative to get the latest information.

Contact the distributor, GE affiliate or sales representative for approved peripherals. For HCATs, contact your sales person.

The following supplies/accessories have been verified to be compatible with the system:

Peripherals

Table 3-5:   Peripherals and Accessories

Accessory	Units
Wireless Adaptor	Each
Bluetooth Adaptor	Each
DVD R/W Kit with SW	Each
1-Pedal Type footswitch	Each
Footswitch MKF 2-MED USB GP26	Each
SONY UP-D898DC Printer	Each
SONY UPD25 Printer	Each
BW PRINTER (UP-D898MD)	Each
USB Stick	Each
ECG Cable Kits	Each
1TB mobile USB HDD	Each
AC printer isolation transformer 110V	Each
AC printer isolation transformer 220V	Each

NOTE: *Other commercial printers not listed in above table must connect with PIT (Printer Isolation Transformer) when being used.*

NOTE: *The transformer does not support the printer with power more than 150VA.*

NOTE: *The Versana Essential system supports two types printer isolation transformers: 110V/220V. Please use the appropriate type according to the local power supply.*

Probe

Table 3-6:   Probes and Accessories

Probe	HCAT	Biopsy Guide	Biopsy Guide HCAT	Biopsy Guide HCAT
4C-RS Convex	H4000SR	Multi-angle, disposable needle guide with a reusable plastic bracket	E8385NA	
C2-5-RS Convex		Not Available	N/A	N/A
E8C-RS Convex	H40402LN	Fixed angle, disposable needle guide with a reusable plastic bracket	E8385MJ	
		Fixed angle, reusable with a Stainless Steel Bracket	H40412LN	
3Sc-RS Sector	H45041DL	Multi-angle, Disposable needle guide with a reusable plastic bracket	H46222LC	
L5-11-RS Linear		Not Available	N/A	N/A

Table 3-6:   Probes and Accessories

Probe	HCAT	Biopsy Guide	Biopsy Guide HCAT	Biopsy Guide HCAT
L6-12-RS Linear	H48062AC	Multi-angle, disposable needle guide with a reusable plastic bracket	H40432LC	
		Multi-angle, disposable needle guide with a reusable plastic bracket	H48392LT	
		Fixed-angle, disposable needle guide with a reusable plastic bracket	H48392LL	

Features/Specifications

Table 3-7:   Physical Attributes

Dimensions and Weight
• Height: approximately 1360±60mm (53.5±2.36 in)
• Width: approximately 560±30mm (22±1.18 in)
• Depth: approximately 576±30mm (22.7±1.18 in)
• Weight: less than 45 kg without any probes or
  peripherals
 	
Console Design
• 2 active probe port (Standard) / 3 active probe ports
  (option)
• Integrated HDD
• SSD (At least 128G)
• Integrated DVD RW (option)
• Onboard reporting package (option)
• Integrated speakers
• Locking mechanism that provides caster lock
• 2 cable hooks
• Front and rear handles
• Easily removable air filter
• Wireless adapter (option)
	Keyboard
	• Alphanumeric keyboard
	• Interactive back-lighting
	
	Monitor
	• 15.6 inch Monitor (standard)
	• 17.3 inch Monitor (option)
	• High-Resolution monitor display
	• Opening angle adjustment: Tilt Angle: up 45
	  degrees, down 90 degrees; rotate angle: left 80
	  degrees, right 80 degrees.
	• Fold-down for transportation
	• Brightness adjustment
	
	Electrical Power
	• Voltage:100-240 V AC
	• Frequency: 50/60 Hz
	• Power: Consumption less than 300 VA with on
	  board peripherals

Table 3-8:   Inputs and Outputs Signal

External Inputs and Outputs • 3 USB ports • Ethernet	Outputs • HDMI • VGA • Composite out • S-Video

Table 3-9:   System Overview

Operating Modes	System Options
• B-Mode • M-Mode • Anatomical-M Mode (option) • Color M Mode (option) • Color Flow Mode (CFM) (option) • Power Doppler Imaging (PDI) • Directional Power Doppler Imaging • PW Doppler • CW Doppler (option) • Cine Mode • Easy 3D (option) • LOGIQ View (option) • Tissue Velocity Imaging (TVI)/Tissue Velocity Doppler (TVD) with QAnalysis (Option)	• Color Flow Mode (CFM) • Power Doppler Imaging (PDI) • CW Doppler (CWD) • Anatomical-M Mode (AMM) • Color M Mode (CMM) • Tissue Velocity Imaging (TVI)/Tissue Velocity Doppler (TVD) • LOGIQ View • Easy 3D • Auto IMT • SonoBiometry (AFB) • Scan Coach • Scan Assistant • OnBoard reporting package • DICOM 3.0 Peripheral Options • B/W image printer • Color image printer • Report printer • External USB Printer connection • ECG • Footswitch • Wireless adapter • Bluetooth adapter

Quality Assurance

Introduction

A good Quality Assurance Evaluation program consists of periodic systematic actions that provide the user with adequate confidence that their diagnostic ultrasound system will produce consistently high quality images and quantitative information.

Therefore, it is in the best interests of every ultrasound user to routinely monitor equipment performance.

The frequency of Quality Assurance evaluations should be based on user's specific needs and clinical practice.

Periodic monitoring is essential in order to detect the performance changes that occur through normal aging of system components. Routine equipment evaluations may also reduce the duration of exams, number of repeat exams, and maintenance time required.

For details on system and peripheral routine preventive maintenance instructions, See 'System Care and Maintenance' on *page 3-30 for more information.*

Typical Tests to Perform

Quality assurance measurements provide results relating to system performance. Typically these are:

- Axial Measurement Accuracy
- Lateral Measurement Accuracy
- Axial and Lateral Resolution
- Penetration
- Functional & Contrast Resolution
- Gray Scale Photography.

With these tests, a performance baseline can be set at installation with the phantom in your department. Future test results can be compared to the baseline in order to maintain a record of system performance trends.

Frequency of tests

Quality assurance tests are used to determine whether a scanner is providing the same level of performance from day to day.

The frequency of testing varies with the amount of system usage and modes to be tested. It is recommended that the user perform quality assurance tests at least every three months or every 400 patient studies. Tests should also be performed when a question about system performance exists.

A mobile system may require more frequent tests.

Image quality should also be tested immediately after the following events:

- Service calls
- System upgrades/modifications
- Dropped probe, power surge, etc.

Phantoms

Quality Assurance Evaluations should be done with phantoms and test objects that are applicable to the parameters being evaluated or to the user's clinical practice.

Typical phantoms are composed of material that acoustically mimic human tissue. Pins, anechoic and echogenic targets are physically positioned to provide information for a variety of tests.

Doppler phantoms are currently expensive and complicated to deal with on the user level. If a problem with any Doppler parameters or measurement is suspected, contact a local service representative for evaluation.

The RMI 403GS phantom is still available. Due to the superior penetration and resolution capabilities of GE ultrasound systems, the RMI 405GSX is recommended. It is the most current one available to our field service personnel and will provide the targets and extended life necessary for consistent system testing.

Phantoms (continued)
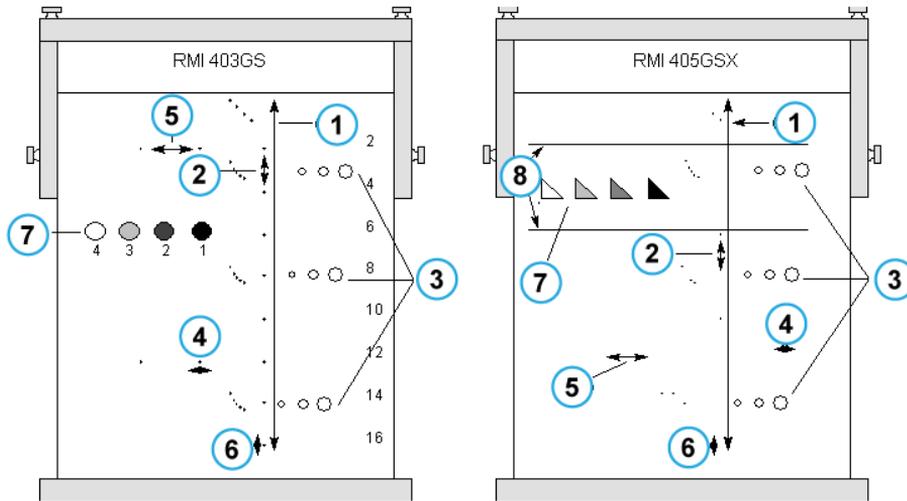
Figure 3-26.   Phantoms

1. Penetration
2. Axial Distance Measurement
3. Functional Resolution
4. Lateral Resolution
5. Lateral Distance Measurement
6. Axial Resolution
7. Contrast Resolution and Gray Scale Photography
8. Gray Scale Plane Targets

Baselines

An absolute necessity for a quality assurance program is establishing baselines for each test or check. Baselines are established after the system has been verified to be working properly at installation or after a repair. If a probe or major assembly is replaced, new baselines should be generated.

Baselines can be made by adjusting system parameters to prescribed levels or to the best possible image. The key factor to remember is reproducibility. The same conditions must be reproduced for each periodic check.

All system parameters not displayed on the monitor should be recorded for the permanent record.

Periodic Checks

Periodic checks should be performed in accordance with your facility's quality assurance requirements. For the data to be valid, periodic checks should mimic the baseline setup parameters.

The resulting image, when scanning the phantom exactly as before, should be recorded and compared to the baseline. When a matching image is obtained, it can be assumed that the system performance has not degraded from the baseline.

If a significant difference between the baseline and periodic check is noted, double check the system setup and repeat the test. If the difference between the baseline and periodic check persists, contact a local Service Representative.

Failing to reproduce the control settings as in the baselines will introduce errors in the data and potentially invalidate the results.

Results

Lack of standardization among test instruments, the wide range of acceptance criteria, and incomplete knowledge regarding the significance of certain performance parameters prohibit the establishment of absolute performance criteria for these tests.

Quality Assurance Evaluation results should be compared to previously-recorded results.

Performance trends can then be detected. Unacceptable performance or diminishing trends should be identified for maintenance or repair before a malfunction or inappropriate diagnosis occurs.

The user should determine the best method for recording and archiving the baseline and periodic checks. In most cases the choice is hard copy.

It is important to maintain good consistent records for inspections that may arise, as well as to detect system performance trends.

System Setup

The user should tailor the tests to their particular needs. It is certainly not necessary to make all checks with all probes. A representative example, with the probes used most often by the customer, should be adequate in judging system performance trends.

Use a gray scale phantom as the scan object for the tests. Commercial phantoms are supplied with its own operator manual. Be familiar with proper phantom operating procedures prior to use for quality assurance evaluations.

1. Adjust image monitor. Brightness and contrast should be set to the normal viewing of a good gray scale image.
2. Check all recording devices for proper duplication of image monitor. Ensure that what is seen is what is recorded.
3. Annotate non-displayed image processing controls.
4. Set TGC slide pots to center (detent) position.
5. Place focal zone marker(s) in area of interest for an optimum image.

Test Procedures

The following are recommended Quality Assurance tests. A brief description of the test, the benefit it provides and steps to accomplish the test are supplied.

The importance of recording scan parameters and consistent record keeping cannot be stressed enough. Reproducibility to monitor system trends is the key to quality assurance evaluations.

Using the system's dual image display format is often very convenient and saves recording media.

Axial distance measurements

Description

Axial measurements are the distance measurements obtained along the sound beam. See Figure 3-26 *on page 3-48* for more information.

Benefit

The accurate measurement of the size, depth and volume of a structure is a critical factor in determining a proper diagnosis. Most imaging systems use depth markers and/or electronic calipers for this purpose.

Method

Axial distance should be measured in the near, mid and far fields as well as in zoom. If necessary, different depths or fields of view can be tested.

Procedure

To measure axial distance:

1. Scan a test phantom with precisely-spaced vertical pin targets. Adjust all scan controls, as necessary, for the best image of the pin targets to typical depths for the probe being used.

2. Press **Freeze** to stop image acquisition and perform a standard distance measurement between the pins at different points in the image. Record all images for archiving.

3. Scan the vertical pins in zoom or at different depth/scale factors.

4. Press **Freeze** to stop image acquisition; repeat the distance measurements between pins and record the images for archiving.

5. Document the measurements for reference and future comparison.

Contact a Service Engineer if vertical measurements differ by more than 1.50% of the actual distance.

Lateral distance measurements

Description

Lateral measurements are distance measurements obtained perpendicular to the axis of the sound beam. See Figure 3-26 *on page 3-48* for more information.

Benefit

The purpose is the same as vertical measurements. Precisely-spaced horizontal pin targets are scanned and results compared to the known distance in the phantom.

Method

Lateral distance should be measured in the near, mid and far fields as well as in zoom. If necessary, different depths of fields of view can be tested.

Procedure

To measure lateral distance:

1. Scan a test phantom with precisely-spaced horizontal pin targets. Adjust all scan controls, as necessary, for the best image of the pin targets from side to side.

2. Press **Freeze** to stop image acquisition and perform a standard distance measurement between the pins at different points in the image. Record all images for archiving.

3. Scan the horizontal pins in zoom or at different depth/scale factors.

4. Press **Freeze** to stop image acquisition; repeat the distance measurements between pins and record the images for archiving.

5. Document the measurements for reference and future comparison.

Contact a Service Engineer if horizontal measurements differ by more than 3mm or 3% of that depth, whichever is greater.

Axial resolution

Description

Axial resolution is the minimum reflector separation between two closely-spaced objects to produce discrete reflections along the axis of the sound beam. It can also be monitored by checking the vertical size of known pin targets. See Figure 3-26 *on page 3-48* for more information.

Axial resolution is affected by the transmitting section of the system and the probe.

Benefit

In clinical imaging, poor axial resolution displays small structures lying close together as a single dot. This may lead to improper interpretation of the ultrasound image.

Procedure

To measure Axial resolution:

1. Scan a test phantom with precisely-spaced vertical pin targets.
2. Adjust all scan controls, as necessary, for the best image of the pin targets to typical depths for the probe being used.
3. Press **Freeze** to stop image acquisition.
4. Perform a standard distance measurement of the pin vertical thickness at different points in the image. Record all images for archiving.
5. Scan the vertical pins in zoom or at different depth/scale factors.
6. Press **Freeze** to stop image acquisition; repeat the vertical thickness measurements of the pins and record the images for archiving.
7. Document the measurements for reference and future comparison.

Axial resolution should remain stable over time. Contact a Service Engineer if any changes are observed.

Lateral resolution

Description

Lateral resolution is the minimum reflector separation between two closely spaced objects to produce discrete reflections perpendicular to the axis of the sound beam. It can also be monitored by checking the horizontal size of known pin targets. See Figure 3-26 *on page 3-48* for more information.

Lateral resolution is dependent upon the beam width produced by the probe. The narrower the beam, the better the lateral resolution.

The beam width is affected by the frequency, degree of focusing, and distance of the object from the face of the probe.

Benefit

Clinically, poor lateral resolution will display small structures lying close together as a single dot. This may lead to improper interpretation of the ultrasound image.

Procedure

To measure lateral resolution:

1. Scan a test phantom with precisely-spaced horizontal pin targets.
2. Adjust all scan controls, as necessary, for the best image of the pin targets from side to side.
3. Press **Freeze** to stop image acquisition and perform a standard distance measurement of the horizontal thickness of a pin at different points in the image. Record all images for archiving.
4. Scan the horizontal pins in zoom or at different depth/scale factors.
5. Press **Freeze** to stop image acquisition; repeat the horizontal thickness measurements of the pins and record the images for archiving.
6. Document the measurements for reference and future comparison.

Pin width should remain relatively constant over time ("1mm). Dramatic changes in pin width may indicate beam forming problems. Contact a Service Engineer if beam width changes consistently over 2 to 3 periodic tests.

Penetration

Description

Penetration is the ability of an imaging system to detect and display weak echoes from small objects at large depths. See Figure 3-26 *on page 3-48* for more information.

Penetration can be affected by the system's:

- Transmitter/receiver
- Degree of probe focusing
- Attenuation of the medium
- Depth and shape of reflecting object
- Electromagnetic interference from local surroundings.

Benefit

Weak reflecting echoes are commonly produced from the internal structure of organs. Definition of this tissue texture is important in the interpretation of the ultrasound findings.

Method

Scan a phantom to see how echoes begin to fade as depth is increased. The maximum depth of penetration is the point at which homogeneous material in the phantom begins to lose brightness.

Procedure

To measure penetration:

1. Set the front panel TGC slide pots to their center (detent) position.
2. Gain and acoustic output can be adjusted, as necessary, since these values are displayed on the monitor.
3. Scan a test phantom along the vertical pin targets to typical depths for the probe being used.
4. Perform a standard distance measurement from the top of the image displayed to the point at which homogeneous material in the phantom begins to lose brightness.
5. Document the depth measurement for reference and future comparison.

Contact a Service Engineer if the depth of penetration shifts more than one centimeter (1cm) when using the same probe and same system settings.

Functional resolution

Description

Functional resolution is an imaging system's ability to detect and display the size, shape, and depth of an anechoic structure, as opposed to a pin target. See Figure 3-26 *on page 3-48* for more information.

The very best possible image is somewhat less important than reproducibility and stability over time. Routine tests at the same settings should produce the same results.

Benefit

The data obtained will give a relative indication of the smallest structure the system is capable of resolving at a given depth.

Procedure

To measure functional resolution:

1. Set the front panel TGC slide pots to their center (detent) position.
2. Gain and acoustic output can be adjusted as necessary, since these values are displayed on the monitor.
3. Scan a test phantom with a vertical row of anechoic cyst targets to typical depths for the probe being used.
4. Evaluate the cysts at various depths for a good (round) shape, well-defined borders and no fill in. Remember, TGC slide pots are centered and should remain fixed. This may NOT provide optimal cystic clearing.
5. Document all results for future reference and comparison.

Contact a Service Engineer if a greatly distorted image is obtained.

Contrast resolution

Description

Contrast resolution is the ability of an imaging system to detect and display the shape and echogenic characteristics of a structure. See Figure 3-26 *on page 3-48* for more information.

Specific values measured are less important than stability over time. Routine tests at the same settings should produce the same results.

Benefit

A correct diagnosis is dependent upon an imaging system's ability to differentiate between a cystic or solid structure versus echo patterns from normal surrounding tissue.

Method

A phantom with echogenic targets of different sizes and depths should be used.

Procedure

To measure contrast resolution:

1. Set the front panel TGC slide pots to their center (detent) position. Set dynamic range to 54 db.
2. Gain and acoustic output can be adjusted, as necessary, since these values are displayed on the monitor.
3. Scan a test phantom with echogenic targets at the depths available.
4. Evaluate the echogenic targets for contrast between each other and between the surrounding phantom material. Remember, TGC slide pots are centered and should remain fixed. This may NOT provide an optimal scan image.
5. Document all results for future reference and comparison.

Contact a Service Engineer if the echogenic characteristics or shapes of the targets appear distorted.

Gray Scale photography

Description

Poor photography will cause loss of low level echoes and the lack of contrast between large amplitude echoes. See Figure 3-26 *on page 3-48* for more information.

Benefit

When photographic controls and film processors are properly adjusted, weak echoes, as well as strong echoes, are accurately recorded on film.

Procedure

1. Adjust the camera according to the manufacturer's instructions until the hard copy and video display are equal.
2. Scan the phantom and it's echogenic contrast targets.
3. Make a hard copy photograph of the display and compare it to the image on the video monitor for contrast and weak echo display.
4. Document all results for future reference and comparison.

Contact a Service Engineer if camera cannot duplicate what is on the image monitor.

NOTE: *Optimization of brightness/contrast controls on the display monitor is imperative in order to make sure that the hardcopy and monitor look alike.*

The display monitor is adjusted first. The hardcopy camera or printer is adjusted to match the display monitor.

Setting up a Record Keeping System

Preparation

The following is needed:

- Quality Assurance binder.
- Hard copy or electronic file of images.
- Quality Assurance Checklists.
- Display the following information while testing quality assurance:
  - Acoustic Output
  - Gain
  - Depth
  - Probe
  - Dynamic Range
  - Set up new patient to be the name of the test.
- Annotate the following:
  - Any control where its value is **NOT** displayed.
  - Significant phantom information.

Record Keeping

Complete the following:

1. Fill out the Ultrasound Quality Assurance Checklist for each probe, as scheduled.
2. Make a hard copy or archive the image.
3. Compare images to baseline images and acceptable values.
4. Evaluate trends over previous test periods.
5. File hard copy or electronic file of images and checklist in Quality Assurance binder.

Ultrasound Quality Assurance Checklist

Table 3-10:   Ultrasound Quality Assurance Checklist (Part 1)

Performed By		Date
System		Serial Number
Probe Type	Probe Model	Serial Number
Phantom Model	Serial Number	Room Temperature
Acoustic Output	Gain	Focal Zone
Gray Map	TGC	Depth
Monitor Setting		
Peripheral Settings		
Other Image Processing Control Settings		

Table 3-11:   (Part 2)

Test	Baseline Value Range	Tested Value	Image Hardcopy/ Archived	Acceptable? Yes/No	Service Called (Date)	Date Resolved
Vertical Measurement Accuracy						
Horizontal Measurement Accuracy						
Axial Resolution						
Lateral Resolution						
Penetration						
Functional Resolution						
Contrast Resolution						
Gray Scale Photography						

Contact Information

Contacting GE Ultrasound

For additional information or assistance, please contact your local distributor or the appropriate support resource listed on the following pages:

INTERNET

http://www.gehealthcare.com

http://www.gehealthcare.com/usen/ultrasound/products/probe_care.html

Clinical Questions

For information in the United States, Canada, Mexico and parts of the Caribbean, call the Customer Answer Center.
TEL: (1) 800-682-5327 or (1) 262-524-5698

In other locations, contact your local Applications, Sales, or Service Representative.

Service Questions

For service in the United States, call GE CARES.

TEL: (1) 800-437-1171

In other locations, contact your local Service Representative.

Information Requests

To request technical product information in the United States, call GE.

TEL: (1) 800-643-6439

In other locations, contact your local Applications, Sales, or Service Representative.

Placing an Order

To order accessories, supplies, or service parts in the United States, call the GE Healthcare Technologies Contact Center.

TEL: (1) 800-558-5102

In other locations, contact your local Applications, Sales, or Service Representative.

Contacting GE Ultrasound (continued)

AMERICAS

ARGENTINA	GEME S.A. Miranda 5237 Buenos Aires - 1407 TEL: (1) 639-1619 FAX: (1) 567-2678
BRAZIL	GE do Brasil Comércio e Serviços para Equipamentos Médico-Hospitalares Ltda Av. Das Nações Unidas, 8501 3º andar parte - Pinheiros São Paulo SP – CEP: 05425-070 C.N.P.J.: 02.029.372/0001-40 TEL: 3067-8010 FAX: (011) 3067-8280
CANADA	GE Ultrasound Service Engineering 9900 Innovation Drive Wauwatosa, WI 53226 TEL: (1) 800-668-0732 Customer Answer Center TEL: (1) 262-524-5698
LATIN & SOUTH AMERICA	GE Ultrasound Service Engineering 9900 Innovation Drive Wauwatosa, WI 53226 TEL: (1) 262-524-5300 Customer Answer Center TEL: (1) 262-524-5698
MEXICO	GE Sistemas Medicos de Mexico S.A. de C.V. Rio Lerma #302, 1° y 2° Pisos Colonia Cuauhtemoc 06500-Mexico, D.F. TEL: (5) 228-9600 FAX: (5) 211-4631
USA	GE Ultrasound Service Engineering 9900 Innovation Drive Wauwatosa, WI 53226 TEL: (1) 800-437-1171 FAX: (1) 414-721-3865

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CHINA	GE - Asia No. 1, Yongchang North Road Beijing Economic & Technology Development Area Beijing 100176, China TEL: (8610) 5806 8888 FAX: (8610) 6787 1162
INDIA	Wipro GE Pvt Ltd No. 4, Kadugodi Industrial Area Bangalore, 560067 TEL: +(91) 1-800-425-8025
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SINGAPORE	ASEAN 1 Maritime Square #13-01 HarbourFront Center Singapore 099253 TEL: +65 6291 8528

Contacting GE Ultrasound (continued)

EUROPE

For all other European countries not listed, please contact your local GE distributor or the appropriate support resource listed on www.gehealthcare.com.

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Cardiology TEL: (+33) 13 449 52 31
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Budaors 2040 Hungary
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Victoria Business Park
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Oak Drive, Dublin 22
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ITALY   GE Medical Systems Italia spa
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LUXEMBORG   See Belgium.

NETHERLANDS   GE
De Wel 18 B, 3871 MV Hoevelaken
PO Box 22, 3870 CA Hoevelaken
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Chapter 4

Safety

*Describes the safety and regulatory information
pertinent for operating this ultrasound system.*

Owner Responsibility

Owner requirements

It is the responsibility of the owner to ensure that anyone operating the system reads and understands this section of the manual. However, there is no representation that the act of reading this manual renders the reader qualified to operate, inspect, test, align, calibrate, troubleshoot, repair or modify the system. The owner should make certain that only properly trained, fully-qualified service personnel undertake the installation, maintenance, troubleshooting, calibration and repair of the equipment.

The owner of the ultrasound unit should ensure that only properly trained, fully qualified personnel are authorized to operate the system. Before authorizing anyone to operate the system, it should be verified that the person has read, and fully understands, the operating instructions contained in this manual. It is advisable to maintain a list of authorized operators.

Should the system fail to operate correctly, or if the unit does not respond to the commands described in this manual, the operator should contact the nearest field GE Ultrasound Service Office.

For information about specific requirements and regulations applicable to the use of electronic medical equipment, consult the local, state and federal agencies.

Notice against user modification

Never modify this product, including system components, software, cables, and so on. User modification may cause safety hazards and degradation in system performance. All modification must be done by a GE qualified person.

Safety Precautions

Precaution Levels

Icon description

Various levels of safety precautions may be found on the equipment and different levels of concern are identified by one of the following flag words and icons which precede the precautionary statement.

 DANGER
Indicates that a specific hazard is known to exist which through inappropriate conditions or actions will cause:

- Severe or fatal personal injury
- Substantial property damage.

 WARNING
Indicates that a specific hazard is known to exist which through inappropriate conditions or actions may cause:

- Severe personal injury
- Substantial property damage.

 CAUTION
Indicates that a potential hazard may exist which through inappropriate conditions or actions will or can cause:

- Minor injury
- Property damage.

NOTE: *Indicates precautions or recommendations that should be used in the operation of the ultrasound system, specifically:*

- *Maintaining an optimum system environment*
- *Using this Manual*
- *Notes to emphasize or clarify a point.*

Hazard Symbols

Icon Description

Potential hazards are indicated by the following icons:

Table 4-1:   Potential Hazards

Icon	Potential Hazard	Usage	Source
	Biological Hazard Describes precautions necessary to prevent the risk of disease transmission or infections. • Patient/user infection due to contaminated equipment.	• Cleaning and care instructions • Sheath and glove guidelines	ISO 7000 No. 0659
	Electrical Hazard Describes precautions necessary to prevent the risk of injury through electric hazards. • Electrical micro-shock to patient, e.g., ventricular	• Probes • ECG, if applicable • Connections to back panel	
	Moving Hazard Describes precautions necessary to prevent the risk of injury through moving or tipping hazard! • Console, accessories or optional storage devices that can fall on patient, user, or others. • Collision with persons or objects may result in injury while maneuvering or during system transport. • Injury to user from moving the console.	• Moving • Using brakes • Transporting	
	Acoustic Output Hazard • Patient injury or tissue damage from ultrasound radiation.	• ALARA, the use of Power Output following the 'as low as reasonably achievable' principle	
	Explosion Hazard Describes precautions necessary to prevent the risk of injury through explosion hazard! • Risk of explosion if used in the presence of flammable anesthetics.	• Flammable anesthetic	
	Fire and Smoke Hazard • Patient/user injury or adverse reaction from fire or smoke. • Patient/user injury from explosion and fire.	• Replacing fuses • Outlet guidelines	

Important Safety Considerations

The following topic headings (Patient Safety, and Equipment and Personnel Safety) are intended to make the equipment user aware of particular hazards associated with the use of this equipment and the extent to which injury can occur if precautions are not observed. Additional precautions may be provided throughout the manual.

⚠ CAUTION Improper use can result in serious injury. The use of the system outside the described conditions or intended use, and disregarding safety related information is considered abnormal use. The user must be thoroughly familiar with the instructions and potential hazards involving ultrasound examination before attempting to use the device. Training assistance is available from GE if needed.

Disregarding information on safety is considered abnormal use.

⚠ CAUTION The use of the system outside the described conditions or intended use, and disregarding safety related information is considered as abnormal use. The manufacturer is not liable for damage caused by abnormal use of the device.

Patient Safety

Related Hazards

⚠ WARNING

The concerns listed in this section can seriously affect the safety of patients undergoing a diagnostic ultrasound examination.

Patient identification

Always include proper identification with all patient data and verify the accuracy of the patient's name and ID numbers when entering such data. Make sure correct patient ID is provided on all recorded data and hard copy prints. Identification errors could result in an incorrect diagnosis.

The ultrasound system is not meant to be long term storage for patient data or images. The customers are responsible for the data on the system and a regular backup is highly recommended.

It is advisable to back up system data prior to any service repairs to the hard drive. It is always possible during system failure and repair to lose patient data. GE will not be held responsible for the loss of this data.

Diagnostic information

The images and calculations provided by the system are intended for use by competent operators, as a diagnostic tool. They are explicitly not to be regarded as the sole, irrefutable basis for clinical diagnosis. Operators are encouraged to study the literature and reach their own professional conclusions regarding the clinical utility of the system.

The operator should be aware of the product specifications and of the system accuracy and stability limitations. These limitations must be considered before making any decision based on quantitative values. If in doubt, the nearest GE Ultrasound Service Office should be consulted.

Equipment malfunction or incorrect settings can result in measurement errors or failure to detect details within the image. The equipment user must become thoroughly familiar with the equipment operation in order to optimize its performance and recognize possible malfunctions. Applications training is available through the local GE representative. Added confidence in the equipment operation can be gained by establishing a quality assurance program.

⚠ CAUTION   The system provides calculations (e.g estimated fetal weight) and charts based on published scientific literature. The selection of the appropriate chart and clinical interpretation of calculations and charts is the sole responsibility of the operator. The operator must consider contraindications for the use of a calculation or chart as described in the scientific literature. The diagnosis, decision for further examinations and medical treatment must be performed by qualified personnel following good clinical practice.

⚠ CAUTION   Be certain to ensure privacy data of patient information.

Mechanical hazards

The use of damaged probes or improper use and manipulation of intracavity probes can result in injury or increased risk of infection. Inspect probes often for sharp, pointed, or rough surface damage that could cause injury or tear protective barriers. Become familiar with all instructions and precautions provided with special purpose probes.

Electrical Hazard

A damaged probe can also increase the risk of electric shock if conductive solutions come in contact with internal live parts. Inspect probes often for cracks or openings in the housing and holes in and around the acoustic lens or other damage that could allow liquid entry. Become familiar with the probe's use and care precautions outlined in *Probes and Biopsy*.

CAUTION

Ultrasound transducers are sensitive instruments which can easily be damaged by rough handling. Take extra care not to drop transducers and avoid contact with sharp or abrasive surfaces. A damaged housing, lens or cable can result in patient injury or serious impairment or operation.

WARNING

Observe probe immersion levels (see Figure 5-4 *on page 5-13*).

Inspect probes for sharp edges or rough surfaces that could injure sensitive tissue.

DO NOT bend or pull the cable forcefully, to avoid mechanical shock or impact to the probe.

Scanner and electrosurgical units

⚠ CAUTION   This equipment provides no special means of protection from high frequency (HF) burns that may result from using an electrosurgical unit (ESU). To reduce the risk of HF burns, avoid contact between the patient and ultrasound transducer or ECG electrodes while operating the ESU. Where contact cannot be avoided, make sure the transducer or ECG electrodes are not located between the ESU active and dispersive electrodes and keep the ESU cables away from the transducer or ECG cables.

ALARA

⚠ CAUTION   Ultrasound can produce harmful effects in tissue and potentially result in patient injury. Always minimize exposure time and keep ultrasound levels low when there is no medical benefit. Use the principle of ALARA (As Low As Reasonably Achievable), increasing output only when needed to obtain diagnostic image quality. Observe the acoustic output display and be familiar with all controls affecting the output level. See the *Bioeffects section* of the *Acoustic Output chapter* in the *Advanced Reference Manual* for more information.

⚠ CAUTION   The operator of the device must sufficiently understand the acoustic output and be able to obtain the related thermal index values. The probe with self-heating in the air cannot be used in transvaginal scanning. Always minimize exposure time to the irradiation and keep ultrasound acoustic output level low for embryos or fetuses.

Training

During each ultrasound examination the user is expected to weigh the medical benefit of the diagnostic information that would be obtained against the risk of potentially harmful effects. Once an optimal image is achieved, the need for increasing acoustic output or prolonging the exposure cannot be justified. It is recommended that all users receive proper training in applications before performing them in a clinical setting. Contact the GE sales representative for training assistance.

Equipment and Personnel Safety

The concerns listed below can seriously affect the safety of equipment and personnel during a diagnostic ultrasound examination.

Related Hazards

WARNING

This equipment contains dangerous voltages that are capable of serious injury or death.

If any defects are observed or malfunctions occur, stop operating the equipment and perform the proper action for the patient. Inform a qualified service person and contact a Service Representative for information.

There are no user replaceable or serviceable components inside the console. Refer all servicing to GE qualified service personnel only.

Ensure that unauthorized personnel do not tamper with the unit.

Electrical Hazard

To avoid injury:

- Do not remove protective covers. No user serviceable parts are inside. Refer servicing to qualified service personnel.
- To assure adequate grounding, connect the attachment plug to a reliable (hospital grade) grounding outlet (having equalization conductor ⩊).
- Never use any adaptor or converter of a three-prong-to-two-prong type to connect with a mains power plug. The protective earth connection will loosen.
- Do not place liquids on or above the console. Spilled liquid may contact live parts and increase the risk of shock.

Related Hazards (continued)

⚠ CAUTION	Servicing must be performed by GE qualified service personnel.

⚠ WARNING	The internal circuits of the unit use high voltages, capable of causing serious injury or death by electrical shock.

⚠ WARNING	To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

Smoke & Fire Hazard	The system must be supplied from an adequately rated electrical circuit. The capacity of the supply circuit must be as specified.

⚠ WARNING	Only approved and recommended peripherals and accessories should be used.
	All peripherals and accessories must be securely mounted to the Versana Essential.

Related Hazards (continued)

⚠ WARNING	The Versana Essential is not intended to be used as a data storage device; backup of the Patient and Image Database is your institution's responsibility. GE is NOT responsible for any lost patient information or for lost images.
⚠ Explosion Hazard	Risk of explosion if used in the presence of flammable anesthetics.
⚠ Explosion Hazard	Never operate the equipment in the presence of flammable or explosive liquids, vapors or gases. Malfunctions in the unit, or sparks generated by fan motors, can electrically ignite these substances. Operators should be aware of the following points to prevent such explosion hazards.

- If flammable substances are detected in the environment, do not plug in or turn on the system.
- If flammable substances are detected after the system has been turned on, do not attempt to turn off the unit, or to unplug it.
- If flammable substances are detected, evacuate and ventilate the area before turning off the unit.

⚠ CAUTION	Do not use this equipment if a safety problem is known to exist. Have the unit repaired and performance verified by qualified service personnel before returning to use.

Related Hazards (continued)

Biological Hazard	For patient and personnel safety, be aware of biological hazards while performing invasive procedures. To avoid the risk of disease transmission:

- Use protective barriers (gloves and probe sheaths) whenever possible. Follow sterile procedures when appropriate.
- Thoroughly clean probes and reusable accessories after each patient examination and disinfect or sterilize as needed. Refer to *Probes and Biopsy* for probe use and care instructions.
- Follow all infection control policies established by your office, department or institution as they apply to personnel and equipment.

CAUTION	Contact with natural rubber latex may cause a severe anaphylactic reaction in persons sensitive to the natural latex protein. Sensitive users and patients must avoid contact with these items. Refer to package labeling to determine latex content and FDA's March 29, 1991 Medical Alert on latex products.

CAUTION	To avoid injury or system damage, NEVER place any object or liquid on the operator panel.

CAUTION	Archived data is managed at the individual sites. Performing data backup (to any device) is recommended.

CAUTION	

- Make sure to verify the media after writing of data, such as EZBackup, SaveAs or Export.
- Before deleting a patient or image from the patient screen, make sure you have saved the data by EZBackup/Backup or Export and verify that the media transfer of data was successful.

Related Hazards (continued)

⚠ CAUTION   Do not unpack the Versana Essential. This must be performed by qualified service personnel only.

⚠ CAUTION   DO NOT touch the patient and any of the connectors on the ultrasound unit simultaneously, including ultrasound probe connectors.

DO NOT touch the conducting parts of the USB, Ethernet, Video, Audio cables when connecting equipment to the unit.

⚠ CAUTION   To minimize accidental loss of data, perform EZBackup and Backup on a regular basis.

1.   First, perform EZBackup to save the images.

2.   Next, perform Backup at Utility -> System ->Backup/ Restore. Enable the following checkboxes under Backup:

- Patient Archive
- Report Archive
- User defined configuration
- Service

⚠ CAUTION   DO NOT load non-system software on the system computer.

Material Safe Data

Rubber Part

Material: GFE 15&17

Where Used: Probe holder/Rubber cover for arm stopper/ Rubber plug

Related Hazards (Monitor)

⚠ CAUTION	• **DO NOT** place a finger, hand or any object on the joint of the monitor or monitor arm to avoid injury when moving the monitor and monitor arm.

- **DO NOT** place a finger, hand or any object on the joint of the monitor or monitor arm to avoid injury when moving the monitor and monitor arm.
- To avoid result of injury or system damage, **NEVER** place any object or liquid on the monitor, whether in the home or flip down/transport position.
- **DO NOT** scratch or press on the panel with any sharp objects, such as a pencil or pen, as this may result in damage to the panel.
- To avoid injury or damage, make sure nothing is within the range of motion before moving the monitor and monitor arm. This includes both objects and people.
- Pay attention to the monitor arm position to avoid hitting it against anyone or anything.
- Before moving the system to another location, be sure to lock monitor/monitor arm in transport position.
- The monitor screen may have defective pixels. These pixels may appear as a slightly light or dark area on the screen. This is due to the characteristics of the panel itself, and not the product.
- The backlight of the monitor panel has a fixed life span. When the screen becomes dark or begins to flicker, contact a qualified Service Representative for information.

Material Safe Data

Rubber part

Material: Silicon

Where Used: Handle Screw Cap/Monitor Rubber

Allergic reactions to latex-containing medical devices

⚠ CAUTION   Due to reports of severe allergic reactions to medical devices containing latex (natural rubber), the FDA advises health-care professionals to identify latex-sensitive patients, and be prepared to treat allergic reactions promptly. Latex is a component of many medical devices, including surgical and examination gloves, catheters, incubation tubes, anesthesia masks and dental dams. Patient reaction to latex has ranged from contact urticaria, to systemic anaphylaxis.

For more details regarding allergic reaction to latex, refer to FDA Medical Alert MDA91-1, March 29.

Use of ECG

⚠ CAUTION   Do not use the Versana Essential Ultrasound system ECG wave for diagnostic and monitoring.

Electrical safety

Device classifications

The ultrasound unit is a Class I device, type BF, type CF, according to IEC 60601-1.

Internally connected peripheral devices

The system, together with peripheral devices, such as video printer, meets IEC 60601-1 standards for electrical isolation and safety. These standards are applicable only when the specified peripheral devices are plugged into the AC outlets provided on the unit.

External Connection of other peripheral devices

⚠ CAUTION — External devices can be used only if CE marked and in compliance with related standards (EN 60601-1 or EN 60950). Conformance to EN 60601-1 must be verified.

Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC standards (e.g. IEC 60950 for data processing equipment and IEC 60601-1 for medical equipment). Furthermore all complete configurations shall comply with the valid version of the system standard IEC 60601-1. Anybody connecting additional equipment to the signal input part or signal output part of the ultrasound unit configures a medical system, and is therefore responsible that the system complies with the requirements of the valid version of IEC 60601-1. If in doubt consult the technical service department or your local GE representative.

Other external devices, such as printers, and external monitors, usually exceed allowable leakage limits and, when plugged into separate AC outlets that are then connected to the unit, are in violation of patient safety standards. Suitable electrical isolation of such external AC outlets may be required in order to meet UL60601-1 and IEC 60601-1 standards for electrical leakage.

EMC (Electromagnetic Compatibility)

NOTE: *This equipment generates, uses and can radiate radio frequency energy. The equipment may cause radio frequency interference to other medical and non-medical devices and radio communications. To provide reasonable protection against such interference, this product complies with emissions limits for a Group 1, Class A Medical Devices Directive as stated in EN 60601-1-2. However, there is no guarantee that interference will not occur in a particular installation.*

NOTE: *If this equipment is found to cause interference (which may be determined by turning the equipment on and off), the user (or qualified service personnel) should attempt to correct the problem by one or more of the following measure(s):*

- *reorient or relocate the affected device(s)*
- *increase the separation between the equipment and the affected device*
- *power the equipment from a source different from that of the affected device*
- *consult the point of purchase or service representative for further suggestions.*

NOTE: *The manufacturer is not responsible for any interference caused by using other than recommended interconnect cables or by unauthorized changes or modifications to this equipment. Unauthorized changes or modifications could void the users' authority to operate the equipment.*

NOTE: *To comply with the regulations on electromagnetic interference for a Class A FCC Device, all interconnect cables to peripheral devices must be shielded and properly grounded. Use of cables not properly shielded and grounded may result in the equipment causing radio frequency interference in violation of the FCC regulations.*

EMC (Electromagnetic Compatibility) (continued)

NOTE: *Do not use devices which intentionally transmit RF Signals (cellular phones, transceivers, or radio controlled products) other than those supplied by GE (wireless microphone, broadband over power lines, for example) in the vicinity of the equipment as it may cause performance outside the published specifications. Keep the power to these type devices turned off when near this equipment.*

The medical staff in charge of this equipment is required to instruct technicians, patients, and other people who maybe around this equipment to fully comply with the above requirement.

EMC Performance

All types of electronic equipment may characteristically cause electromagnetic interference with other equipment, either transmitted through air or connecting cables. The term EMC (Electromagnetic Compatibility) indicates the capability of equipment to curb electromagnetic influence from other equipment and at the same time not affect other equipment with similar electromagnetic radiation from itself.

Proper installation following the service manual is required in order to achieve the full EMC performance of the product.

The product must be installed as stipulated in 'Notice upon Installation of Product' on *page 4-21*.

In case of issues related to EMC, please call your service personnel.

The manufacturer is not responsible for any interference caused by using other than recommended interconnect cables or by unauthorized changes or modifications to this equipment. Unauthorized changes or modifications could void the users' authority to operate the equipment.

EMC Performance (continued)

Portable and mobile radio communications equipment (e.g. two-way radio, cellular/cordless telephones and similar equipment) should be used no closer to any part of this system, including cables, than determined according to the following method:

Table 4-2:   Portable and mobile radio communications equipment distance requirements

Frequency Range:	150 kHz - 80 MHz	80 MHz - 800 MHz	800 MHz - 2.5 GHz
Calculation Method:	$d=[3.5/V_1]$ square root of P	$d = [3.5/E_1]$ square root of P	$d = [7/E_1]$ square root of P
Where: d= separation distance in meters, P = rated power of the transmitter, V_1=compliance value for conducted RF, E_1 = compliance value for radiated RF			
If the maximum transmitter power in watts is rated	**The separation distance in meters should be**		
5	2.6	2.6	5.2
20	5.2	5.2	10.5
100	12.0	12.0	24.0

ᵂ ⚠ WARNING   Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the [MEDICAL ELECTRICAL EQUIPMENT or MEDICAL ELECTRICAL SYSTEM], including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Notice upon Installation of Product

Separation distance and effect from fixed radio communications equipment: field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast transmitter cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ultrasound system is used exceeds the applicable RF compliance level as stated in the immunity declaration, the ultrasound system should be observed to verify normal operation. If abnormal operation is observed, additional measures may be necessary, such as re-orienting or relocating the ultrasound system or using an RF shielded examination room may be necessary.

1. Use either power supply cords provided by GE or ones designated by GE. Products equipped with a power source plug should be plugged into the fixed power socket which has the protective grounding conductor. Never use any adaptor or converter to connect with a power source plug (e.g. three-prong-to-two-prong converter).

2. Locate the equipment as far away as possible from other electronic equipment.

3. Be sure to use only the cables provided by or designated by GE. Connect these cables following the installation procedures (e.g. wire power cables separately from signal cables).

4. Lay out the main equipment and other peripherals following the installation procedures described in the service manuals and peripherals manufacture's manuals.

General Notice

1. Designation of Peripheral Equipment Connectable to This Product.

    The equipment indicated in the Supplies/Accessories section can be hooked up to the product without compromising its EMC performance.

    Avoid using equipment not designated in the list. Failure to comply with this instruction may result in poor EMC performance of the product.

2. Notice against User Modification

    The user should never modify this product. User modifications may cause degradation in EMC performance.

    Modification of the product includes changes in:

    a. Cables (length, material, wiring, etc.)

    b. System installation/layout

    c. System configuration/components

    d. Securing system parts (cover open/close, cover screwing)

3. Operate the system with all covers closed. If a cover is opened for some reason, be sure to shut it before starting/resuming operation.

4. Operating the system with any cover open may affect EMC performance.

Peripheral Update for EC countries

The following is intended to provide the users in EC countries with updated information concerning the connection of the Versana Essential to image recording and other devices or communication networks.

Peripherals used in the patient environment

The Versana Essential has been verified for overall safety, compatibility and compliance with the image recording devices listed in Supplies/Accessories section.

The Versana Essential has also been verified for compatibility, and compliance for connection to a local area network (LAN) via the rear panel Ethernet connection, provided the LAN components are IEC/EN 60950 compliant.

The Versana Essential may also be used safely while connected to devices other than those recommended above if the devices and their specifications, installation, and interconnection with the system conform to the requirements of IEC/EN 60601-1.

Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC standards (i.e., IEC60950 for data processing equipment and IEC60601-1 for medical equipment). Furthermore, all complete configurations shall comply with the valid version of the system standard IEC60601-1. Everyone who connects additional equipment to the signal input part or signal output part of the Versana Essential system configures a medical system, and is therefore responsible to ensure that the system complies with the requirement of the valid version of IEC60601-1. If in doubt, consult the technical service department or your local GE representative.

Peripherals used in the patient environment (continued)

General precautions for installing an alternate on-board device would include:

1. The added device(s) must have appropriate safety standard conformance and CE Marking.

2. The total power consumption of the added devices, which connect to the Versana Essential and are used simultaneously, must be less than or equal to the rated supply of the Versana Essential.

3. There must be adequate heat dissipation and ventilation to prevent overheating of the device.

4. There must be adequate mechanical mounting of the device and stability of the combination.

5. Risk and leakage current of the combination must comply with IEC/EN 60601-1.

6. Electromagnetic emissions and immunity of the combination must conform to IEC/EN 60601-1-2.

General precautions for installing an alternate on-board device would include:

1. The added device(s) must have appropriate safety standard conformance and CE Marking.

2. The added device(s) must be used for their intended purpose having a compatible interface.

3. Signal or mains isolation devices and additional protective earth may be needed to assure compliance with IEC/EN 60601-1.

⚠ CAUTION   The connection of equipment or transmission networks other than as specified in the user instructions can result in an electric shock hazard or equipment malfunction. Substitute or alternate equipment and connections requires verification of compatibility and conformity to IEC/EN 60601-1 by the installer. Equipment modifications and possible resulting malfunctions and electromagnetic interference are the responsibility of the owner.

Peripheral used in the non-patient environment

The Versana Essential has also been verified for compatibility, and compliance for connection to a USB HDD/USB memory via the system USB port, provided the USB HDD/USB memory are IEC/ EN 60950 compliant.

Interference caution

⚠ CAUTION   Use of devices that transmit radio waves near the unit could cause it to malfunction.

Devices which intrinsically transmit radio waves, such as cellular phones, radio transceivers, mobile radio transmitters, radio-controlled toys, etc., should preferably not be operated near the unit. See page 4-28 about the recommended minimum separation distances between portable and mobile RF communications equipment and the ultrasound unit.

Medical staff in charge of the unit are required to instruct technicians, patients, and other people who may be around the unit to fully comply with the above recommendations.

Any electrical device can unintentionally emit electromagnetic waves. However, minimum device separation distances cannot be calculated for such unspecified radiation. When the ultrasound unit is used adjacent to or in close proximity to other equipment the user should be attentive to unexpected device behavior which may be caused by such radiation.

The ultrasound unit is intended for use in the electromagnetic environment specified in the tables below.

The user of the ultrasound unit should ensure that the device is used in such an environment.

Declaration of Emissions

This system is suitable for use in the following environment. The user must assure that it is used only in the electromagnetic environment as specified.

Table 4-3:   Declaration of Emissions

Guidance and manufacturer's declaration - electromagnetic emissions		
The system is intended for use in the electromagnetic environment specified below. The user of the system should assure that it is used in such an environment.		
Emission Type	**Compliance**	**Electromagnetic Environment**
RF Emissions CISPR 11	Group 1	This system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	This system is suitable for use in all establishments, other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: WARNING: This system is intended for use by healthcare professionals only. This system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the system or shielding the location.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/Flicker Emissions IEC 61000-3-3	Complies	

Declaration of Immunity

This system is suitable for use in the following environment. The user must assure that the system is used according to the specified guidance and only in the electromagnetic environment listed.

Table 4-4:   Declaration of Immunity

Immunity Type	Equipment Capability	Regulatory Acceptable Level	EMC Environment and Guidance
IEC 61000-4-2 Static discharge (ESD)	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. Mains power quality should be that of a typical commercial and/or hospital environment. If the user requires continued operation during power mains interruptions, it is recommended that the system be powered from a UPS or a battery. NOTE: UT is the a.c. mains voltage prior to application of the test level. Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial and/or hospital environment. Separation distance to radio communication equipment must be maintained according to the method below. Interference may occur in the vicinity of equipment marked with the symbol: Image degradation or interference may occur due to conducted RF noise on the equipment mains power supply or other signal cable. Such interference is easily recognized and distinguishable from patient anatomy and physiological waveforms. Interference of this type may delay the examination without affecting diagnostic accuracy. Additional mains/signal RF isolation or filtering may be needed if this type interference occurs frequently.
IEC 61000-4-4 Electrical fast transient/burst	± 2 kV for mains ± 1 kV for SIP/SOP	± 2 kV for mains ± 1 kV for SIP/SOP	
IEC 61000-4-5 Surge Immunity	± 1 kV differential ± 2 kV common	± 1 kV differential ± 2 kV common	
IEC 61000-4-11 Voltage dips, short interruptions and voltage variations on mains supply	< 5% U_T (> 95% dip in U_T) for 0.5 cycle; 40% U_T (60% dip in U_T) for 5 cycles; 70% U_T (30% dip in U_T) for 25 cycles; < 5% U_T (>95% dip in U_T) for 5 sec	< 5% U_T (> 95% dip in U_T) for 0.5 cycle; 40% U_T (60% dip in U_T) for 5 cycles; 70% U_T (30% dip in U_T) for 25 cycles; < 5% U_T (>95% dip in U_T) for 5 sec	
IEC 61000-4-8 Power frequency (50/60 Hz) magnetic field	3 A/m	3 A/m	
IEC 61000-4-6 Conducted RF	3 V_{RMS} 150 kHz - 80 MHz	3 V_{RMS} 150 kHz - 80 MHz	
IEC 61000-4-3 Radiated RF	3 V/m 80 MHz - 2.5 GHz	3 V/m 80 MHz - 2.5 GHz	
NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people. If noise generated from other electronic equipment is near the probe's center frequency, noise may appear on the image. Good power line isolation is required.			

Minimum distances

<table>
<tr><td colspan="4">Recommended separation distances between portable and mobile RF communications equipment and the ultrasound unit</td></tr>
<tr><td colspan="4">The ultrasound unit is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ultrasound unit can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ultrasound unit as recommended below, according to the maximum output power of the communications equipment. Portable and mobile radio communications equipment (e.g. two-way radio, cellular/cordless telephones and similar equipment) should be used no closer to any part of this system, including cables, than determined according to the following method:</td></tr>
<tr><td rowspan="2">Rated maximum output of transmitter
W</td><td colspan="3">Separation distance according to frequency of transmitter
m</td></tr>
<tr><td>150 kHz to 80 MHz
$d=[1.2]\sqrt{P}$</td><td>80 MHz to 800 MHz
$d=[1.2]\sqrt{P}$</td><td>800 MHz to 2.7 GHz
$d=[2.3]\sqrt{P}$</td></tr>
<tr><td>0.01</td><td>0.12</td><td>0.12</td><td>0.23</td></tr>
<tr><td>0.1</td><td>0.38</td><td>0.38</td><td>0.73</td></tr>
<tr><td>1</td><td>1.2</td><td>1.2</td><td>2.3</td></tr>
<tr><td>10</td><td>3.8</td><td>3.8</td><td>7.3</td></tr>
<tr><td>100</td><td>12</td><td>12</td><td>23</td></tr>
<tr><td colspan="4">For transmitters rated at a maximum output power not listed above the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1: At 80 MHz and 800 MHz, 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.</td></tr>
</table>

Basic Safety

1. The creepage distances and air clearance should meet the requirements.
2. The protective earthing should meet the requirements.
3. The leakage current should meet the requirements.

Essential performance

The essential performance of the ultrasound unit is:

1. The ability to display physiological images as input for diagnosis by trained physician.
2. The ability to display physiological traces as aid for diagnosis by trained physician.
3. The ability to display quantified data as input for diagnosis by trained physician.
4. No component failures.
5. No changes in programmable parameters.
6. No reset to factory defaults (manufacturer's presets).
7. No change of operating mode.

Patient Environmental Devices

Figure 4-1.   Patient Environmental Devices for Versana Essential

1.   Right side
     •   2 probe holders
     •   1 gel bottle holder

2.   Front panel
     •   Inside Printer Box
     •   2 or 3 active probe ports

3.   Left side
     •   1 USB Port (Only for USB memory disk)
     •   2 probe holders

4.   Rear panel
     •   1 HDMI port
     •   2 USB ports
     •   1 Ethernet port (100MBase-T)
     •   1 VGA port
     •   1 Composite out port
     •   1 S-Video port

Acceptable Devices

The Patient Environmental devices shown on the previous page are specified to be suitable for use within the PATIENT ENVIRONMENT.

⚠ CAUTION   DO NOT connect any probes or accessories without approval by GE within the PATIENT ENVIRONMENT.

See 'Supplies/Accessories' on *page 3-39 for more information.*

Unapproved Devices

⚠ CAUTION   DO NOT use unapproved devices.

If devices are connected without the approval of GE, the warranty will be INVALID.

Any device connected to the Versana Essential must conform to the requirements for IEC or equivalent standards appropriate to devices.

Accessories, Options, Supplies

⚠ CAUTION   Unsafe operation or malfunction may result. Use only the accessories, options and supplies approved or recommended in these instructions for use.

Acoustic Output

⚠ CAUTION Allowing the machine to transmit acoustic output with the probe not in use (or in its holder) can cause the transducer to build up heat. Always lower the acoustic power or freeze the image when not in use.

Located on the upper right section of the system display monitor, the acoustic output display provides the operator with real-time indication of acoustic levels being generated by the system. See the *Acoustic Output chapter* in the *Advanced Reference Manual* for more information. This display is based on NEMA/AIUM Standards for Real-time Display of Thermal and Mechanic Acoustic Output Indices on Diagnostic Ultrasound Equipment.

Acoustic Output Display Specifications

The display consists of three parts: Thermal Index (TI), Mechanical Index (MI), and a relative Acoustic Output (AO) value. Although not part of the NEMA/AIUM standard, the AO value informs the user of where the system is operating within the range of available output.

The TI and MI are displayed at all times. The TI and MI display starts at a value of 0 and increments in steps of 0.2.

Always be aware of the acoustic output level by observing the Acoustic Output Display. In addition, become thoroughly familiar with the Acoustic Output Display and equipment controls affecting output.

Thermal Index

Depending on the examination and type of tissue involved, the TI parameter will be one of three types:

- **Soft Tissue Thermal Index (TIS)**. Used when imaging soft tissue only, it provides an estimate of potential temperature increase in soft tissue.
- **Bone Thermal Index (TIB)**. Used when bone is near the focus of the image as in the third trimester OB examination, it provides an estimate of potential temperature increase in the bone or adjacent soft tissue.
- **Cranial Bone Thermal Index (TIC)**. Used when bone is near the skin surface as in transcranial examination, it provides an estimate of potential temperature increase in the bone or adjacent soft tissue.

Acoustic Output Display Specifications (continued)

Mechanical Index

MI recognizes the importance of non-thermal processes, cavitation in particular, and the Index is an attempt to indicate the probability that they might occur within the tissue.

Changing the Thermal Index Type

You can select the displayed TI type on Utility -> Imaging -> B-Mode. This preset is application dependent so each application could specify a different TI type.

TI and MI Display Accuracy

When display MI>= 0.6, TI>= 3.6, the displayed values of MI and IT is not lower than 50% or higher than 150% of the measured value.

When display MI < 0.6, TI < 3.6, the absolute error of MI <= 0.3, the absolute error of TI <= 1.8.

Ispta

The Ispta is the Spatial Peak Temporal Average Intensity. The absolute maximum regulatory limit of Ispta is 720 mW/cm^2 as set by the FDA 510(k) guidance of September 9, 2008.

Controls Affecting Acoustic Output

The potential for producing mechanical bioeffects (MI) or thermal bioeffects (TI) can be influenced by certain controls.

Direct. The Acoustic Output control has the most significant effect on Acoustic Output.

Indirect. Indirect effects may occur when adjusting controls. Controls that can influence MI and TI are detailed under the Bioeffects portion of each control in the Optimizing the Image sections.

Always observe the Acoustic Output display for possible effects.

Best practices while scanning

HINTS — Raise the Acoustic Output only after attempting image optimization with controls that have no effect on Acoustic Output, such as Gain and TGC.

NOTE: *Refer to the Optimizing the Image sections for a complete discussion of each control.*

WARNING — Be sure to have read and understood control explanations for each mode used before attempting to adjust the Acoustic Output control or any control that can effect Acoustic Output.

Acoustic Output Hazard — Use the minimum necessary acoustic output to get the best diagnostic image or measurement during an examination. Begin the exam with the probe that provides an optimum focal depth and penetration.

Acoustic Output Default Levels

In order to assure that an exam does not start at a high output level, the Versana Essential initiates scanning at a reduced default output level. This reduced level is preset programmable and depends upon the exam category and probe selected. It takes effect when the system is powered on or *Patient* is selected.

To modify acoustic output, adjust the Power Output level.

Safety statement

GE safety statement

Although no harmful biological effects have been demonstrated for ultrasound frequencies, intensities, or exposure times used in examination with the GE system, GE recommends using the lowest acoustic output settings which will produce diagnostically acceptable information.

General Caution

⚠ CAUTION	Standard maintenance must be performed by authorized service personnel for the lifetime of the product (7 years).

⚠ CAUTION	Proceed cautiously when crossing door or elevator thresholds. Use the handle to push/pull the system, e.g., do not use the monitor. Failure to do so may cause serious injury or system damage.

ROHS Versana Essential Hazardous Substances

The following product pollution control information is provided according to SJ/T11364-2014 Marking for Control of Pollution caused by Electronic Information Products.

This symbol indicates the product contains hazardous materials in excess of the limits established by the Chinese standard GB/T 26572 Requirements for Concentration Limits for Certain Hazardous Substances in Electronic Information Products. The number in the symbol is the Environment-friendly Use Period (EFUP), which indicates the period during which the toxic or hazardous substances or elements contained in electronic information products will not leak or mutate under normal operating conditions so that the use of such electronic information products will not result in any severe environmental pollution, any bodily injury or damage to any assets. The unit of the period is "Year".

In order to maintain the declared EFUP, the product shall be operated normally according to the instructions and environmental conditions as defined in the product manual, and periodic maintenance schedules specified in Product Maintenance Procedures shall be followed strictly.

Consumables or certain parts may have their own label with an EFUP value less than the product. Periodic replacement of those consumables or parts to maintain the declared EFUP shall be done in accordance with the Product Maintenance Procedures. This product must not be disposed of as unsorted municipal waste, and must be collected separately and handled properly after decommissioning.

Name and Concentration of Hazardous Substances

Table 4-5:   Table of hazardous substances' name and concentration for Versana Essential

Component Name	Hazardous substances' name					
	Pb	**Hg**	**Cd**	**Cr (VI)**	**PBB**	**PBDE**
Monitor	X	O	O	O	O	O
Printed Circuit Board Assemblies	X	O	O	O	O	O
Keyboard Assemblies	X	O	O	O	O	O
Power Assemblies	X	O	O	O	O	O
Console Cabinet	O	O	O	O	O	O
Ultrasound Probes	X	O	O	O	O	O
Wheels	O	O	O	O	O	O

This table is prepared according to SJ/T 11364.
O: Indicates that hazardous substance contained in all of the homogeneous materials for this part is below the limit requirement in GB/T 26572.
X: Indicates that hazardous substance contained in at least one of the homogeneous materials used for this part is above the limit requirement in GB/T 26572.
• Data listed in the table represents best information available at the time of publication.
• Applications of hazardous substances in this medical device are required to achieve its intended clinical uses, and/or to provide better protection to human beings and/or to environment, due to lack of reasonably (economically or technically) available substitutes. For example: Lead is could be used in Printed circuit solder.

Device Labels

Label Icon Description

The following table describes the purpose and location of safety labels and other important information provided on the equipment.

Table 4-6:   Label Icons

Label/Icon	Purpose/Meaning	Location
Identification and Rating Plate	Manufacture's name and address	• Rear Panel • Rating Plate • Probes
Identification and Rating Plate	**Date of manufacture:** The date could be a year, year and month, or year, month and day, as appropriate. See ISO 8601 for date formats.	Rating Plate
SN	Serial Number	Rating Plate
REF	Catalog Number	Rating Plate
Type/Class Label	Used to indicate the degree of safety or protection.	
IP Code (IPX8) IPX8: FSU-1000, MKF 2-MED GP26	Indicates the degree of protection provided by the enclosure per IEC60 529.	Bottom of footswitch
	Type BF Applied Part (man in the box) symbol is in accordance with IEC 60878-02-03.	Beside the probe connector
	General Warning.	Various

Table 4-6:   Label Icons (continued)

Label/Icon	Purpose/Meaning	Location
	"CAUTION" - Dangerous voltage" (the lightning flash with arrowhead) is used to indicate electric shock hazards.	Various
	Indicates the power on and power off position of the power switch. **CAUTION:** This Power Switch **DOES NOT ISOLATE** Mains Supply.	See the Console Overview section for location information.
	"Protective Earth" indicates the protective earth (grounding) terminal.	Inside Power Box and Console
	"Equipotentiality" indicates the terminal to be used for connecting equipotential conductors when interconnecting (grounding) with other equipment. Connection of additional protective earth conductors or potential equalization conductors is not necessary in most cases and is only recommended for situations involving multiple equipment in a high-risk patient environment to provide assurance that all equipment is at the same potential and operates within acceptable leakage current limits. An example of a high-risk patient would be a special procedure where the patient has an accessible conductive path to the heart such as exposed cardiac pacing leads. IEC60417-5021.	Rear panel
	This symbol indicates that waste electrical and electronic equipment must not be disposed of as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.	Rear Panel and probe connector

Table 4-6:   Label Icons (continued)

Label/Icon	Purpose/Meaning	Location
	This symbol indicates the product contains hazardous materials in excess of the limits established by the Chinese standard GB/T 26572 Requirements of Concentration Limits for Certain restricted Substances in electrical and electronic Products.The number in the symbol is the Environment-friendly Use Period (EFUP), which indicates the period during which the hazardous substances contained in electrical and electronic products will not leak or mutate under normal operating conditions so that the use of such electrical and electronic products will not result in any severe environmental pollution, any bodily injury or damage to any assets. The unit of the period is "Year".	Probe and Rear Panel, China Rating Plate
	Do not place any objects on the monitor.	Back of Monitor
	Do not force the monitor with your hands.	Back of Monitor
	There is a pinch point on the monitor. Take care to avoid injuring hands or fingers when flipping down the monitor.	Back of Monitor
	Use the rear handle for horizontal movement only.	Back of Monitor
	"Consult accompanying documents" is intended to alert the user to refer to the operator manual or other instructions when complete information cannot be provided on the label.	Various

Table 4-6:   Label Icons (continued)

Label/Icon	Purpose/Meaning	Location
	Warning: crushing of hands.	Top of Arm
	DO NOT put your whole body weight on the foot-rest holder.	Foot rest
	The maximum load weight is 1.5kg.	Various
	NRTL Listing and Certification Mark is used to designate conformance to nationally recognized product safety standards. The Mark bears the name and/or logo of the testing laboratory, product category, safety standard to which conformity is assessed and a control number.	Rating plate
	Type CF Defib-Proof Applied Part (heart in the box with paddle) symbol is in accordance with IEC 60878-02-06.	ECG Module
	Do not push the system	Back of Monitor
	Do not connect the DVD-RW to the system while scanning.	DVD-RW
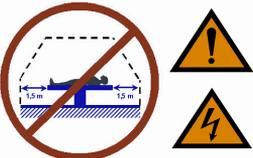
Table 4-6:   Label Icons (continued)

Label/Icon	Purpose/Meaning	Location
	GOST symbol: Russia Regulatory Country Clearance.	Rating plate Note: Only after Russian regulatory registration is complete, this label will be located on the console rating plate.
	"Eurasian Conformity" mark; the single conformity mark for circulation of products on the markets of member-states of Customs Union. This product passed all conformity assessment (approval) procedures that correspond to the requirements of applicable technical regulations of the Customs Union.	Rear panel Note: Only after Russian regulatory registration is complete, this label will be located on the console.
UA.TR.116	Mark of conformity with the Technical Regulations.	This product meets the requirements of the Technical Regulations on medical devices, approved by Resolution No.753 of the Cabinet of Ministers of Ukraine of 2 October 2013. Note: Only after Ukrainian regulatory registration is complete, this label will be located on the console.

Table 4-6:   Label Icons (continued)

Label/Icon	Purpose/Meaning	Location
Segurança TÜVRheinland	INMETRO Certification: TUV Rheinland Brazil	Rating plate Note: Only after Brazilian regulatory registration is complete, this label will be located on the console rating plate.
⚠ CAUTION 주의 注意 This machine should be used in compliance with law. Some jurisdictions restrict certain uses, such as gender determination. 전기기는 법규를 준수하여 사용되어야 합니다. 특정한 사용제품 들어 태아의 성별 감지 복 려와 사용등이 제한됩니다. 应合法使用该设备，某些国家相关法法等禁止使用其做胎儿性别鉴定等。	**CAUTION**: This machine should be used in compliance with law. Some Jurisdictions restrict certain uses, such as gender determination.	Rating plate Note: For China, Korea and India only.
UDI (01) 0 0840682 12561 1 (11) XXXXXXXXXXXXXXXXX	Every system has a unique marking for identification, the Unique Device Identification (UDI) Label. The UDI label consists of a series of alpha-numeric characters and barcode which uniquely identify the Versana Essential system as a medical device manufactured by General Electric. Scan or enter the UDI information into the patient health record as required by country-specific laws.	Rating plate

Warning Label Locations

Versana Essential warning labels are provided in English.
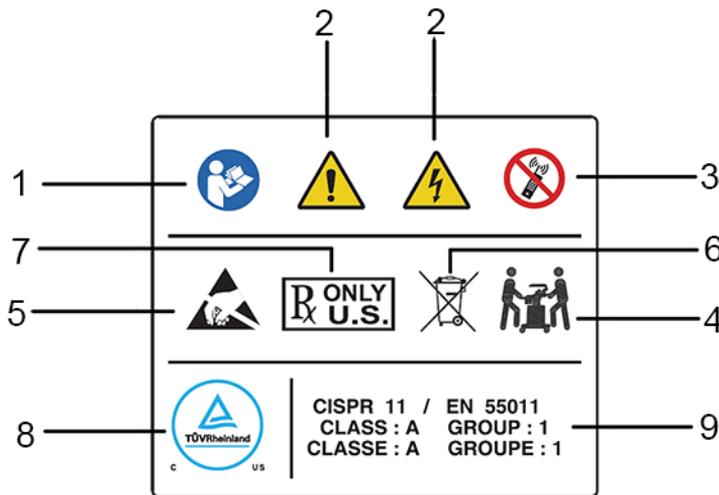
Figure 4-2.   Label location explanations

Table 4-7:   Label Location Explanations

1. "Consult accompany document" is intended to alert the user to refer to the operator manual or other instructions when complete information cannot be provided on the label.
2. Possible shock hazard. Do not remove covers or panels. No user serviceable parts are inside. Refer servicing to qualified service personnel.
3. Do not use the following devices near this equipment: cellular phone, radio receiver, mobile radio transmitter, radio controlled toy, etc. Use of these devices near this equipment could cause this equipment to perform outside the published specifications. Keep power to these devices turned off when near this equipment.
4. The equipment weighs approximately 40 kg (88 lbs). To avoid possible injury and equipment damage when transporting from one area of use to another:
   • Be sure the pathway is clear.
   • Limit movement to a slow careful walk.
   • Use two or more persons to move the equipment on inclines or long distance

5. Be careful of static
6. WEEE Label
7. United States only
   • Prescription Requirement label
8. NRTL Listing and Certification Mark is used to designate conformance to nationally recognized product safety standards. The Mark bears the name and/or logo of the testing laboratory, product category, safety standard to which conformity is assessed and a control number.
9. CISPR **CAUTION**: The Versana Essential conforms to the CISPR11, Group 1, Class A of the international standard for Electromagnetic disturbance characteristics.

Warning Label Locations (continued)

> *NOTE:* *The warning labels are on the rear of the system. The label content may be different for different regions. Please refer to the warning labels on the system for the actual content.*

Figure 4-3.   Versana Essential Rating Plate Label Location

Probe Label Explanation

The following information appears on all probe labels, regardless of the connector type, except for "IPX7", "CE Mark", and "XDclearTM" which only appears on applicable probes.

NOTE: *The probe label displayed in this manual is only for illustrational purposes. Refer to the actual probe label for the specific information.*

Figure 4-4.   Probe label

1. GE Logo
2. Probe Model (Name)
3. UDI Symbol and Data Matrix
4. UDI Human Readable Label Text: Global Trade Item Number, GTIN, (01), Manufacturing Date (11), Serial Number (21)
5. Type BF/CF Applied Part
6. Caution: Consult the Manual
7. WEEE Waste Symbol
8. Chinese RoHS Hazardous Substance Symbol
9. CE Mark and Notified Body Number
10. REF: Catalog/model number
11. Serial Number
12. Manufacturer's site country of origin
13. Legal Manufacturer's Name and Address
14. Date of Manufacture, as YYYY-MM
15. IP Classification

NOTE: *Non-GE probes will also have a UDI symbol and equivalent information.*

Probe Box Label

> *NOTE:* The probe box label displayed in this manual is only for illustrational purposes. Refer to the actual probe box label for the specific information.

Figure 4-5.   Probe box label

UDI Global Trade Item Number (GTIN) Label and Probe Box Barcode Locations
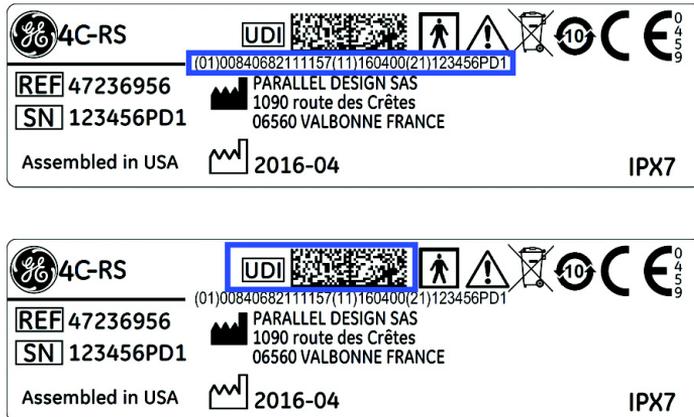
Figure 4-6.   Probe Label UDI GTIN and Barcode Locations

UDI Global Trade Item Number (GTIN) Label and Probe Box Barcode

Locations (continued)
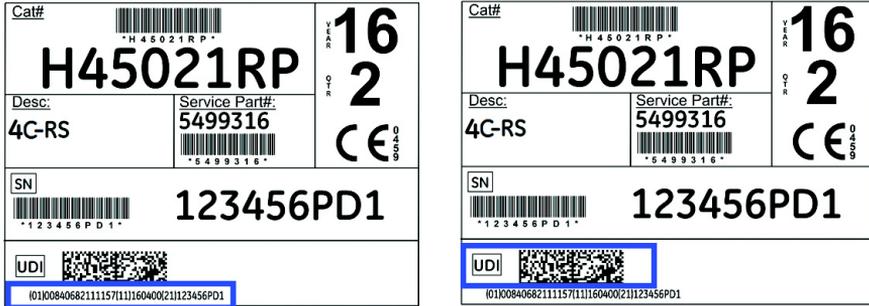
Figure 4-7.   Probe Box Label UDI GTIN and Barcode Locations

Chapter 5

Probes and Biopsy

This chapter consists of the information of each probe and describes some special concerns, biopsy kits and accessories as well as basic procedures for attaching a biopsy guide to the different types of probes.

Probe Overview

Ergonomics

Probes have been ergonomically designed to:

- Handle and manipulate with ease
- Connect to the system with one hand
- Be lightweight and balanced
- Have rounded edges and smooth surfaces.
- Stand up to typical wear by cleaning and disinfectant agents, contact with approved gel, etc.

Cables have been designed to:

- Connect to system with appropriate cable length

Cable handling

Take the following precautions with probe cables:

- Keep free from wheels
- Do not bend the cable acutely
- Avoid crossing cables between probes.

Probe orientation

Each probe is provided with an orientation marking. This mark is used to identify the end of the probe corresponding to the side of the image having the orientation mark on the display.

1
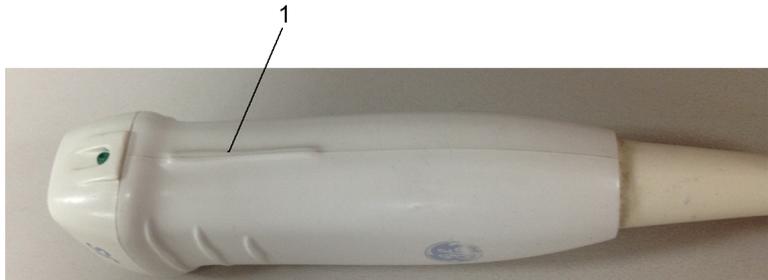
Figure 5-1.   Orientation Marking on Probe (Example)

1.   Orientation Mark

Labeling

Each probe is labeled with the following information:

- Seller's name and manufacturer
- GE part number
- Probe serial number
- Month and year of manufacture
- Probe designation-provided on the probe grip and the top of the connector housing, so it is easily read when mounted on the system and is also automatically displayed on the screen when the probe is selected.

Figure 5-2.   Displayed Probe Information

Probe Naming Conventions

Table 5-1:   Probe Naming Convention

Type	Frequency	Connector Type
C = Convex L = Linear S = Sector	"4" in 4C-RS	RS

Probe Usage

For details on connecting, activating, deactivating, disconnecting, transporting and storing the probes, See 'Probes' on *page 1-40 for more information.*

Care and Maintenance

Inspecting probes

⚠️ **CAUTION**   If any damage is found, DO NOT use the probe until it has been inspected and released for further use by a GE service representative.

Before each use

1. Inspect the probe's lens, cable, casing, and connector for cracks, cuts, tears, and other signs of physical damage.
2. Test the functionality of the probe.
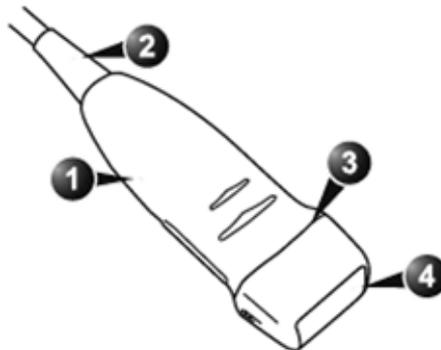
Figure 5-3.   Probe parts

1.	Housing	3.	Seal
2.	Strain relief	4.	Lens

After each use

1. Inspect the probe's lens, cable, casing, and connector for cracks, cuts, tears, and other signs of physical damage.
2. Look for any damage that would allow liquid to enter the probe.

Environmental Requirements

Probes should be operated, stored, or transported within the parameters outlined below.

⚠️ CAUTION   Ensure that the probe face temperature does not exceed the normal operation temperature range.

Table 5-2:   Probe Environmental Requirements

	Operational	**Storage**	**Transport**
Temperature	10° - 40° C 50° - 104° F	-5° - 50° C 23° - 122° F	-5° - 50° C 23° - 122° F
Humidity	30 - 80% non-condensing	10 - 90% non-condensing	10 - 90% non-condensing
Pressure	700 - 1060hPa	700 - 1060hPa	700 - 1060hPa

⚠️ CAUTION   Check the room temperature before you use the probe.

Probe Safety

Handling precautions

⚠ WARNING   Ultrasound probes are highly sensitive medical instruments that can easily be damaged by improper handling. Use care when handling and protect from damage when not in use. DO NOT use a damaged or defective probe. Failure to follow these precautions can result in serious injury and equipment damage.

Electrical shock hazard

Electrical Hazard   The probe is driven with electrical energy that can injure the patient or user if live internal parts are contacted by conductive solution:

- **DO NOT** immerse the probe into any liquid beyond the level indicated by the immersion level diagram. Refer to the immersion illustration in the Probe Cleaning Process section. Never immerse the probe connector or probe adaptors into any liquid.

- **DO NOT** drop the probes or subject them to other types of mechanical shock or impact. Degraded performance or damage such as cracks or chips in the housing may result.

- Prior to each use, visually inspect the probe lens and case area for cracks, cuts, tears, and other signs of physical damage. DO NOT use a probe which appears to be damaged until you verify functional and safe performance. You must perform a more thorough inspection, including the cable, strain relief, and connector, each time you clean the probe.

- Before inserting the connector into the probe port, inspect the probe connector pins. If a pin is bent, do not use the probe until it has been inspected and repaired/replaced by a GE Service Representative.

- **DO NOT** kink, tightly coil, or apply excessive force on the probe cable. Insulation failure may result.

- Electrical leakage checks should be performed on a routine basis by GE Service or qualified hospital personnel. Refer to the service manual for leakage check procedures.

Mechanical hazards

⚠ CAUTION	A defective probe or excessive force can cause patient injury or probe damage:
	• Observe depth markings and do not apply excessive force when inserting or manipulating intracavitary probes.
	• Inspect probes for sharp edges or rough surfaces that could injure sensitive tissue.
	• DO NOT apply excessive force to the probe connector when inserting into the probe port. The pin of a probe connector may bend.

Special handling instructions

Using protective sheaths

⚠ CAUTION

Protective barriers may be required to minimize disease transmission. Probe sheaths are available for use with all clinical situations where infection is a concern. Use of legally marketed, sterile probe sheaths is mandatory for intra-cavitary and intra-operative procedures. Use of legally marketed, sterile, pyrogen free probe sheaths is REQUIRED for neurological intra-operative procedures.

Instructions. Custom made sheaths are available for each probe. Each probe sheath kit consists of a flexible sheath used to cover the probe and cable and elastic bands used to secure the sheath.

Sterile probe sheaths are supplied as part of biopsy kits for those probes intended for use in biopsy procedures. In addition to the sheath and elastic bands, there are associated accessories for performing a biopsy procedure which are included in the kit. Refer to the biopsy instructions for the specific probes in the Discussion section of this chapter for further information.

Reordering. To reorder sheaths, please contact your local distributor or the appropriate support resource.

⚠ CAUTION

Devices containing latex may cause severe allergic reaction in latex sensitive individuals. Refer to FDA's March 29, 1991 Medical Alert on latex products.

⚠ CAUTION

Do not use pre-lubricated condoms as a sheath. In some cases, they may damage the probe. Lubricants in these condoms may not be compatible with probe construction.

⚠ CAUTION

DO NOT use an expired probe sheath. Before using probe sheaths, verify whether the term of validity has expired.

Endocavitary Probe Handling Precautions

If the sterilization solution comes out of the endocavitary probe, please follow the cautions below.

⚠ CAUTION — Sterile/sanitary sheaths are to be used on the probe during its actual use with patients. Wearing gloves protects the patient and operator.

⚠ CAUTION — **Sterilant Exposure to Patient (e.g., Cidex)**—Contact with a sterilant to the patient's skin or mucous membrane may cause an inflammation. If this happens, refer to the sterilant's instruction manual.

Sterilant Exposure from Probe Handle/Connector to Patient (e.g., Cidex)—DO NOT allow the sterilant to contact the patient. Only immerse the probe to its specified level. Ensure that no solution has entered the probe's handle before scanning the patient. If sterilant comes into contact with the patient, refer to the sterilant's instruction manual.

Endocavitary Probe Point of Contact—Refer to the sterilant's instruction manual.

Probe handling and infection control

This information is intended to increase user awareness of the risks of disease transmission associated with using this equipment and provide guidance in making decisions directly affecting the safety of the patient as well as the equipment user.

Diagnostic ultrasound systems utilize ultrasound energy that must be coupled to the patient by direct physical contact. Depending on the type of examination, this contact occurs with a variety of tissues ranging from intact skin in a routine exam to recirculating blood in a surgical procedure. The level of risk of infection varies greatly with the type of contact.

One of the most effective ways to prevent transmission between patients is with single use or disposable devices. However, ultrasound transducers are complex and expensive devices that must be reused between patients. It is very important, therefore, to minimize the risk of disease transmission by using barriers and through proper processing between patients.

⚠ CAUTION — Risk of Infection. ALWAYS clean and disinfect the probe between patients to the level appropriate for the type of examination and use FDA-cleared probe sheaths where appropriate.

⚠ CAUTION — Adequate cleaning and disinfection are necessary to prevent disease transmission. It is the responsibility of the equipment user to verify and maintain the effectiveness of the infection control procedures in use. Always use sterile, legally marketed probe sheaths for intra-cavitary and intra-operative procedures.

For neurological intra-operative procedures, use of a legally marketed, sterile, pyrogen free probe sheath is REQUIRED. Probes for neuro surgical use must not be sterilized with liquid chemical sterilants because of the possibility of neuro toxic residues remaining on the probe.

Probe Cleaning Process

Cleaning probes

To clean the probe:

NOTE: *Do not immerse the probe into any liquid beyond the level specified for that probe (Figure 5-4 on page 5-13). Never immerse the transducer connector into any liquid.*

1. Inspect the probe's lens, cable, casing, and connector for cracks, cuts, tears, and other signs of physical damage.
2. Disconnect the probe from the ultrasound console and remove all coupling gel from the probe by wiping with a soft cloth and rinsing with flowing water.

NOTE: *DO NOT wipe the probe with a dry cloth.*

3. Soak the probe head in water. Scrub the probe as needed using a soft sponge, gauze, or cloth to remove all visible residue from the probe surface.

⚠ CAUTION   Take extra care when handling the lens face of the ultrasound transducer. The lens face is especially sensitive and can easily be damaged by rough handling. NEVER use excessive force when cleaning the lens face.

4. Rinse the probe with enough clean potable water.
5. Air dry or dry with a soft cloth.
6. After cleaning, inspect the probe's lens, cable, casing and connector. Look for any damage that would allow liquid to enter the probe. Also, inspect the probe functionality by live scan. If any damage is found, do not use the probe until it has been inspected and repaired/replaced by a GE service representative.

Cleaning probes (continued)

C2-5-RS L6-12-RS E8C-RS 3Sc-RS L5-11-RS 4C-RS
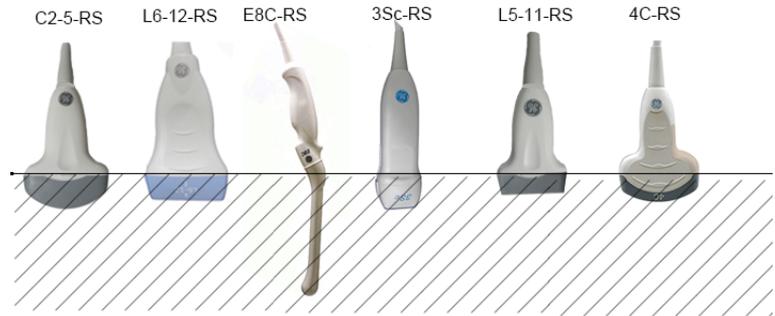
Figure 5-4.   Probe Immersion Levels

Table 5-3:   Description of Pictogram for Probe Immersion
Levels

Pictogram	Description
////////////	Fluid Level

Disinfecting probes

Perform After Each Use   Ultrasound probes can be disinfected using liquid chemical germicides. The level of disinfection is directly related to the duration of contact with the germicide. Increased contact time produces a higher level of disinfection.

Table 5-4:   Description of Pictogram on Care card

Pictogram	Description
	"ATTENTION" - Consult accompanying documents is intended to alert the user to refer to the operator manual or other instructions when complete information cannot be provided on the label.
	"CAUTION" - Dangerous voltage (the lightning flash with arrowhead) is used to indicate electric shock hazards.
	Biohazard - Patient/user infection due to contaminated equipment. Usage • Cleaning and care instructions • Sheath and glove guidelines
	Ultrasound probes are highly sensitive medical instruments that can easily be damaged by improper handling. Use care when handling and protect from damage when not in use.
	Do not immerse the probe into any liquid beyond the level specified for that probe. Refer to the user manual of the ultrasound system.
	Since there is a possibility of having negative effects on the probe, observe the specified immersing time by the germicide manufacturer strictly. Do not immerse the probe in liquid chemical germicides more than the time prescribed in the care card.
	"Consult accompany document" - Refer to the ultrasound system user manual for important probe care and cleaning instruction.

Disinfecting probes (continued)

⚠ CAUTION	Review the probe care card that is packed with each probe. Please refer to the probe care card for GE approved probe disinfectants.

⚠ CAUTION	In order for liquid chemical germicides to be effective, all visible residue must be removed during the cleaning process. Thoroughly clean the probe, as described earlier before attempting disinfection.

You MUST disconnect the probe from the Versana Essential prior to cleaning/disinfecting the probe. Failure to do so could damage the system.

DO NOT soak probes in liquid chemical germicide for longer than is stated by the germicide instructions for use. Extended soaking may cause probe damage and early failure of the enclosure, resulting in possible electric shock hazard.

1. Prepare the germicide solution according to the manufacturer's instructions. Be sure to follow all precautions for storage, use and disposal.

2. Place the cleaned and dried probe in contact with the germicide for the time specified by the germicide manufacturer. High-level disinfection is recommended for surface probes and is required for endocavitary and intraoperative probes (follow the germicide manufacturer's recommended time).

⚠ CAUTION	Probes for neuro surgical intra-operative use must NOT be sterilized with liquid chemical sterilants because of the possibility of neuro toxic residues remaining on the probe. Neurological procedures must be done with the use of legally marketed, sterile, pyrogen free probe sheaths.

3. After removing from the germicide, rinse the probe following the germicide manufacturer's rinsing instructions. Flush all visible germicide residue from the probe and allow to air dry.

Disinfecting probes (continued)

CAUTION

CREUTZFIELD-JACOB DISEASE

This device is not indicated for neurological use. Neurological contact on patients with this disease must be avoided. If a device/probe becomes contaminated, there is no adequate means to disinfect it. In this case, the contaminated device/probe must be discarded in accordance with local biologic waste hazard procedures.

Biological Hazard

WARNING

Ultrasound transducers can easily be damaged by improper handling and by contact with certain chemicals. Failure to follow these precautions can result in serious injury and equipment damage.

- Do not immerse the probe into any liquid beyond the level specified for that probe. Never immerse the transducer connector or probe adapters into any liquid.
- Avoid mechanical shock or impact to the transducer and do not apply excessive bending or pulling force to the cable.
- Transducer damage can result from contact with inappropriate coupling or cleaning agents:
  - Do not soak or saturate transducers with solutions containing alcohol, bleach, ammonium chloride compounds or hydrogen peroxide
  - Avoid contact with solutions or coupling gels containing mineral oil or lanolin
  - Avoid temperatures above 50°C.
- Inspect the probe prior to use and after use for damage or degeneration to the housing, strain relief, lens and seal. Do not use a damaged or defective probe.

Coupling gels

⚠ WARNING

Do not use unrecommended gels (lubricants). They may damage the probe and void the warranty. Please refer to the probe care card for GE approved probe gels.

Applying

In order to assure optimal transmission of energy between the patient and probe, a conductive gel or couplant must be applied liberally to the patient where scanning will be performed.

⚠ CAUTION

Do not apply gel to the eyes. If there is gel contact to the eye, flush eye thoroughly with water.

Precautions

Coupling gels should not contain the following ingredients as they are known to cause probe damage:

- Methanol, ethanol, isopropanol, or any other alcohol-based product
- Mineral oil
- Iodine
- Lotions
- Lanolin
- Aloe Vera
- Olive Oil
- Methyl or Ethyl Parabens (para hydroxybenzoic acid)
- Dimethylsilicone
- Polyether glycol based
- Petroleum

⚠ WARNING

User should select the Non-toxic and nonirritating GEL.

Planned Maintenance

The following maintenance schedule is suggested for the system and probes to ensure optimum operation and safety.

Table 5-5:   Planned Maintenance Program

Do the Following	Daily	After Each Use	As Necessary
Inspect the Probes	X	X	X
Clean the Probes		X	X
Disinfect Probes		X	X

Returning/Shipping Probes and Repair Parts

US Department of Transportation and GE policy requires that equipment returned for service MUST be clean and free of blood and other infectious substances.

When you return a probe or part for service (Field Engineer or customer), you need to clean and disinfect the probe or part prior to packing and shipping the equipment.

Ensure that you follow probe cleaning and disinfection instructions provided in the Basic User Manual.

This ensures that employees in the transportation industry as well as the people who receive the package are protected from any risk.

Sterile Ultrasound Procedures

ONLY ultrasound gel that is labeled as sterile, is sterile.

Ensure you always use sterile ultrasound gel for those procedures that require sterile ultrasound gel.

Once a container of sterile ultrasound gel is opened, it is no longer sterile and contamination during subsequent use is possible.

Probe Discussion

Introduction

The Versana Essential supports the following types of probes:

- **Convex Array.** Convex Array probes.
- **Linear Array.** Linear Array probes.
- **Sector Phased Array.** Sector Phased Array probes.

⚠ CAUTION Probes for transvaginal and transrectal applications require special handling. Transvaginal/transrectal examinations and probe insertions should be performed only by personnel with adequate training. Refer to the user documentation enclosed with these probes.

Application

Table 5-6:   Probe Indications for Use

Probe Application	4C-RS	C2-5-RS	E8C-RS	3Sc-RS	L5-11-RS	L6-12-RS
Abdomen	X	X		X		
Obstetrics	X	X	X			
Gynecology	X	X	X			
Small Parts					X	X
Vascular/Peripheral Vascular	X	X			X	X
Transcranial				X		
Pediatrics/Neonatal	X	X			X	X
Musculoskeletal	X	X			X	X
Urology	X	X	X			
Cardiac				X		
Transvaginal/Transrectal			X			
Biopsy	X		X	X		X

Features

Table 5-7:   Probe Features

Probe Application	4C-RS	C2-5-RS	E8C-RS	3Sc-RS	L5-11-RS	L6-12-RS
LOGIQ View	X	X	X	X	X	X
Easy 3D	X	X	X	X	X	X
TVI/TVD				X		
Scan Coach/Scan Assistant	X	X	X	X	X	X
Auto IMT					X	X
AMM	X	X		X		
Color M Mode				X		
CWD				X		
Sono Biometry	X	X				
Biopsy	X		X	X		X

NOTE: *Not all features, products, probes or peripherals described in this document may be available or cleared for sale in all markets. Please contact your local GE Ultrasound representative to get the latest information.*

Specifications

Table 5-8:   System Probe Definitions

Probe Designation	Center Image Frequency (MHz)	Frequency Range (MHz)	Doppler Frequency Range (MHz)
4C-RS	3.10 ± 10%	2.0~5.0	2.0~3.6
E8C-RS	6.5 ± 20%	4.2~10.0	4.2~6.3
3Sc-RS	2.75 ± 20%	1.7~4.0	1.7~3.3
C2-5-RS	3.5 ± 15%	2.0~5.0	2.0~3.6
L6-12-RS	7.75 ± 20%	4.0~13.0	4.0~6.0
L5-11-RS	7.5 ± 7%	3.7~12.0	3.7~5.6

Slice Thickness Specification

Table 5-9:   Slice Thickness Specification

Probe Designation	Probe Slice Thickness Specification [mm]
4C-RS	<= 12.0mm
E8C-RS	<= 13.0mm
3Sc-RS	<= 16.0mm
C2-5-RS	<= 13.0mm
L6-12-RS	<= 15.0mm
L5-11-RS	<= 8.0mm

Probe Illustration

Convex Probe

Table 5-10:   Convex Probe Illustration

Probe	Illustration	Probe	Illustration
4C-RS		E8C-RS	
C2-5-RS			

Linear Probe

Table 5-11:   Linear Probe Illustration

Probe	Illustration	Probe	Illustration
L6-12-RS		L5-11-RS	

Sector Probe

Table 5-12:   Sector Probe Illustration

Probe	Illustration	Probe	Illustration
3Sc-RS			

Biopsy Special Concerns

Precautions Concerning the Use of Biopsy Procedures

 WARNING   Do not freeze the image during a biopsy procedure. The image must be live to avoid a positioning error.

Biopsy guidezones are intended to assist the user in determining optimal probe placement and approximate the needle path. However, actual needle movement is likely to deviate from the guideline. Always monitor the relative positions of the biopsy needle and the subject mass during the procedure.

 CAUTION   The use of biopsy devices and accessories that have not been evaluated for use with this equipment may not be compatible and could result in injury.

 CAUTION   The invasive nature of biopsy procedures requires proper preparation and technique to control infection and disease transmission. Equipment must be cleaned as appropriate for the procedure prior to use.

- Follow the probe cleaning and disinfection procedures and precautions to properly prepare the probe.
- Follow the manufacturer's instructions for the cleaning of biopsy devices and accessories.
- Use protective barriers such as gloves and probe sheaths.
- After use, follow proper procedures for decontamination, cleaning, and waste disposal.

Precautions Concerning the Use of Biopsy Procedures (continued)

<table>
<tr>
<td>⚠ CAUTION</td>
<td>Improper cleaning methods and the use of certain cleaning and disinfecting agents can cause damage to the plastic components that will degrade imaging performance or increase the risk of electric shock.

See 'Probe Safety' on *page 5-7 for more information.*</td>
</tr>
<tr>
<td>⚠ WARNING</td>
<td>NEVER reuse the TR5° disposable biopsy guide attachment and Disposable sterile Ultra-Pro II Needle guide kits.</td>
</tr>
</table>

Preparing for a Biopsy

Displaying the Guidezone

Activate the Biopsy Kit by selecting it from the B-Mode.

The available biopsy options appear when Biopsy Kit is selected. There are fixed and adjustable angle biopsy kits and plastic/disposable and reusable biopsy guides available with the Versana Essential depending on the probe. Select the desired biopsy kit.

Displaying the Guidezone (continued)
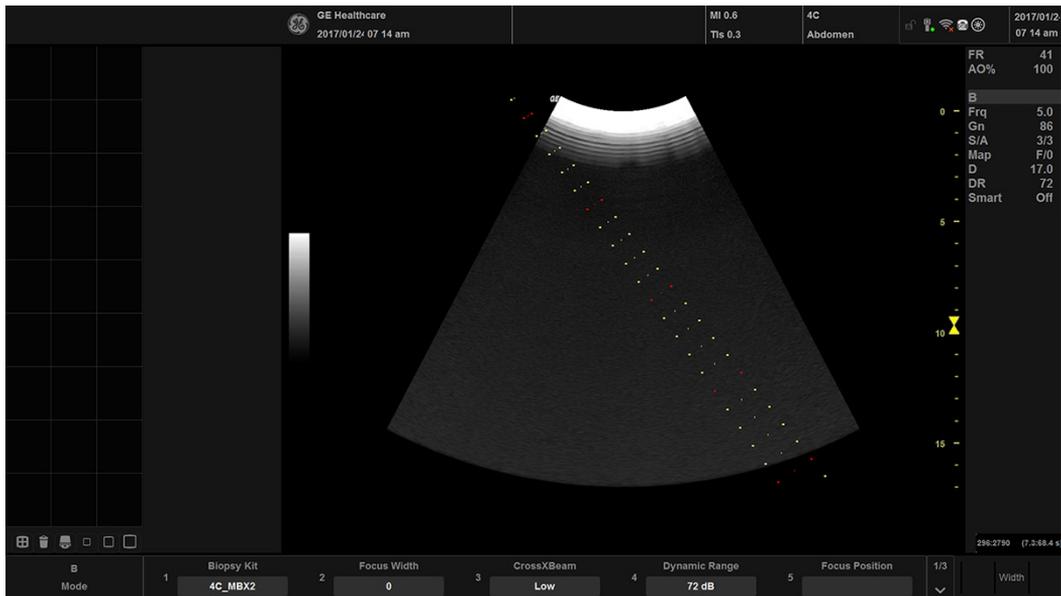
Figure 5-5.   Biopsy Guidezones for the 4C-RS Probe

The biopsy guidezone represents a path of the needle. The dots which make up the guidezones is the depth readout where:

- Yellow represent 1 cm increments.
- Red represents 5 cm increments.

The display should be carefully monitored during a biopsy for any needle deviation from the center line or guidezone.

Before scanning, verify the needle can be visualized within the imaging plane. User appropriate needle length to reach target area.

Displaying the Guidezone (continued)

The Biopsy Guidezone adjusts along with image adjustments, such as image inversion/rotations, zoom and depth changes.

The needle may vary from the center line or guidezone for various reasons:

- Needle barrel to needle clearance or strength.
- Bracket manufacturing tolerance.
- Needle deflection due to tissue resistance.
- Needle size chosen. Thinner needles may deflect more.

Table 5-13:   Biopsy Guide Availability

Probe	Fixed Angle	Multi-Angle		
		MBX1 (cm)	MBX2 (cm)	MBX3 (cm)
E8C-RS	TR5: 85 Degree (15.3 cm) RU: 90 Degree			
4C-RS		4.0	6.0	10.0
3Sc-RS		4.2	5.7	8.2
L6-12-RS		1.5	2.5	3.5

 DANGER

Failure to match the guidezone displayed to the guide may cause the needle to track a path outside the zone.

It is extremely important that when using the adjustable angle biopsy guides, the angle displayed on the screen matches the angle set on the guide, otherwise the needle will not follow the displayed guidezone which could result in repeated biopsies or patient injury.

Preparing the Biopsy Guide Attachment

Convex, Sector and Linear probes have optional biopsy guide attachments for each probe. The guide consists of a non-disposable bracket to attach to the probe, disposable needle clip to attach to the bracket, sheath, gel (sterile gel if necessary) and disposable needle barrels.

The disposable needle barrels are available for a variety of needle sizes.

⚠ CAUTION

Please refer to the manufacturer's instructions included in the biopsy kit.

The bracket is packaged non-sterile and is reusable. To avoid possible patient contamination, ensure bracket is properly cleaned, sterilized or disinfected before each use.

Disposable components are packaged sterile and are single-use only. Do not use if integrity of packing is violated or if expiration date has passed.

Fixed Needle Biopsy Guide Assembly

	WARNING	**DO NOT** use the needle with the catheter (soft tube). There is a possibility of breaking the catheter in the body.

	CAUTION	Before inserting the needle, scan the patient to determine the correct puncture depth and site. Only the sterile/sanitary sheath and rubber band are on the probe during the pre-needle placement scanning.

Preparation

To prepare the endocavitary probe for use:

1. Remove the probe from the box and carefully examine it for any damage.

2. If the biopsy guide is to be attached, use the filling removal tool to clean out the attachment area on the probe head.
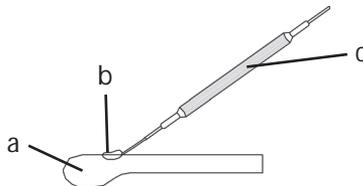
Figure 5-6.   Attachment Filling Removal

a.   Probe Head
b.   Attachment
c.   Filling Removal Tool

3. Clean, then disinfect the probe.

NOTE: *Ensure that protective gloves are worn.*

Installing the sheath

To install the sheath:

1. Remove the sheath from its package. Do not unroll the sheath.

NOTE: *Remember to rinse all sanitary probe sheaths of powder before placing on the probe. Powder can degrade the displayed image.*

2. Place an adequate amount of ultrasound gel inside the sheath tip (the gel is between the sheath inner surface and the probe aperture).

NOTE: *Ensure that only acoustic coupling gel is used for this purpose.*

3. Place the sheath tip over the probe aperture and then pull the sheath end toward the probe handle.

4. Inspect the sheath for nicks, cuts or tears.
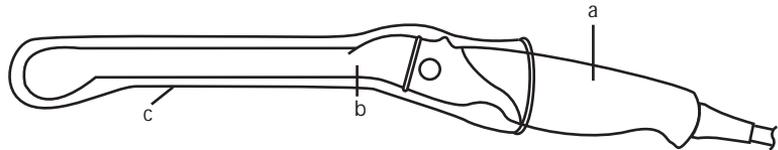
Figure 5-7.   E8C-RS Probe with Sheath

a. Probe Handle

b. Probe Body

c. Sanitary Sheath

5. Rub a finger over the tip of the probe to ensure all air bubbles have been removed.

Biopsy Guide Preparation

1. If a biopsy is to be performed, snap the metal or plastic biopsy guide on to the probe over the sheath.

> c ⚠ CAUTION   Patient injury or repeated biopsies may result. The needle placement will not be as intended if the needle guide is not properly seated and secure.
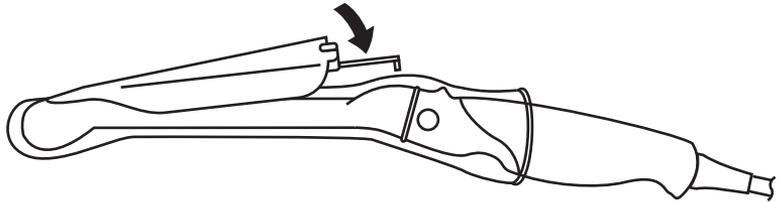
Figure 5-8.   Disposable Biopsy Guide 5 degree Angle
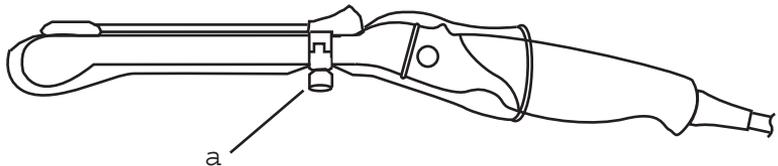
Figure 5-9.   Reusable Biopsy Guide

a. Fix with a screw

2. Place an adequate amount of ultrasound gel on the gel-filled sheath tip's outer surface.
3. Ensure the guide is properly seated and secure by pushing forward on the needle insertion end of the guide until the attachment node is firmly in place in it's hole.

Multi Angle Biopsy Guide Assembly

⚠ WARNING	DO NOT attempt to use the biopsy bracket and needle guide until the manufacturer's instructions, provided with the biopsy bracket and needle guide in the kit, have been read and thoroughly understood.

1. Scan the patient and identify the target for biopsy. Move the probe to locate the target to the center of the image. Enable the system biopsy guidezone and try guidezone angles MBX1 to MBX3 to decide the best angle setting for needle path.

Figure 5-10.   Example

2. Pull up on the knob (Figure 5-11 a) to freely move the needle guide attachment. Align the knob with the selected position of the needle guide attachment.

   Push the knob down (Figure 5-11 b) into the desired slot to secure the angle position of the needle guide attachment.

Figure 5-11.   Pull up and push down the knob

Multi Angle Biopsy Guide Assembly (continued)

3. Fit a convex of the biopsy bracket (a) in a concave of the probe (b).
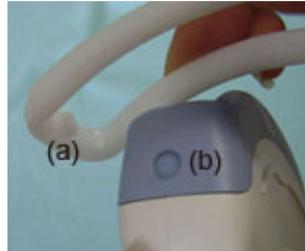
Figure 5-12.   Probe/Bracket Alignment

Hold the side (a) and tuck down the needle guide side (b) until it clicks or locks in place.
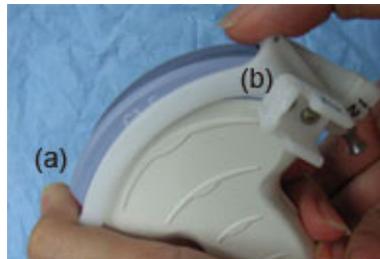
Figure 5-13.   Probe/Multi-angle Bracket Alignment 2

4. Place an adequate amount of coupling gel on the face of the probe.

Multi Angle Biopsy Guide Assembly (continued)

5. Place the proper sanitary sheath tightly over the probe and biopsy bracket. Use the rubber bands supplied to hold the sheath in place.
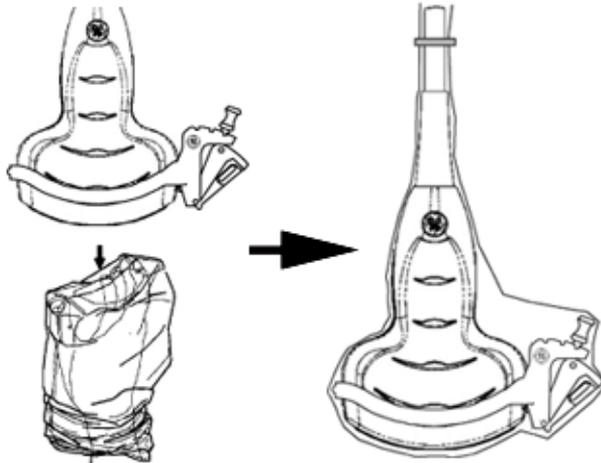
Figure 5-14.   Applying Sanitary Sheath

6. Snap the needle guide onto the biopsy guide bracket.
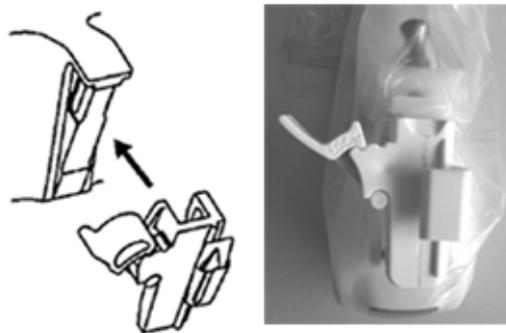
Figure 5-15.   Snap the needle guide

Multi Angle Biopsy Guide Assembly (continued)

7. Push the locking mechanism towards the bracket to secure the lock (a). Make sure the needle guide is firmly attached to the bracket.

Figure 5-16.   Lock the Needle guide

8. Choose the desired gauge (size) needle barrel. Twist it back and forth to remove it from the plastic tree.

Figure 5-17.   Needle Barrel

9. Place the needle barrel into the needle clip with the desired gauge facing the needle clip and snap into place.

Figure 5-18.   Needle Barrel Installation

Multi Angle Biopsy Guide Assembly (continued)

Remove the biopsy guide

1. Hold the other side and push out the needle clip attachment side. See Figure 5-19.

Figure 5-19.   Remove the biopsy guide

⚠ CAUTION   Prevent damage to the probe lens with finger nails.

Releasing the needle

According to the following procedure, you remove the needle from a probe and an assembly without moving the needle.
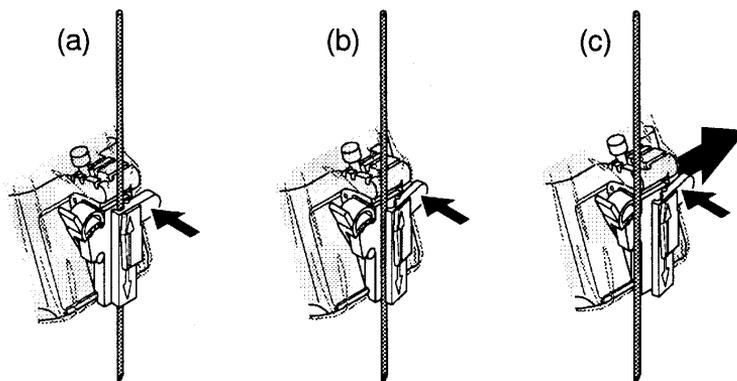
Figure 5-20.   Release the needle from assembly

a.   Push the knob portion of a sleeve in the direction of the arrow.

b.   The needle is released from the assembly.

c.   Push the probe and the assembly in the direction of the larger arrow to remove the needle.

Biopsy Needle Path Verification

To verify that the path of the needle is accurately indicated within the guidezone on the system monitor, perform the following:

•   Properly install the bracket and biopsy guide.

•   Scan in a container filled with water (47° C).

•   Display the biopsy guidezone on the monitor.

•   Ensure that the needle echo falls within the guidezone markers.

The Biopsy Procedure

WARNING   Biopsy procedures must only be performed on live images.

1. Place coupling gel on the scanning surface of the probe/ sheath/biopsy guide assembly.
2. Activate the biopsy guidezone on the system through the B-Mode menu. When using multi-angle guides, ensure that the proper guidezone angle is displayed.
3. Scan to locate the target. Center the target in the electronic guidezone path.

NOTE: *Enabling color flow would allow for visualization of the vascular structure around the area to be biopsied.*

4. Place the needle in the guide between the needle barrel and needle clip. Direct it into the area of interest for specimen retrieval.

Post Biopsy

When the biopsy is complete, remove the needle barrel, needle clip and probe sheath. Properly dispose of these items in accordance with current facility guidelines.

Clean and disinfect the probe. See 'Probe Cleaning Process' on *page 5-12 for more information.*

The biopsy bracket can be cleaned and disinfected in a recommended disinfecting agent and reused.

⚠ CAUTION	When the biopsy needle guide kit is opened, all parts must be discarded after the procedure whether they have been used or not.

Surgery/Intra-operative Use

Preparing for Surgery/Intra-operative Procedures

Preparing the transducer for intra-operative use follows the same sterile procedure as for biopsy use except that no biopsy attachments are used. See 'Preparing the Biopsy Guide Attachment' on *page 5-31 for more information.* Sterile gel is applied to the transducer face and a sterile sheath completely covers the transducer and cable which has first undergone a thorough cleaning and high-level disinfection.

The invasive nature of biopsy procedures requires proper preparation and technique to control infection and disease transmission. Equipment must be cleaned as appropriate for the procedure prior to use.

⚠ CAUTION For surgery/intra-operative procedures, a sterile environment is required. Therefore, both the operator and probe needs to be sterile.

Preparing for Surgery/Intra-operative Procedures (continued)

To ensure a sterile environment during the procedure, it is recommended that this be a two-person job.

1. Perform a high level disinfection of the probe.
2. The scanner (surgeon, sonographer, etc.) should be sterile and gloved.
3. Place an adequate amount of sterile coupling gel on the face of the probe.
4. Place the proper sterile sheath over the probe and cord.
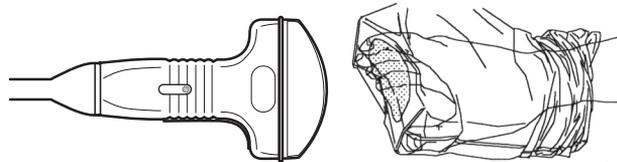
Figure 5-21.   Applying Sterile Sheath

5. Depending on the type of procedure, use either sterile water or sterile gel on the sheath cover.

NOTE: *Follow your institutions guidelines on post surgery/ intra-operative procedures for probe cleaning and disinfection.*

Index