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CE 0459

LOGIQ E9 User Guide

Version R4

Operating Documentation

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Regulatory Requirement

LOGIQ E9 complies with regulatory requirements of the following European Directive 93/42/EEC concerning medical devices.

CE 0459

This manual is a reference for the LOGIQ E9. It applies to Version R4 software for the LOGIQ E9 ultrasound system.

GE Healthcare

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Revision History

Reason for Change

REV	DATE (YYYY/MM/DD)	REASON FOR CHANGE
Rev. 1	2012/11/09	Initial Release

List of Effective Pages

PAGE NUMBER	REVISION NUMBER	PAGE NUMBER	REVISION NUMBER
Title Page	Rev. 1	Chapter 2	Rev. 1
Revision History	Rev. 1	Chapter 3	Rev. 1
Regulatory Requirements	Rev. 1	Chapter 4	Rev. 1
Table of Contents	Rev. 1	Index	Rev. 1
Chapter 1	Rev. 1		

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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 B with BF or CF Applied Parts.
- According to CISPR 11,
  - Equipment is Group 1, Class A ISM Equipment.

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.

EC REP

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Conformance Standards (continued)

- International Electrotechnical Commission (IEC).
  - IEC/EN 60601-1 Medical Electrical Eqiupment, Part 1 General Requirements for Safety.
  - IEC/EN 60601-1-1 Safety requirements for medical electrical systems.
  - IEC/EN 60601-1-2 Electromagnetic compatibility - Requirements and tests.
  - IEC/EN 60601-1-4 Programmable electrical medical systems.
  - IEC 60601-1-6 (Usability), EN 1041 (Information supplied with medical devices)
  - IEC 60601-2-37 Medical electrical equipment. 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.
- Underwriters' Laboratories, Inc. (UL), an independent testing laboratory.
  - UL 60601-1 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 UD-3).
- Medical Device Good Manufacturing Practice Manual issued by the FDA (Food and Drug Administration, Department of Health, USA).

Certifications

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

Original Documentation

- The original document was written in English.

Country Specific Approval

- JAPAN

  MHLW Certified Number: 220ABBZX00177000
- KOREA

  KFDA License 09-180
- USA AND TERRITORIES



The following optional features ARE NOT available in the USA and its territories:

– Elastography Quanitfication

– Contrast Enhanced Ultrasound

– Breast Measure Assistant

– OB Measure Assistant

Importer Information

- Turkey

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  Y. AYRANCI / ANKARA

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Chapter 1

Getting Started

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

Console Overview

Attention

This manual contains necessary and sufficient 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 before attempting to use the LOGIQ E9 system.

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

Disregarding information on safety is considered abnormal use.

Not all features or products described in this document may be available or cleared for sale in all markets. Please contact your local GE Healthcare 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 at the time of publication of the user manual.

Prescription Device



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

Indications for Use

The LOGIQ E9 is intended for use by a qualified physician for ultrasound evaluation.

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.

Clinical Applications

Specific clinical applications and exam types include:

- Fetal/Obstetrics
- Abdominal (includes renal, GYN/Pelvic)
- Pediatric
- Small Organ (breast, testes, thyroid)
- Neonatal Cephalic
- Adult Cephalic
- Cardiac (adult and pediatric)
- Peripheral Vascular
- Musculo-skeletal Conventional and Superficial
- Urology (including prostate)
- Transrectal
- Transvaginal
- Transesophageal
- Intraoperative (abdominal, thoracic, vascular and neurosurgical)



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

Contraindication

The LOGIQ E9 ultrasound system is not intended for ophthalmic use or any use causing the acoustic beam to pass through the eye.

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

Important Notices

Do not attempt to install the system alone. General Electric, Affiliate, or Distributor Field Engineers and Application Specialists will install and setup the system. See ‘Contact Information’ on *page 3-42 for more information.*

NOTICE

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:

- A separate power outlet with a 20 amp circuit breaker for 120 VAC for 120V area, 7.5 amp circuit breaker for 220-240VAC for 220/240V area or 15 amp circuit breaker for 100 VAC for Japan.
- Take precautions to ensure that the console is protected from electromagnetic interference.

  Precautions include:

  - Operate the console at least 5 meters (15 feet) away from motors, typewriters, elevators, and other sources of strong electromagnetic radiation (non-medical grade UPS must be at least 2 meters (6 feet) away from console).
  - 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.

Important Notices (continued)

WARNING

To avoid risk of fire, the system power must be supplied from a separate, properly rated outlet.

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

Use caution to ensure that the power cable does not disconnect during system use.

If the system is accidentally unplugged, data may be lost.

CAUTION

To avoid leakage current above safety limits as prescribed by IEC 60601-1 and to ensure continuity of protective earth. DO NOT connect LOGIQ E9 and mains-operated accessories to a single or multiple socket extension cord or power strip.

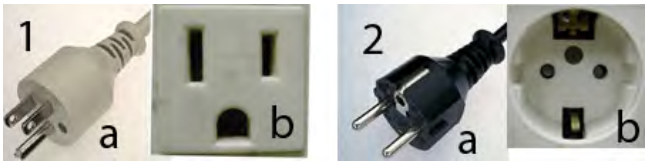


Figure 1-1. Example Plug and Outlet Configurations

1. 100-120 VAC, 1200 VA
   Plug and Outlet Configuration
2. 220-240 VAC, 1200 VA
   Plug and Outlet Configuration

Console Graphics

The following are illustrations of the console:

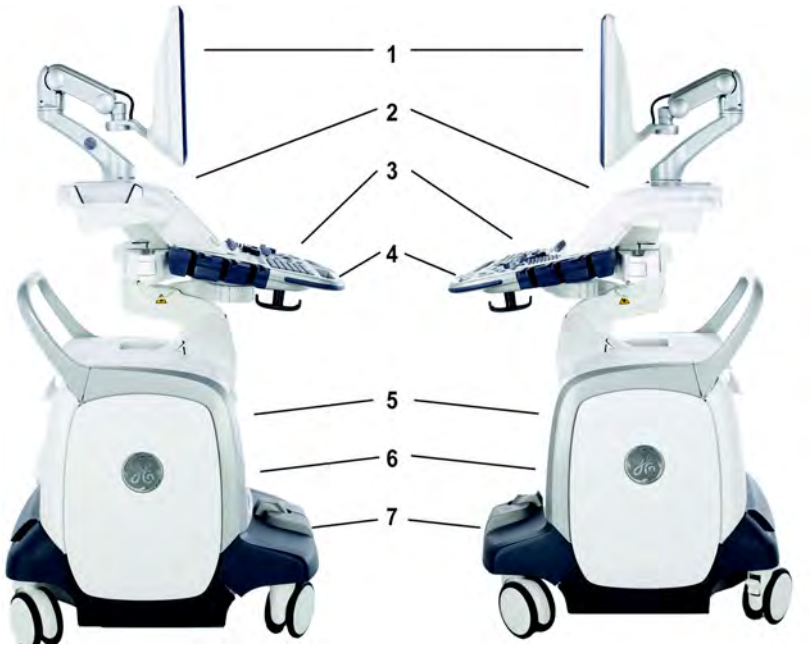


Figure 1-2. LOGIQ E9 System (right and left side views)

1. LCD
2. Gel Holder / Specialty Probe Holder
3. Operator Panel, Probe Holders with Cable Management
4. Brake Release / Up/Down Controls
5. Peripherals (Black/White Printer, CD/DVD Drive), V Nav option, and Network Activity/ Speed (Green=1 Gigabyte and Yellow=100 Mb) and Hard Disk Drive Indicator
6. Probe Connectors
7. Brakes

CAUTION

For compatiblity reasons, use only GE approved probes, peripherals or accessories.

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

Console Graphics (continued)

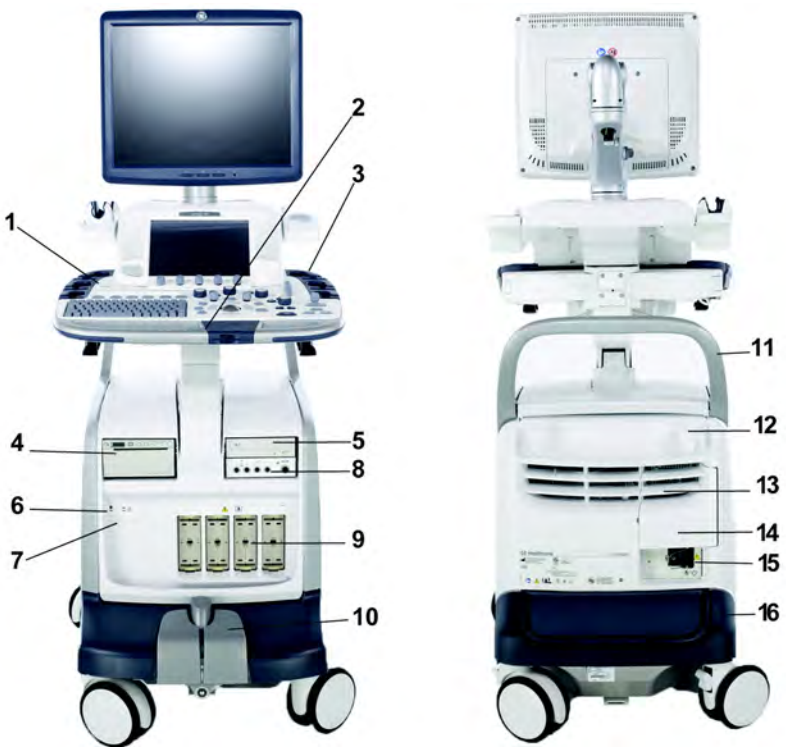


Figure 1-3. LOGIQ E9 System (front and back views)

1. Power On/Off; Operator Panel USB Ports
2. Brake and Up/Down Controls
3. Probe Cable Management Hooks (underneath Operator Panel)
4. Black/White Printer
5. CD/DVD Drive
6. Network and Hard Disk Drive Indicators. USB Ports
7. Patient I/O (ECG, CW Probe Connector)
8. Volume Navigation Connectors
9. Probe Connectors
10. Brake Pedal
11. Rear Handle
12. Power Cord Hook
13. Op Panel Up/Down Manual Release Lever
14. Access to Peripheral USB Ports, Audio In/Out, DVI Connector, Ethernet Connectors, S-Video
15. Breaker, Ground and Power Cord
16. Back Filter

WARNING

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.

USB Ports


CAUTION

Peripheral devices that use their own AC power source cannot be attached to the system.

Operator Panel

The two Operator Panel USB Ports SHOULD ONLY BE USED for Bus-powered USB Hard Disk Drives and USB Flash Drives. The following configurations can be used:

- One or two USB Flash Drives
- One Flash Drive and One Bus-powered Hard Disk Drive
- One Bus-powered Hard Disk Drive


CAUTION

DO NOT plug in TWO Bus-powered Hard Disk Drives at the same time.

Below Operator Panel and Rear of System

The two USB ports at the back of the system and the two USB ports below the Operator Panel SHOULD ONLY BE USED for the following devices:

- Color or Report Printer

NOTE: When connecting an external printer to the LOGIQ E9 via the USB port on the back of the system, you MUST ensure that the power supplied to the printer is fed from the same power feed as the LOGIQ E9. This assures compliance to leakage currents.

- Flash Drive
- Service Key


CAUTION

ONLY plug in devices to the USB ports located at the rear of the system WHILE the LOGIQ E9 is NOT powered up. If you plug in a device while the LOGIQ E9 is powered on, your system may become unusable.

Peripheral/Accessory Connector Panel

LOGIQ E9 peripherals CAN ONLY BE properly connected using the Peripheral/Accessory Connector Panel located behind the rear door: Color Digital or Report printer, Audio In/Out, DVI Analog Video Output, S-Video, and Ethernet.



For compatiblity reasons, use only GE-approved probes, peripherals, or accessories.

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



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 60601-1-1 by the installer.



To avoid breaking the back cover while opening it in order to connect up the network cable, use a paper clip and pull hard to open up the back cover door.

Peripheral/Accessory Connector Panel (continued)

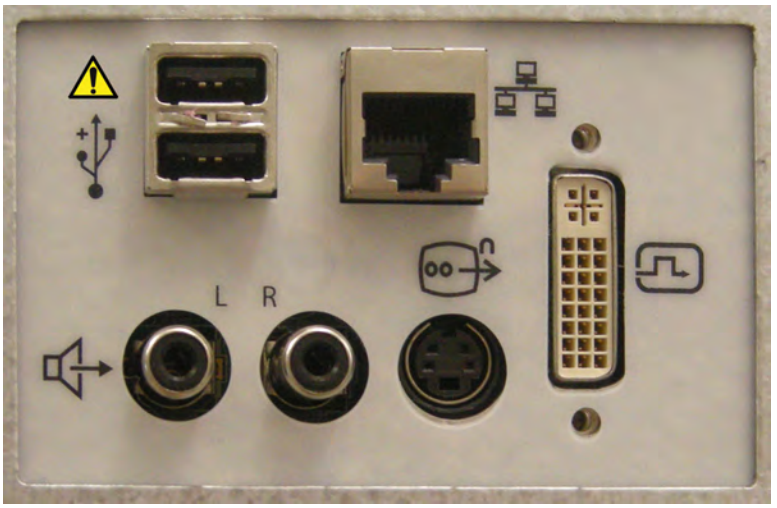


Figure 1-4. Peripheral/Accessory Connector Panel

Table 1-1: Peripheral/Accessory Connector Panel Descriptions

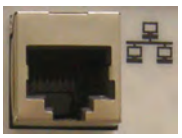
No.	Item	Type of connector
	USB Ports	USB 2.0
	Ethernet	RJ-45 Modular, 8-pin

Table 1-1: Peripheral/Accessory Connector Panel Descriptions (Continued)

No.	Item	Type of connector
	DVI Port Connector	DVI Analog Video Output. Note: Use a DVI to VGA Adapter in order to connect an analog monitor.
	Audio In/Out	ACR
	S-Video	S-Video

Control Panel Map



Figure 1-5. Control Panel

1. Probe and Cord Holder
2. USB Ports (2)
3. Touch Panel and Joystick controls
4. Keyboard
5. Feature Keys
6. Mode/Gain/XYZ (3D) Controls
7. TGC
8. Trackball, Trackball Keys, Pointer, Measure, Comment, Body Pattern, Clear, Zoom, 3D/4D, P1
9. L/R, Start/Stop, Freeze
10. Steer/Width/Depth/Reverse
11. Auto
12. P2, P3, P4

Touch Panel

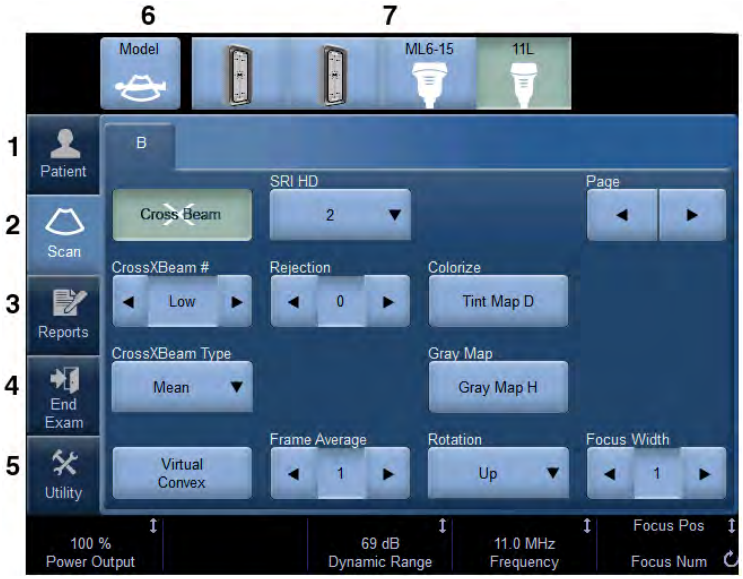


Figure 1-6. Exam Function Controls

1. Patient: Enters Patient screen
2. Scan: Enters scanning mode screen
3. Reports: Activates default report and Touch Panel of report choices.
4. End Exam: Activates Image Management and Touch Panel with end of exam options.
5. Utility: Activates system configuration menus.
6. Model: Selects the application to use.
7. Probe Indicator: Indicates and selects the probes.

NOTE: Different menus are displayed depending on which Touch Panel is selected.

At the bottom of the Touch Panel, there are five combination rotary dials/push buttons. The functionality of these rotaries changes, depending upon the currently-displayed menu. Press the button to switch between controls, or rotate the dial to adjust the value, or move the control left/right or up/down to adjust the value.

Monitor Display

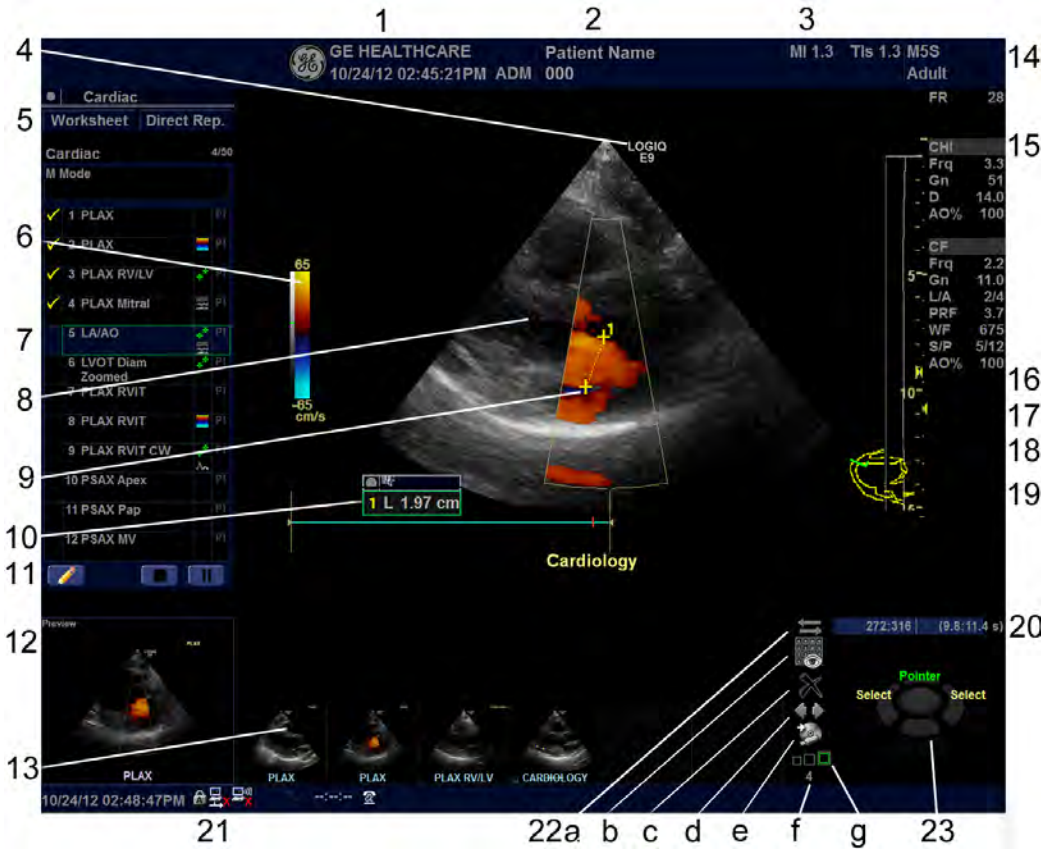


Figure 1-7. Monitor Display Tour



Figure 1-8. Monitor Display Tour 2

NOTE: The date on the monitor may truncate the century when using the YYYY-MM-DD date format.

Monitor Display (continued)

1. Institution/Hospital Name, Date, Time, Operator Identification.
2. Patient Name, Patient Identification, Alternate (Second) Patient Name/Patient Identification.
3. Power Output Readout
4. GE Symbol: Probe Orientation Marker.
5. Worksheet/Direct Report.
6. Gray/Color Bar.
7. Measurement Summary Window.
8. Image.
9. Measurement Calipers.
10. Measurement Results Window.
11. Scan Assistant Icons
12. Image Preview.
13. Image Clipboard.
14. Probe Identifier. Exam Preset.
15. Imaging Parameters by Mode, SoS indicator (if applicable).
16. Focal Zone Indicator.
17. TGC.
18. Depth Scale.
19. Body Pattern.
20. Cine Gauge.
21. Current date and time, Caps Lock: (lit when on), network connection indicator (PC=connected, PC with X=not connected), wireless LAN indicator (WLAN=connected, WLAN with X=not connected), DVR status, InSite ExC status, InSite ExC controls, system messages display.
22. Image Management Icons:
    a. Compare Assistant
    b. Active Images screen
    c. Delete Images screen
    d. Next/Previous Image(s); and Clipboard Slide Show if you press and hold down the [Ctrl] key + Next or Previous Arrow
    e. Save As Menu
    f. Number of Images in Exam
    g. Thumbnail Size
23. Trackball Key Functionality Status.
24. 6Tc Probe temperature display
25. 6Tc Probe angle display

Brightness

Adjusting the monitor's brightness is one of the most important factors for proper image quality. If these controls are set incorrectly, the Gain, TGC, Dynamic Range and even Power Output may have to be changed more often than necessary to compensate.

The proper setup displays a complete gray scale. The lowest level of black should just disappear into the background and the highest white should be bright, but not saturated.

To adjust the brightness:

1. Press the right adjustment button to increase brightness.
2. Press the left adjustment button to decrease brightness.

   The amount of brightness is shown on a slide bar on the screen.

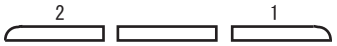


Figure 1-9. Brightness adjustment button

1. Adjustment (+) Button
2. Adjust (-) Button

Record any changes to the final brightness settings and leave this information with the system. Generally speaking, do not change the controls once they have been set. Once set, the display then becomes the reference for the hard copy device(s).

Table 1-2: Brightness Settings (Recommended)

Room Condition	Brightness
Dark Room (Factory default)	60
Bright Room	100

NOTE: After readjusting the monitor's Brightness, readjust all preset and peripheral settings.

Moving the System

Before moving the system

1. Press the **Power On/Off** switch to power off the system. See ‘Power Off’ on *page 1-25 for more information.*
2. Unplug the power cord.
3. All cables from off-board peripheral devices (external Color Digital/Report printer, etc.) and the ethernet connection must be disconnected from the console.
4. Ensure that no loose items are left on the console.
5. Wind the power cable around the cable hook below the rear handle.

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

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 Operator Panel to further secure the probe cables.

NOTE: If more than four (4) probes are intended to be used, store the additional probes securely.

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

Before moving the system (continued)

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



DO NOT place probes into the front pocket storage area when moving the system. This is not a storage space for probes.

9. Adjust the LCD monitor and control panel to their lowest positions by using the up/down switch on the front of the operator panel. Make sure the operator panel is locked in place.



To prevent system damage while not in use AND/OR before moving the system, flip down the monitor and lock the monitor arm and operator panel firmly in place.

10. Unlock the wheels.

When moving the system

1. Always use the front handle grips to move the system.
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 approximately 140kg (309lbs). 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.

Operator Panel Movement Controls

The system Operator Panel can be freely moved in all directions. The vertical displacement of the Operator Panel is motor driven. The control buttons are located adjacent to the handles.



Figure 1-10. Operator Panel Movement Controls

To move the Operator Panel sideways, press and hold down the left button to release and move the Operator Panel sideways until it is in the desired position.

To park the Operator Panel, after moving Operator Panel sideways to the desired position, release the left button. After releasing the left button, the system will lock into position after 3 seconds.

To raise/lower the Operator Panel, press and hold down the Up/Down toggle button (right button) accordingly to raise or lower the Operator Panel. Release the Up/Down button when the Top Console is in the desired height.

To manually adjust the Operator Panel, manipulate the metal lever located in-between the slots on the rear of the LOGIQ E9.

CAUTION

When power is on, the brakes are applied to the Operator Panel. To move the Operator Panel, release it by using the Operator Panel Movement Controls. This helps to ensure the life of the brakes.

Shutdown

Make sure to dock the Operator Panel prior to powering down the system. You cannot lock the Operator Panel into place during shutdown or after the system has been shut down.

If you shutdown the system wiithout parking the Operator Panel, the message “The operator keyboard is not in parked position.” appears. Place the Operator Panel in the parked position.

NOTE: Once you select Shutdown, both Operator Panel controls are disabled. The brakes are released; XY movement is free but you cannot move the Operator Panel in the Z plane.

CAUTION

When power is off, the Operator Panel is loose, no breaks are applied. If you do not dock the operator panel, it will move freely. Please dock the Operator Panel if you will be moving or transporting the system.

Park Lock Reset

The **Park Lock Reset** control releases (undocks) the Operator Panel and resets the position of the Park Lock.

Park Lock Reset is located on the Utility--> System--> Peripherals screen under “Miscellaneous.”

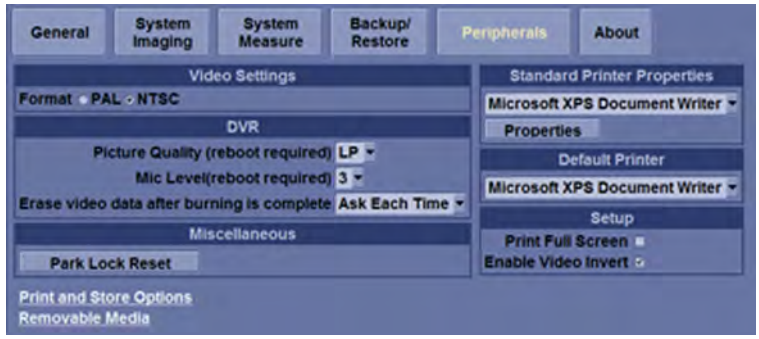


Figure 1-11. Park Lock Reset

After you press the Park Lock Reset control, you can hear the motor moving, releasing the Operator Panel for you to position as you need.

Setting the front wheels lock

The pedal is located between the front wheels of the unit and enables the user to control the movement of the wheels.



Figure 1-12. Front Pedal Lock/Brake

Table 1-3: Front Pedal Functions

	Pedal position	Function
1.	Left—Swivel Lock	Swivel Lock. To move the system, press the Swivel Lock to set the wheels in a forward-to-back position. First move the system in the direction you will be going, then press the Swivel Lock. To release the Swivel Lock, press the center brake release (3).
2.	Right—Parking Brake	Park. To set the brake, press the right pedal. To release the brake, press the center brake release.
3.	Center—Brake Release	Press the center brake to release the swivel lock/parking brake (3).

CAUTION

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

System Start-Up

Power On

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 1-27* for more information.

Login

Personal IDs and associated passwords can be preset on the LOGIQ E9.

If the User Auto Logon preset is blank, you are prompted to login.



Figure 1-13. Operator Login Window

1. **Operator**: Select the Operator.
2. **Password**: Enter Operator’s password (optional).
3. Select type of Logon or Cancel.
   - **Emergency**: Data stored only for the duration of the current examination.
   - **OK**: Standard logon
   - **Cancel**: Cancel logon

Power Off

To power off the system:

1. Set the brake and use the operator panel movement controls to lock the control panel in place.



If the Park Lock does not engage when you attempt to dock the Operator Panel in place, reset the Park Brake by selecting “Park Brake Reset” in the Miscellaneous section on the Utility -> System -> Peripherals page.

2. 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. Instead, lightly press the Power On/Off switch and select Shutdown.

3. Using the **Trackball**, select Shutdown.

   The shutdown process may take up to two (2) minutes and is completed when the control panel illumination shuts down.

NOTE: If the system appears non-responsive, press the Power On/Off switch. After about six (6) seconds, the “Application not responding” system dialog appears. Select to end all system processes and shut down the system.

4. 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.



DO NOT turn off the circuit breaker before the Power On/Off switch LED is off.

Data may be lost or system software damaged if the circuit breaker is turned off before the Power On LED is off.

NOTE: When the Extended Power Supply (EPS) is installed, battery replacement may be necessary if the circuit breaker is turned off for long periods of time (3 to 6 months).

Additional System Information

For optimum system operation, we recommend that you restart the system at least once every 24-hour period. If you shut down the system at the end of the day, no other action is needed.

Crash Recovery Instructions

In case of a system crash, power cycle the system. Upon boot-up, all images and measurements, except for generic worksheets, are preserved in the system. When the system returns, the system alerts you that unsaved images are still in the system from the previous patient. Respond to the prompt to continue the current patient. Check that all images and measurements have been preserved in the system. Then resume the exam.

If the system fails to respond to your commands within a typical period of time, you need to manually reset the system. Simply hold down the power switch to initiate a normal power down sequence. After the system has completely shut down (power switch amber), restart the system using the standard power-up sequence. All images and measurements, except for generic worksheets, are preserved in the system. When the system has fully powered up, the system alerts you that unsaved images are still in the system from the previous patient. Respond to the prompt to continue the current patient. Check that all images and measurements have been preserved in the system. If you do not have any images on the clipboard, the patient must be retrieved from the database. Then resume the exam.

Unexpected Power Loss

In case of unexpected power loss,

1. Check the system On/Off LED color (green is on, amber is off).
2. If the LCD monitor shuts down along with the system, then the system has detected a power failure. It will then activate the extended power supply (EPS). The EPS permits us to maintain the integrity of the scanner database. The system On/Off switch will be green in this situation.
3. Wait about 2 minutes after such an incident and then turn the circuit breaker off (rear panel of the LOGIQ E9) or unplug the scanner.
4. Wait approximately one minute. The system On/Off switch should be dark.
5. Turn on the LOGIQ E9 by either turning on the circuit breaker or plugging in the scanner.
6. Turn on the scanner by pressing the system On/Off switch.

NOTE: The LOGIQ E9 should be plugged into the regular power outlet and not the emergency 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.

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.

*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.



Figure 1-14. Circuit Breaker (located at the rear of the system)

Probes

Introduction

Only use approved probes.



Figure 1-15. 4 DLP Probe Port Connectors

DO NOT plug any LOGIQ 9 probes into the LOGIQ E9 system. Use the left-most probe port for the 3CRF, S1-5, S4-10, and 6Tc probes; use the 3 right probe ports for any "___-D" probe.



Figure 1-16. 1 Non-DLP and 3 DLP Probe Port Connectors

1. 3CRF, S1-5, S4-10, and 6Tc Probe Connector
2. _____-D Probe Connector

Connecting the Probe

Probes can be connected at any time, regardless of whether the console is powered on or off. To ensure that the ports are not active, place the system in the image freeze condition.

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. DO NOT allow the probe head to hang free. Impact to the probe head could result in irreparable damage. Use the integrated cable management hook to wrap the cord.

   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.
4. Hold the probe connector vertically with the cable pointing upward.
5. Align the connector with the probe port and carefully push into place.

   Before inserting the 3CRF, S1-5, S4-10, or 6Tc probe connector into the left-most (non-DLP) probe port (see Figure 1-16 *on page 1-28*), inspect the probe connector pin. If the pin is bent, do not use the probe until it has been inspected and repaired/replaced by a GE Service Representative.
6. Turn the connector locking handle to the right to secure the probe connector.
7. Carefully position the probe cord so it is free to move and is not resting on the floor.



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.

Cable Handling

Take the following precautions with probe cables:

- Keep free from wheels. Use the cable hooks located below the operator panel.
- Do not bend the cable acutely
- Avoid crossing cables between probes.

Activating the Probe

To activate the probe, select the appropriate probe from the probe indicators on the Touch Panel.

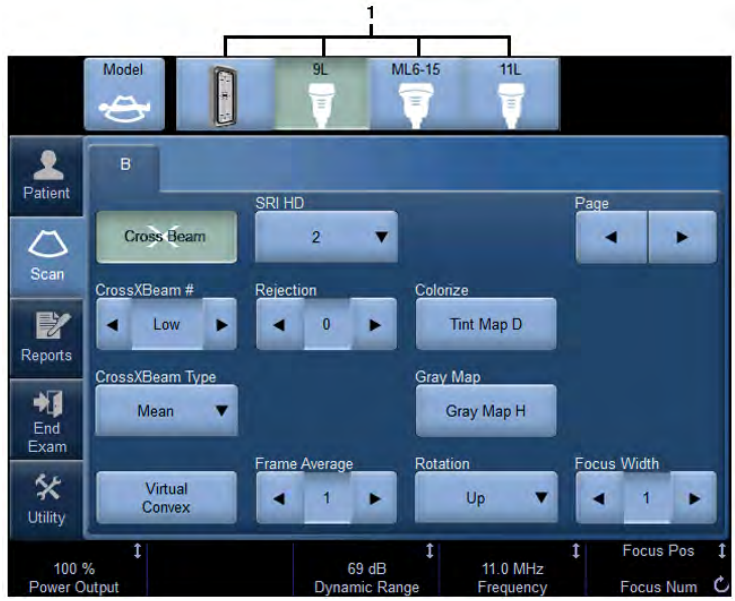


Figure 1-17. Probe Indicators

1. Probe Indicators

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

Disconnecting the Probe

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

1. Ensure the probe is deactivated. Deactivate by selecting another probe or pressing Freeze.
2. Move the probe locking handle to the left.
3. Pull the probe connector straight out of the probe port carefully.
4. Carefully slide the probe and connector away from the probe port and around the right side of the keyboard.
5. Ensure the cable is free.
6. Be sure that the probe head is clean before placing the probe in its storage box or wall hanging unit.
7.

Probe Discussion

The LOGIQ E9 supports the following types of probes:

- **Matrix Array.** Matrix Array probes.
- **Convex Array.** Convex Array probes.
- **Linear Array.** Linear Array probes.
- **Micro Convex Array.** Micro Convex Array probes.
- **Sector Phased Array.** Sector Phased Array probes.
- **Volume Probes**. 4D probes: Convex Array, Micro Convex Array, Linear Array.



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.

Convex Probes

Table 1-4: Common Convex Probe features

Common Features available for all convex probes	
• Coded Harmonics • SRI-HD • LOGIQView • Easy 3D • Advanced 3D • Raw Data • PDI	• Scan Assistant • Anatomical M-Mode • Retain Field of View • Speed of Sound • Image Quality Check • Compare Assistant • Biopsy capability

Additional probe features, not common to all convex probes, are listed in the Capabilities and Features column in Table 1-5 and Table 1-6:

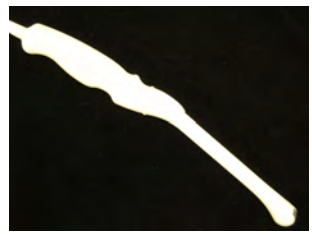
Table 1-5: Active Matrix Array Probes

Probe	Indications for Use	Capabilities and Features	Illustration
M6C-D	• Abdomen • OB/GYN • Pediatric	• CrossXBeam • Anatomical Color M	

Table 1-6: Convex and Micro Convex Probes

Probe	Indications for Use	Capabilities and Features	Illustration
C1-5-D	• Abdomen • OB/GYN	• Coded Contrast • Tru3D • V Nav • CrossXBeam • Anatomical Color M • Elastography • Elastography Quantification (Not available in USA)	

Table 1-6: Convex and Micro Convex Probes (Continued)

Probe	Indications for Use	Capabilities and Features	Illustration
C1-6-D	• Abdomen • OB/GYN	• Coded Contrast • Tru3D • V Nav • Anatomical Color M • B Flow / B Flow Color • Elastography • Elastography Quantification (Not available in USA)	
C2-9-D	• Abdomen • OB/GYN • Pediatric	• Coded Contrast • Tru3D • V Nav • Elastography • Elastography Quantification (Not available in USA)	
3CRF	• Abdomen • OB/GYN	• Coded Contrast • Tru3D • V Nav • CrossXBeam • Anatomical Color M	
IC5-9-D	• OB/GYN • TV/TR • Urology	• Coded Contrast • Tru3D • V Nav • CrossXBeam • Anatomical Color M • Elastography • Elastography Quantification (Not available in USA)	

Linear Probes

Table 1-7: Common Linear Probe features

Common Features available for all linear probes	
• Coded Harmonics • SRI-HD • LOGIQView • Virtual Convex • Easy 3D • Advanced 3D • Raw Data	• CrossXBeam • PDI • Scan Assistant • Retain Field of View • Speed of Sound • Image Quality Check • Compare Assistant

Additional probe features, not common to all linear probes, are listed in the Capabilities and Features column in Table 1-8:

Table 1-8: Linear Array Probes

Probe	Indications for Use	Capabilities and Features	Illustration
9L-D	• Abdomen • Musculoskeletal • OB/GYN • Pediatric • Peripheral Vascular • Small Parts	• Coded Contrast • Tru3D • V Nav • B Flow/B Flow Color • Elastography • Elastography Quantification (Not available in USA) • Biopsy capability	
11L-D	• Abdomen • Musculoskeletal • Peripheral Vascular • Small Parts	• Biopsy capability	
ML6-15-D	• Musculoskeletal • Neonatal • Pediatric • Peripheral Vascular • Small Parts	• Coded Contrast • Tru3D • V Nav • B Flow/B Flow Color • Elastography • Elastography Quantification (Not available in USA) • Biopsy capability	
L8-18i-D	• Intraoperative • Musculoskeletal • Neonatal • Pediatric • Peripheral Vascular • Small Parts	• Tru3D • V Nav • B Flow/B Flow Color	

Sector Probes

Table 1-9: Common Sector Probe features

Common Features available for all sector probes	
• SRI-HD • LOGIQView • Virtual Convex • Raw Data • PDI	• Scan Assistant • Retain Field of View • Speed of Sound • Image Quality Check • Compare Assistant

Additional probe features, not common to all sector probes, are listed in the Capabilities and Features column in Table 1-10:

Table 1-10: Sector Probes

Probe	Indications for Use	Capabilities and Features	Illustration
M4S-D	• Adult Cephalic	• Easy 3D • Advanced 3D • Anatomical M-Mode • Anatomical Color M	
M5S-D	• Abdomen • Adult Cephalic • Cardiac • OB/GYN • Pediatric	• Coded Contrast • Easy 3D • Advanced 3D • Tru3D • V Nav • Anatomical M-Mode • CW • CAMM • Color M • TVI • TVD	

Table 1-10: Sector Probes (Continued)

Probe	Indications for Use	Capabilities and Features	Illustration
S1-5	• Abdomen • OB/GYN	• Coded Harmonics • Coded Contrast • Easy 3D • Advanced 3D • Tru3D • V Nav • Anatomical M-Mode • Anatomical Color M • Biopsy capability	
S1-5-D	• Abdomen • OB/GYN	• Coded Harmonics • Coded Contrast • Easy 3D • Advanced 3D • Tru3D • Anatomical M-Mode • Anatomical Color M • Biopsy capability	
S4-10	• Cardiac, Pediatric • Neonatal • Pediatric	• Coded Harmonics • Easy 3D • Advanced 3D • Tru3D • V Nav • Anatomical M-Mode • CW • Anatomical Color M • Color M • TVI • TVD	
S4-10-D	• Cardiac, Pediatric • Neonatal • Pediatric	• Coded Harmonics • Easy 3D • Advanced 3D • Tru3D • Anatomical M-Mode • Anatomical Color M • Color M • TVI • TVD	
6S-D	• Cardiac, Pediatric	• Coded Harmonics • Easy 3D • Advanced 3D • Anatomical M-Mode • CW • CAMM • Anatomical Color M • Color M • TVI • TVD	

Table 1-10: Sector Probes (Continued)

Probe	Indications for Use	Capabilities and Features	Illustration
6Tc	• Cardiac, Adult • Transesophageal	• Anatomical M-Mode • CW • CAMM • Color M	

Sector Probes (continued)

CAUTION

Transesophageal probes require special handling. Refer to the user documentation (KZ192871) enclosed with these probes.

6Tc Probe

The maximum insertion portion width of 6Tc shall not be larger than 14 +/- 0.22mm.

After the probe has been selected, the scan plane positioning system automatically calibrates. This calibration cycle lasts 10 to 15 seconds. After the calibration is completed, the probe temperature sensor is activated, and the probe temperature is displayed. A message appears on the system display to remind the user of the importance of using a bite guard when conducting a TEE examination. When the message disappears and the calibration cycle is completed, the probe is ready for operation.

In case the initialization of the probe fails (no response from the scan plane buttons after initialization), re-select the probe to repeat the initialization routine.

Non-Imaging CW Probes

Table 1-11: CW Probes

Probe	Indications for Use	Capabilities and Features	Illustration
P2D	• Adult Cephalic • Cardiac • Peripheral Vascular	• Scan Assistant • CW • Speed of Sound • Compare Assistant	
P6D	• Adult Cephalic • Cardiac • Peripheral Vascular	• Scan Assistant • CW • Speed of Sound • Compare Assistant	

4D Probes

Table 1-12: Common 4D Probe features

Common Features available for all 4D probes	
• Coded Harmonics • SRI-HD • LOGIQ View • 4D • Raw Data • PDI	• Scan Assistant • Retain Field of View • Speed of Sound • Image Quality Check • Compare Assistant

Additional probe features, not common to all sector probes, are listed in the Capabilities and Features column in Table 1-13:

Table 1-13: 4D Probes

Probe	Indications for Use	Capabilities and Features	Illustration
RNA5-9-D	• Neonatal • Pediatric	• Anatomical M-Mode • Beta View • Anatomical Color M • CrossXBeam • Biopsy capability	
RAB2-5-D	• Abdomen • OB/GYN	• Coded Contrast • Anatomical M-Mode • Anatomical Color M • CrossXBeam • Biopsy capability	
RAB4-8-D	• Abdomen • OB/GYN • Pediatric	• Anatomical M-Mode • Anatomical Color M • CrossXBeam • Biopsy capability	

Table 1-13: 4D Probes (Continued)

Probe	Indications for Use	Capabilities and Features	Illustration
RAB6-D	• Abdomen • OB/GYN • Pediatric	• Coded Contrast • Anatomical M-Mode • Anatomical Color M	
RIC5-9-D	• OB/GYN • TV/TR • Urology	• Coded Contrast • Anatomical M-Mode • Beta View • Anatomical Color M • CrossXBeam • Biopsy capability	
RSP6-16-D	• Musculoskeletal • Pediatric • Peripheral Vascular • Small Parts	• Coded Contrast • Virtual Convex • CrossXBeam • Biopsy capability	

Beta View

Beta View enables you to steer the probe head in elevation direction without moving the probe. This feature is available on the 4D RIC5-9-D and RNA5-9-D probes during live scanning and is especially useful during an endovaginal or neonatal head exams.

The Beta View Touch Panel control appears on the B-Mode Touch Panel when you select either of these two probes. You can adjust the Beta View control Right/Left or Up/Down. When you press down on the Beta View control, the probe head re-centers itself.

Beta View is not available while the image is Frozen, during an image Recall, during a Biopsy procedure, or during Volume Navigation. When these controls are selected, the Beta View Touch Panel control is hidden and unavailable.

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)


CAUTION

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.


WARNING

NEVER reuse the TR5° disposable biopsy guide attachment and Disposable sterile Ultra-Pro II Needle guide kits.

Preparing for a Biopsy

Displaying the Guidezone

Activate the Biopsy Kit by selecting it from the B-Mode Touch Panel.

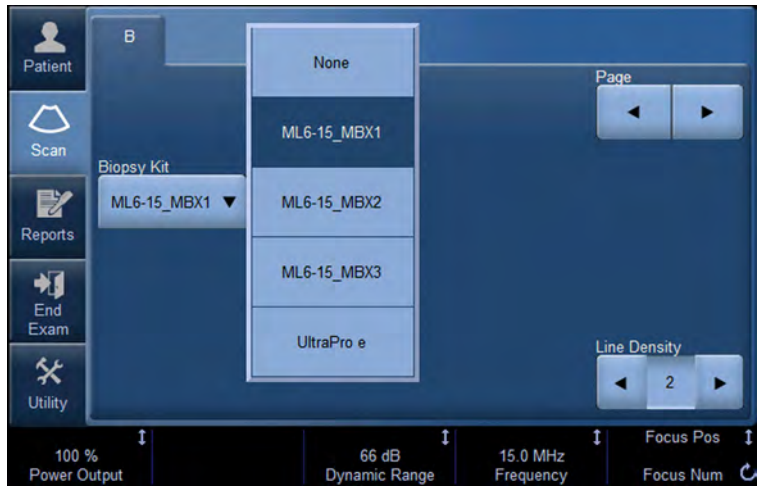


Figure 1-18. B-Mode Touch Panel Menu

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 LOGIQ E9 depending on the probe. Select the desired biopsy kit.

NOTE: You can display the biopsy guideline on the CFM image in simultaneous mode. Select the Show Biopsy Mark on CFM simultaneous Mode preset in the Utility -> System -> System Image -> Biopsy Guide screen.

Displaying the Guidezone (continued)

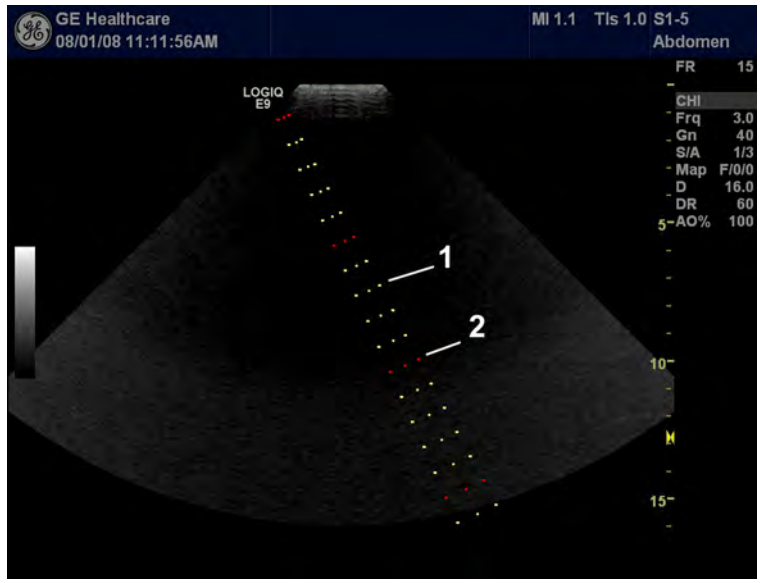


Figure 1-19. Biopsy Guidezones for the S1-5 Probe

1. 1 cm increments
2. 5 cm increments

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.

NOTE: To set up biopsy guidezones, refer to Table 16-9 for more details.

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.


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.



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 contaimination, 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 vilated or if expiration date has passed.

Fixed Needle 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. Identify the appropriate biopsy guide bracket by matching the label on the bracket with the probe to be used.
2. Orient the bracket so that the needle clip attachment will be on the same side as the probe orientation mark (ridge).

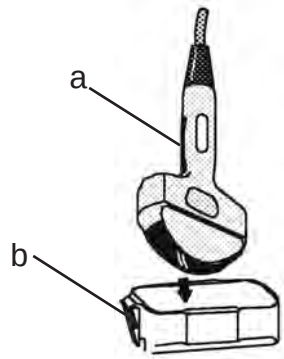


Figure 1-20. Probe/Bracket Alignment

a. Probe Orientation Mark
b. Bracket

3. Attach the biopsy bracket to the probe by sliding the bracket over the end of the probe until it clicks or locks in place.
4. Place an adequate amount of coupling gel on the face of the probe.

Fixed Needle Biopsy Guide Assembly (continued)

5. Place the proper sanitary sheath over the probe and biopsy bracket. Use the rubber bands supplied to hold the sheath in place.

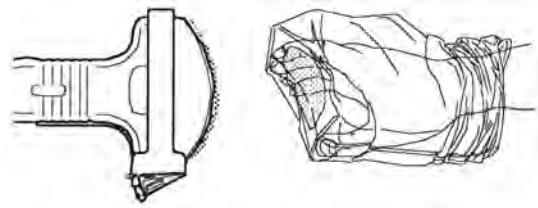


Figure 1-21. Applying Sanitary Sheath

6. Snap the fixed or adjustable needle clip onto the biopsy guide bracket.

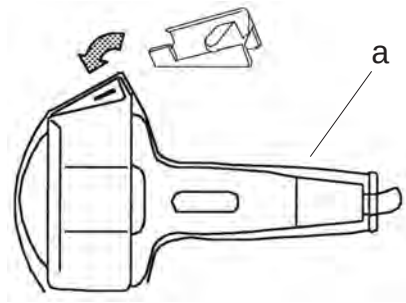


Figure 1-22. Fixed Needle Clip Attachment

a. Sheath

Fixed Needle Biopsy Guide Assembly (continued)

7. Push the locking mechanism towards the bracket to secure the lock. Make sure the needle guide is firmly attached to the bracket.



Figure 1-23. Locking the Needle Clip

NOTE: If using an in-plane needle guide, the needle clip appears as shown here. Be sure to choose an in-plane guide that matches the gauge of the needle being used. The in-plane guide does not support any on-screen graphics. This is because the guide allows variable angles. For in-plane needle guides, steps 8 and 9 are not applicable.



Figure 1-24. Example of In-Plane Needle Guide

Fixed Needle Biopsy Guide Assembly (continued)

8. Choose the desired gauge (size) needle barrel. Twist it back and forth to remove it from the plastic tree.

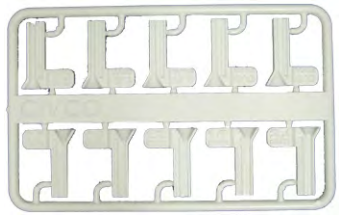


Figure 1-25. Needle Barrel Selection

9. Place the needle barrel into the needle clip with the desired gauge facing the needle clip and snap into place.

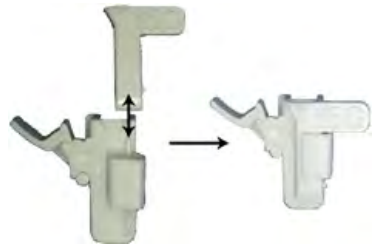


Figure 1-26. Needle Barrel Installation

CAUTION

Ensure that all guide parts are seated properly prior to performing a biopsy.

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.

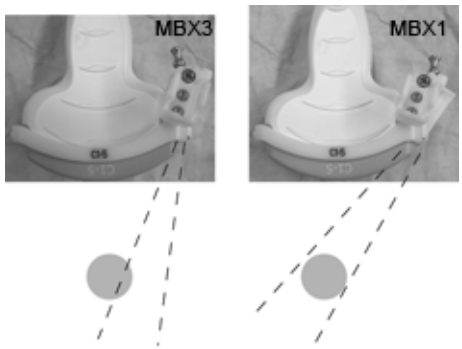


Figure 1-27. Example

2. Pull up on the knob (Figure 1-28 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 1-28 b) into the desired slot to secure the angle position of the needle guide attachment.



Figure 1-28. 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).

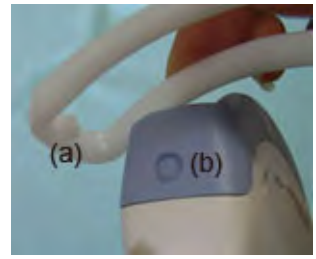


Figure 1-29. Probe/Bracket Alignment

Hold the side (a) and tuck down the needle guide side (b) until it clicks or locks in place.



Figure 1-30. 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.

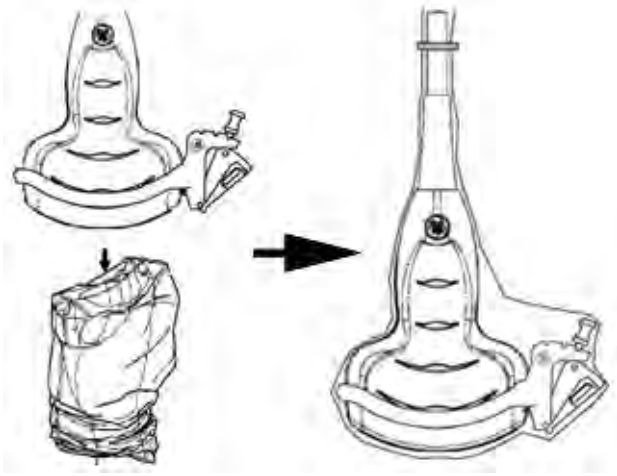


Figure 1-31. Applying Sanitary Sheath

6. Snap the needle guide onto the biopsy guide bracket.

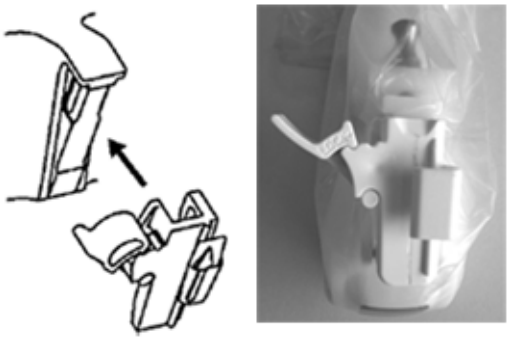


Figure 1-32. Snap the needle guide

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 1-33. Lock the Needle guide

8. Choose the desired gauge (size) needle barrel. Twist it back and forth to remove it from the plastic tree.

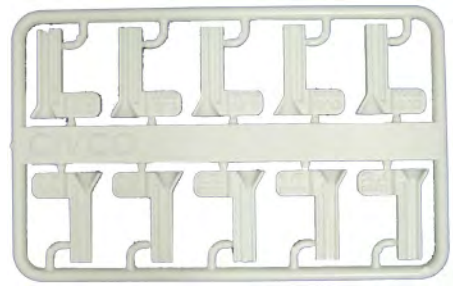


Figure 1-34. Needle Barrel

9. Place the needle barrel into the needle clip with the desired gauge facing the needle clip and snap into place.



Figure 1-35. 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 1-36.



Figure 1-36. 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.

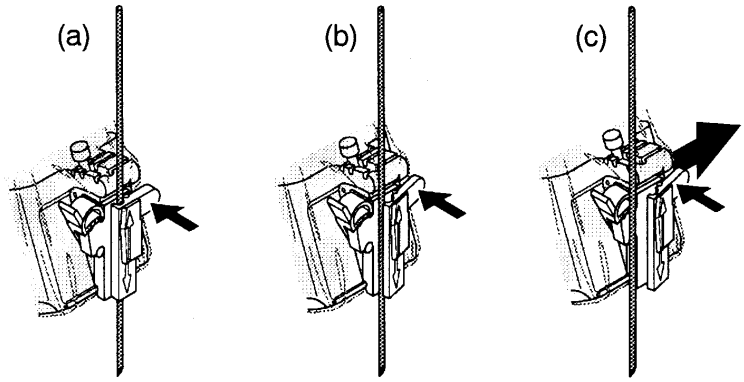


Figure 1-37. Release the needle from assembly

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.

Endocavitary Probe Biopsy Guide Assembly - Representative Example

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.

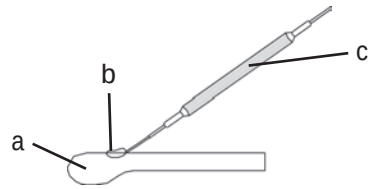


Figure 1-38. Attachment Filling Removal

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.

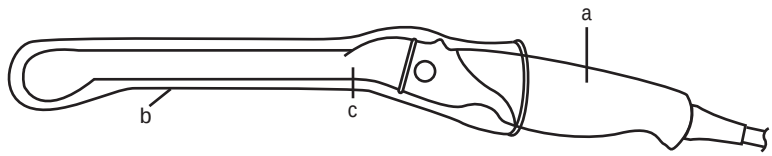


Figure 1-39. Endocavitary Probe with Sheath

a. Probe Handle
b. Sanitary Sheath
c. Probe Body

5. Rub a finger over the tip of the probe to ensure all air bubbles have been removed.

Endocavitary Probe 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.

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.

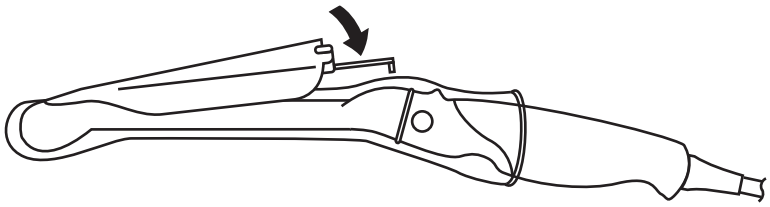


Figure 1-40. Disposable Biopsy Guide 5 degree Angle

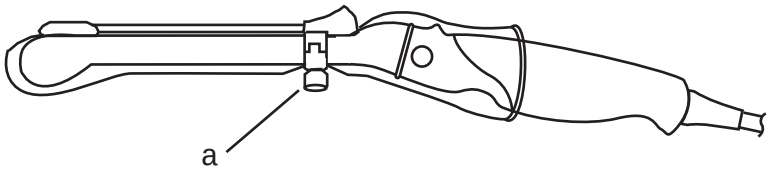


Figure 1-41. Reusable Biopsy Guide

a. Fix with a screw

NOTE: For the RIC5-9-D and IC5-9-D probes, use the TR5 guidelines for the plastic (disposable-only) biopsy guides; use the RU guidelines with the stainless steel reusable biopsy guides.

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.

4D Biopsy Guide Assembly - Representative Example

4D Probe



Figure 1-42. Mounting the Biopsy Needle Guide to the 4D Probe

1. Place the needle guide onto the probe.
2. Push the needle forward until the bracket catches in the support on the housing of the probe.
3. Fix the biopsy guide by locking the frame on the opposite side.
4. Pull lightly and rotate the needle guide barrel to position with the needle hole on the front side.

NOTE: Needle guide sterilization with autoclave possible.

4D Endocavitary Probe

1. Press the needle guide onto the probe shaft and push it forward until the small swelling of the needle guide cacthes in the notch at the probe tip.

NOTE: Material: Stainless Steel

NOTE: Needle guide sterilization with autoclave possible.

4D Probe Biopsy Needle Path Selection

To select the needle path and verify that the path of the needle is accurately indicated within the guidezone on the system monitor, perform the following before use:

1. Properly install the bracket and biopsy guide.
2. Scan in a container filler with water (47° C).
3. Select ***Biopsy kit***. The available biopsy options from the Touch Panel.

   Select the biopsy guidezone where the needle echo passes through the center of the guidezone. Use the selected biopsy guidezone when performing the biopsy.

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 Touch Panel. When using multi-angle guides, ensure that the proper guidezone angle is displayed.

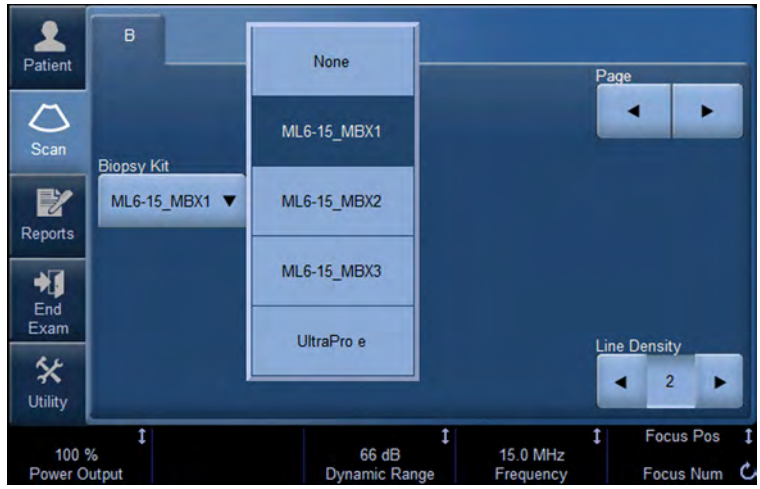


Figure 1-43. B-Mode Touch Panel

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 3-5 for more information.*

The biopsy bracket can be cleaned and disinfected in a recommended disinfecting agent and reused.



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 1-46 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.

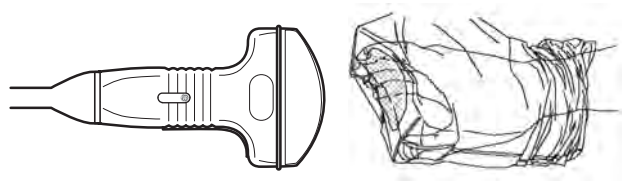


Figure 1-44. Applying Sterile Sheath

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.

Beginning an Exam

Scanning a New Patient

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

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

NOTE: The system can 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. A different dataflow for permanent storage of patient data should be selected.

6. 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.

Columns drive the ordering of the patients displayed. The column that you select drives the order of the displayed patient database.

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

" ' \ / : ; . , * < > | + = [ ] &

7. Select ***Register***.
8. Select the probe to start scanning (or select Exit, Esc, Scan, or Freeze).
9. Perform the exam.

Scanning a New Patient (continued)

10. 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 **P1** (or the assigned Print key).

    To store the cineloop, press **Freeze** and run the cineloop using the **Trackball**. Select the start/end frame and run the selected loop. Press **P1** (or the assigned Print key).



HINTS

When you press a Print key during scan (Live Store), the LOGIQ E9 stores the cine for the specified length of time noted in the Time Span(s) preset, found under Time-Based Store in Utility -> Application -> Print Controls.

When you press a Print key during scan (Live Store) with ECG, the LOGIQ E9 stores the cine for the specified number of heart cycles noted in the Number of heart cycles preset, found under ECG-Based Store in Utility -> Application -> Print Controls.

If you set the Number of heart cycles for more than 1 heart cycle in Utility -> Application -> Print Controls, the LOGIQ E9 stores the cine for the length of time specified in "Time Span(s) x Number of heart cycles".

Refer to Chapter 16 for more information on image storage.

11. When you have completed the study, press ***End Exam***. The image management screen displays. Select the images (still frame or cineloop) you want to store or select ***Select All*** to store all images. 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.

NOTE: *Return to the patient screen automatically from the scan screen when you select OK from the "ID is not unique" warning message.*

Patient Screen



Figure 1-45. Patient Screen (Example: Category OB)

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

Patient Screen (continued)

Enter Patient Data with the alphanumeric keyboard.

To navigate through the Patient Entry menu, use the ***Tab*** key or **Trackball** and **Set** to move and fix the cursor.

Image Management

- Patient–Provides a search and creation of patient. (currently selected)
- Image History–Provides a list of images per exam for the currently selected patient.
- Active Images–Provides preview of the currently selected exam and Compare Assistant.
- Data Transfer–Provides an interface to handle patient data from a remote device.

Function Selection

- New Patient–Used to clear patient entry screen in order to input a new patient's data into the database.
- Register–Used to enter new patient information into the database prior to the exam.

NOTE: If you are using the auto-generate Patient ID feature, do not select Register. It is always a good practice to Register all patients.

- Details–Select the Details box to activate/deactivate the exam details. Exam details include Indications, Comments, Admission Number, Performing Physician's Telephone Number, Referring Physician's Telephone Number, Operator Telephone Number, and Exam Description.

NOTE: The Exam Description pull-down selection is used as the DICOM identifier.

EZBackup/EZMove

One-step method to backup (move and delete patient images) to an external media.

Dataflow Selection

Select the appropriate dataflow.

NOTE: If you use a DVD-R, select DICOM CD Read in Dataflow.

If you place the cursor on the icon, the pop-up menu displays disk capacity.

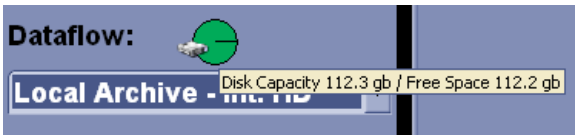


Figure 1-46. Dataflow Pop-up

WARNING

Ensure you have selected a dataflow. If No Archive is selected, no patient data is saved. A Ø appears next to Dataflow if No Archive is selected.

Exit

Used to exit the Patient Menu.

Patient Information

- Patient ID Number
- Patient Name–Last, First and Middle
- Alternate (Other, Second) Patient ID Name and Number. The system now allows you to enter a second identification number for the same patient, which may be required in certain countries. This is only displayed if enabled on the Connectivity -> Miscellaneous screen.
- DOB (Birthdate)
- Age (automatically calculated when birthdate is input)
- Sex

Category Selection

Select from 8 exam application categories: Abdomen, Obstetrics, Gynecology, Cardiology, Vascular, Urology, Small Parts, or Pediatrics.

When a category is selected, the measurement and category presets are displayed.

Exam Information

Shows the Current/Active Exam information. Information pertinent to the selected exam category appears in the window. All possible information needs to be entered.

- Images–Displays the selected exam's images.
- Clear–Clears existing data.
- Past Exam (only for OB)–Input past exam data (register the patient before using).

Scan Assistant Program

The Scan Assistant Program is either selected automatically or manually, depending on the preset as configured on the Utility--> System--> General page.


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.

Patient View/Exam View

- Patient View

  Lists the patients in the database.

*NOTE: Use **Ctrl** + **A** to select all from the Data Transfer list/Patient view.*

*NOTE: When you double-click the patient on the patient list using the **Set** key, the Review screen or New Exam entry screen displays depending on the preset. You set this preset via Select Review or New Exam in Utility -> Connectivity -> Miscellaneous -> "Double click on patient list to start" preset.*

- Search key–select search item from Patient ID, Last Name, First Name, Other ID, Birthdate, Sex, Exam Date, Exam Today, Accesstion Number, Exam Description, Exam Date Before, Exam Date Between, Exam Date After, Locked (Y, N) or Img. Archived (Y, N).

NOTE: If "Exam Date Between" is selected, the Input Dialog displays and you can select the date from the displayed calender.

NOTE: If "Exam Date Between" is used for the Search key, the From and To dates are separated by a "-" (dash) in the Search String.

NOTE: Img. Archived means that the exam was backed up to external media by EZBackup or Export.

Patient View/Exam View (continued)

- String–enter appropriate information.

  If you select Locked (Y, N) or Archived (Y, N) for the Search key, enter Y (Yes) or N (No).
- Clear–Clears the entered string.
- Listing XX of XXX -- Displays the quantity of patients that match the search criteria in the search window and the quantity of patients in the database.
- Review–Select Patient/Exam for review.
- Resume Exam–Continues the exam for that patient if you select the last exam of the day.
- New Exam–Creates a new exam based on a current or searched patient.
- Delete–Deletes Patient/Exam.

NOTE: *"Delete" is only displayed when you login as Administrator.*

- Lock/Unlock–Locks the exam/patient. Prevents move and delete functions.

- Exam View

  Displays the Exam History of the selected patient by date.
  - Disk - Displays the disk name on which you saved the exam's image data. If "+" displays behind the disk name, the data is saved on two or more disks.


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.

Patient Screen (continued)

Maintaining the Patient Database



CAUTION

To maintain optimum system performance and to safeguard patient data, keep the total number of patients in the database below 1,000.

To reduce the total number of patients in the database, perform the following procedure.

1. Before starting EZBackup, select “Unlock All” on the Utility -> Admin -> Logon screen.

   Prepare the unformatted CD-R or DVD-R before EZBackup.

NOTE: Pre-formatted CD-R or DVD-R cannot be used for EZBackup.

2. First perform EZBackup and then Backup (Patient Archive and Report Archive).
3. Go to the patient screen, select the patients/exams to delete. Select “Delete” to delete the selected data.

NOTE: Removing image data with the “EZMove” function does not reduce the patient number in the database.

NOTE: Ensure that all patients are exported or backed up BEFORE deleting them.

We recommend attaching the patient list to the EZBackup media. Insert the media and select DICOM CD Read for the dataflow (if you use a USB drive, select DICOM USB Drive Read). Press the right **Set** key to select the patient. Press the left **Set** key to bring up the print menu. Select Print and press the right **Set** key to print the patient list.

Chapter 2

Performing an Exam

Optimizing the Image and Measurement and Analysis

Optimizing the Image

B-Mode Controls

Table 2-1: B-Mode Controls

Control	Possible Bioeffect	Description/ Benefit
Depth	Yes	Depth controls the distance over which the B-Mode images anatomy. To visualize deeper structures, increase the depth. If there is a large part of the display which is unused at the bottom, 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 or moves the focal zone(s) 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.
Auto Optimize	No	Auto Optimize (Auto) lets you optimize the image based upon a the actual B Mode image data (Auto Tissue Optimize, ATO). The preset levels (Low, Medium, and High) allow you to pick a preference for the contrast enhancement in the resulting image. Low does the least amount of contrast enhancement, high does the most. Auto is available in single or multi image, on live, frozen or CINE images (in B-Mode only), while in zoom, and in Spectral Doppler. Auto in PW Doppler Mode optimizes the spectral data. Auto adjusts the Velocity Scale (live imaging only), baseline shift, dynamic range, and invert (if preset). Upon deactivation, the spectrum is still optimized.
Mode Cursor	No	Displays the M/D-Mode cursor on the B-Mode image.

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

Control	Possible Bioeffect	Description/ Benefit
SRI-HD	No	SRI-HD (Speckle Reduction Imaging High Definition) is an adaptive algorithm to reduce the unwanted effects of speckle in the ultrasound image. Image speckle usually appears as a grainy texture in otherwise uniform areas of tissue. Its appearance is related to image system characteristics, rather than tissue characteristics, so that changes in system settings, such as probe type, frequency, depth, and others, can cange the appearance of the speckle. Too much speckle can impair image quality and make it difficult to see the desired detail in the image. Likewise, too much filtering of speckle can mask or obscure desired image detail. Extra care must be taken to select the optimal SRI-HD level. SRI-HD is available in B-Mode imaging and may be used with any transducer or clinical application when image speckle appears to interfere with the desired image detail.
CrossXBeam	No	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 (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	Multi Frequency mode lets you downshift to the probe's next lower frequency or shift up to a higher frequency.
Steer	Yes	You can slant the B-Mode or Color Flow linear image left or right to get more information without moving the probe. The angle steer function only applies to linear probes.
Virtual Convex	Yes	On Linear and Sector probes, Virtual Convex provides a larger field of view in the far field. Virtual Convex is always active with Sector probes.
TGC	No	TGC amplifies returning signals to correct for the attenuation caused by tissues at increasing depths. TGC slide pots are spaced proportionately 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 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. *Tilt* is not available on Linear probes.

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

Control	Possible Bioeffect	Description/ Benefit
Dynamic Range	No	Dynamic Range controls how echo intensities are converted to shades of gray, thereby increasing the adjustable range of contrast. The Dynamic Range control name changes to Compression on frozen images.
Reverse (if Preset)	No	Flips the image 180 degrees left/right.
Line Density	Yes	Optimizes B-Mode frame rate or spatial resolution for the best possible image.
Maps	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 realtime or CINE images or Timeline CINE, but not DVR images.* 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 gray bar displays while Colorize is activated.
Rotation	No	Flips the image 180 degrees up/down. **CAUTION:** When reading a 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.
Speed of Sound	No	Changes the transmitted speed of sound for various tissue types.

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 2-2: Color Flow Mode Controls

Control	Possible Bioeffect	Description/ Benefit
Flow Model Shortcuts	No	In certain applications, you can quickly select the flow state via a shortcut on the Color Flow Mode Touch Panel 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.
Color Width	Yes	Color Width sizes and positions 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 Scale.*
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	Accumulation enhances the flow in an image. Available in Contrast, Color Flow, and PDI.
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.
Threshold	No	Threshold assigns the gray scale level at which color information stops.
Frame Average	No	Averages color frames.
Transparency Map	No	Brings out the tissue behind the color map.

Table 2-2: Color Flow Mode Controls (Continued)

Control	Possible 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.
Sample Vol (Sample Volume)	Yes	Places the sample volume gate on the Color Flow image. The gate is positioned over a specific position within the vessel.
Sample Volume Length (SV Length)	Yes	Sizes the sample volume gate.
Packet Size	Yes	Controls the number of samples gathered for a single color flow vector.
Map Compress	No	When you increase the value, high velocity elements in the map are compressed so that the map darkens. When you decrease the value, low velocity elements in the map are compressed so that the map lightens. The effect is visible in the color bar.
CF/PDI Vertical Size	No	You can set the default CF/PDI ROI vertical size.
CF/PDI Width	No	You can set the default CF/PDI ROI width.
CF/PDI Center Depth	No	You can set the default CF/PDI center depth.
CF/PDI Frequency (MHz)	No	You can set the default CF/PDI Frequency (MHz).
CF/PDI Auto Frequency	No	You can set the default CF/PDI Auto Frequency.
CF/PDI Focus Depth (%)	No	You can set the default CF/PDI center depth.
Power Doppler Imaging (PDI)	No	Power Doppler Imaging (PDI) is a color flow mapping technique used to map the strength of the Doppler signal coming from the flow 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.

M-Mode Controls

Table 2-3: M-Mode Controls

Control	Possible Bioeffect	Description/ Benefit
Sweep Speed	Yes	Changes the speed at which the timeline is swept. Available in M-Mode, Doppler Mode and M Color Flow Mode.
Anatomical M-Mode	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. Curved Anatomical M-Mode (CAMM) displays a distance/time plot from a free-drawn cursor line. CAMM is available in gray scale, color and TVI.

M Color Flow Mode

See ‘Color Flow Mode Controls’ on *page 2-5*.

Doppler Mode Controls

Table 2-4: Doppler Mode Controls

Control	Possible Bioeffect	Description/ Benefit
Update	Yes	Toggles between simultaneous and update presentation while viewing the timeline.
SV Length (Trackball)	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 (SV 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/Auto Angle	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 O), 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.
Audio Volume	No	Controls audio output.
Invert	No	Vertically inverts the spectral trace without affecting the baseline position.
Compression (Dynamic Range)	No	Dynamic range controls how echo intensities are converted to shades of gray, thereby increasing the range of contrast you can adjust.
Trace Method (Spectral Trace)	No	Traces the average mean and peak velocities in realtime 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.

Table 2-4: Doppler Mode Controls (Continued)

Control	Possible Bioeffect	Description/ Benefit
Trace Direction	No	Specifies trace direction.
Cursor Moving	No	Cursor Moving lets you ‘walk’ Doppler through a vessel while the Doppler gate is moving.
Display Format	No	Changes the horizontal/vertical layout between B-Mode and M-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.

3D Mode

Table 2-5: 3D Package Options

3D Type	Description	Sensor/No Sensor	Available Tabs
Easy 3D	Designed for rendering B Mode and Color Flow Mode images, e.g., Baby Face scans.	No sensor	3D Acquisition, Easy 3D, Movie
Advanced 3D	Designed for rendering B Mode and Color Flow Mode images, e.g., vessel trees.	No sensor	3D Acquisition, Easy 3D, Advanced 3D, Movie
Tru3D (Option)	Designed for rendering B Mode and Color Flow Mode images, e.g., vessel trees.	Sensor	3D Acquisition, Easy 3D, Advanced 3D, Movie, Tru3D

Acquiring a 3D Scan

To acquire a 3D scan,

1. Optimize the B-Mode image. Ensure even gel coverage.
2. Press the 3D control panel key. Two screens appear.

NOTE: Set appropriate values for Acq Mode and Scan Plane. Also, set the scan distance before scanning.

3. To start acquiring the image, press ***Start*** (Trackball 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 ***End*** (Trackball key).

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

Other Controls

Trackball Key Map

The current mapping is shown on the trackball mapping display area in the lower, right-hand corner of the display screen. Four Trackball keys surround the Trackball. These Trackball keys are mapped based on the current state of the system (live imaging, frozen imaging, measurements, etc.)

Trackball functionality is labeled on the display. To activate new functionality for the Trackball, press the correct key adjacent to the Trackball, as indicated on the display.

Zoom

Write 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.

To zoom an image, adjust Zoom. A reference image appears in the lower, left-hand section of the display.

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

Split Screen

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

When you activate Split Screen by pressing ***L***, the single image is placed on the left side; when you activate Split screen by pressing ***R***, the single image is placed on the right side.

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

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

Dual Caliper

In split screen, you can draw a caliper, area, ellipse, or spline trace on both the left and right image at the same time. Whichever side of the screen that you annotate is called the “Original” graphic. The copy is called the “Shadow” graphic.

Freezing an image

To freeze an image,

1. Press **Freeze**. The Freeze key backlight turns green.

If you are in a mixed mode, both screen formats stop immediately. Deactivating Freeze restarts both modes and places a black bar on the trace to indicate the time discontinuity.

To reactivate the image,

1. Press Freeze again.

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

Use the Trackball to start CINE after pressing Freeze.

Activating CINE

To activate CINE,

1. Press Freeze.
2. Move the Trackball.

Body Patterns

To activate body patterns, press the ***Body Pattern/Ellipse*** control. A maximum of 6 body pattern packages are displayed on the Touch Panel according to exam category and preset.

Select the desired body pattern on the Touch Panel. The selected body pattern is displayed on the monitor.

Press the **Move Pattern** control on the Touch Panel to reposition the body pattern with the **Trackball** and **Set** controls.

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 ***Ellipse*** control.

The probe mark type is selectable by rotating the **Probe Type** control on the Touch Panel. 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 at the bottom of the Touch Panel.

To clear the body pattern, press the ***Body Pattern/Ellipse*** control to activate body patterns and then press the ***Clear*** key.

Press ***Set*** on the keyboard or **Scan** on the Touch Panel 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 Touch Panel menu.

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 twice immediately 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 ***F2 (Arrow)*** key on the keyboard or by selecting the **Comment** key and then the top **Trackball** key. When the pointer comes up, it is a GREEN color, indicating it is active and can be moved.

Using the Fast Key

A keyboard Fast Key is available to record and run a sequence of often-run keystrokes.

To create a Fast Key, press the ***F5*** key and follow the on-screen prompts.

To start a Fast Key, press the ***F6*** key and follow the on-screen prompts.

Using the Monitor Display Controls to Manage Images

You can manage images from the display via these on-display controls.



Figure 2-1. Menu Icons

1. Active Images Screen
2. Delete Image
3. Next/Previous Image(s); and Clipboard Slide Show if you press and hold down the [Ctrl] key + Next or Previous Arrow..
4. Save As Menu
5. Thumbnail Size
6. Number of Images in Exam

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 2-2. Locating Measurement Controls

1. **Measure**. Activates a measurement caliper and the calculation package associated with the currently selected preset.
2. **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. To remove all annotations/body markers/arrows, hold down the Clear button.
3. **Ellipse**. 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. **Trackball**. Moves the measurement calipers, selects the measurement on the Summary Window. Trackball also selects items on the Touch Panel with the Pointer and Set keys.
5. **Trackball Keys.** The functionality of these keys changes (e.g. Set, Mode Cursor, etc) depending on the mode or action. Current functionality is displayed on the lower-right corner of the monitor.
6. **Pointer Key**. Select to display a pointer on the monitor.

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** once; an active caliper 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 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.

The following hints can help you to perform distance measurements:



HINTS

- **Before** you complete a measurement:
  - To toggle between active calipers, press the top Trackball key.
  - 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 worksheets, 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** once; an active caliper displays.
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. 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 the size, adjust the **Ellipse** control in a clockwise direction. To decrease the size, adjust the **Ellipse** control in a counterclockwise direction.
8. To toggle between active calipers, press the top **Trackball key**.
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 **Measure**.
2. Press the top **Trackball key** to select Trace; a caliper displays.
3. To position the caliper at the start point, move the **Trackball**.
4. To fix the trace start point, press **Set**. The caliper changes to an active caliper.
5. To trace the measurement area, move the **Trackball** around the anatomy. A dotted line shows the traced area.
6. To complete the measurement, press **Set**. The system displays the circumference and the area in the Results Window.

Circumference and area (trace) measurement (continued)

Open Trace

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

1. Press **Measure**.
2. Press the top **Trackball key** to select Open trace; a caliper displays.
3. To position the caliper at the start point, move the **Trackball**.
4. To fix the trace start point, press **Set**. The caliper changes to an active caliper.
5. To trace the measurement area, move the **Trackball** around the anatomy. A dotted line shows the traced area.
6. To complete the measurement, press **Set**. The system displays the circumference and the length 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 **Measure**.
2. Press the top **Trackball key** to select Spline Trace; a caliper displays.
3. To position the first caliper at the start point, move the **Trackball**.
4. 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.*

5. 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.

6. 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.

NOTE: Spline trace is not available through the factory default. The system defaults to trace. To enable spline trace, modify the Measure Key Sequence preset found in Utility -> Measure -> Advanced preset menu.

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.

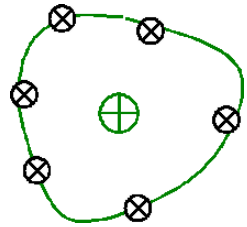


Figure 2-3. Edit spline trace

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 **Measure**.
2. Press the top Trackball key to select Intensity. A caliper displays.
3. To position the caliper at the start point, move the **Trackball**.
4. To fix the trace start point, press **Set**. The caliper changes to an active caliper.
5. To trace the measurement area, move the **Trackball** around the anatomy. A dotted line shows the traced area.
6. 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

Four basic measurements 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**. Press the top Trackball key to select Trace; a caliper displays. Select ***Manual*** on the Touch Panel.
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 velocity spectrum boundary, 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.

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**. Press the top Trackball key to select Trace; an active caliper with a vertical dotted line displays. Select ***Auto*** on the Touch Panel.
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**. Press the top Trackball key 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**. Press the top Trackball key to select Time; 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. Go to the M-Mode part of the display.
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**. Press the top Trackball key 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**. Press the top Trackball key to select Slope; 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.

Viewing and Editing Worksheets

NOTE: Worksheets are not saved if the system crashes.

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

To view a worksheet

To view a worksheet, select ***Worksheet*** on the Touch Panel.

The system displays the worksheet for the current study.

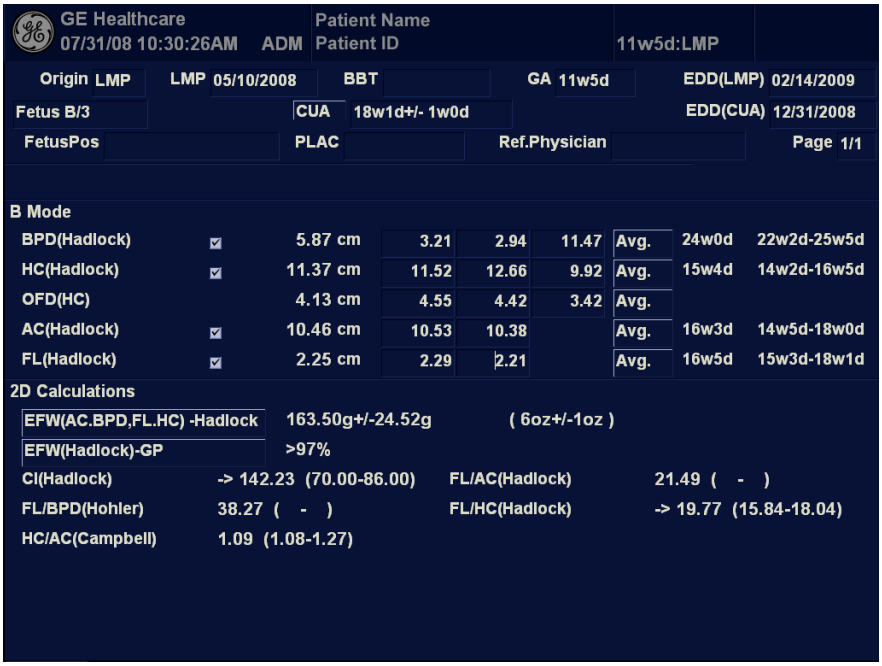


Figure 2-4. OB B-Mode Worksheet

To return to scanning, do one of the following:

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

To view a worksheet (continued)

To view a different worksheet, select the worksheet key for the desired worksheet.

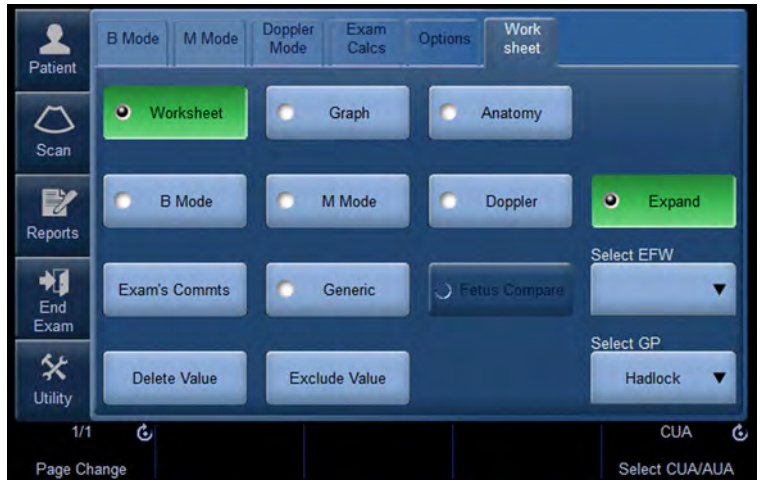


Figure 2-5. Worksheet Display Touch Panel

To view worksheet data for a particular mode, select the key for that mode. To view a worksheet with data for more than one mode, select ***Expand***. When Expand is selected, it defaults to view all measurements, noted by mode, on the worksheet.

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

To edit a worksheet

To change data on a worksheet:

1. To position the cursor at the field you want to change, move the **Trackball**. The field is highlighted.
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 worksheet:

1. To position the cursor at the field you want to delete or exclude, move the **Trackball**. 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 worksheet calculations.
   - To include a value that you previously excluded, select ***Exclude Value***.

To type a comment on a worksheet:

1. Select ***Examiner's Comments***. The Examiner's Comments window opens.
2. Type comments about the exam.
3. To close the Examiner's Comments window, select ***Examiner's Comments***.

To edit a worksheet (continued)

To turn the volume measurement value off:

- Select the method type ***Off***. The value field becomes blank.

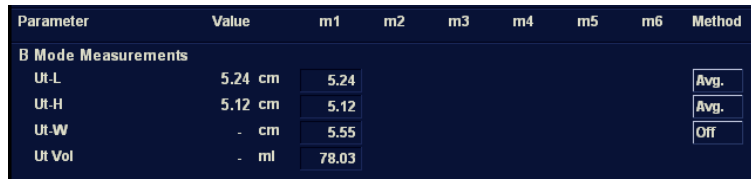


Figure 2-6. Volume Parameter Off

HINTS

Some fields on the worksheet 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 Worksheet Values

You can delete all worksheet values on a worksheet.

1. When the Worksheet is displayed on the monitor, press the **Clear** key; the following warning message appears:



Figure 2-7. Delete All 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 2-6: System Measurements and Accuracies

Measurement	Units	Useful Range	Accuracy	Limitations or Conditions
Depth	mm	Full Screen	±20%	
Distance:				
Axial (Equal to 1540m/s)	mm	Full Screen	±3% or ±1mm, whichever is greater	
Lateral (Equal to 1540m/s)	mm	Full Screen	±5% or ±1mm, whichever is greater	Linear Probes
Lateral (Equal to 1540m/s)	mm	Full Screen	±6.5% or ±3.5mm, whichever is greater	Convex Probes
Lateral (Equal to 1540m/s)	mm	Full Screen	±5% or ±1mm, whichever is greater	Sector Probes
Axial/Lateral (Not Equal to 1540m/s)	mm	Full Screen	±7.5% or ±5.0mm, whichever is greater	All probes Not Equal To 1540m/s
Circumference:				
Trace (Equal to 1540m/s)	mm	Full Screen	±5% or ±1mm, whichever is greater	
Ellipse (Equal to 1540m/s)	mm	Full Screen	±5% or ±1mm, whichever is greater	
Trace (Not Equal to 1540m/s)	mm	Full Screen	±7.5% or ±5mm, whichever is greater	All probes Not Equal To 1540m/s
Ellipse (Not Equal to 1540m/s)	mm	Full Screen	±7.5% or ±5mm, whichever is greater	All probes Not Equal To 1540m/s
Area:				
Trace (Equal to 1540m/s)	mm^2	Full Screen	±10% or ±5mm^2, whichever is greater	
Ellipse (Equal to 1540m/s)	mm^2	Full Screen	±10%, or ±5mm^2, whichever is greater	
Trace (Not Equal to 1540m/s)	mm^2	Full Screen	±20% or ±20mm^2, whichever is greater	All probes Not Equal To 1540m/s
Ellipse (Not Equal to 1540m/s)	mm^2	Full Screen	±20% or ±2mm^2, whichever is greater	All probes Not Equal To 1540m/s
Static 3D/4D Volume Accuracy			±13%	
Time	s	Timeline Display	±5%, not to exceed 10ms	M or Doppler Mode

Table 2-6: System Measurements and Accuracies (Continued)

Measurement	Units	Useful Range	Accuracy	Limitations or Conditions
Slope	mm/s	Timeline Display	±5%, not to exceed 1mm/s	M-Mode Only
Doppler Sample Volume Depth (SVD)	mm	Full Screen	2mm (0.2cm) in any direction	When SVD is at least half the depth of the image
Velocity	cm/s	Full Range	10%	PW and CW Doppler Mode
Doppler Angle Correction	degrees	From 0-59° From 60-90°	±1% ±2%	

Setting up the Off-Line Paper Printer

You can connect an off-line paper printer via the USB port on the rear of the system.

CAUTION

DO NOT place an off-line paper printer inside the patient environment (within the dotted line area noted by “1” in Figure 2-8). Refer to the off-board printer’s manual for details.

Peripheral devices that use their own AC power source CANNOT be connected to the LOGIQ E9. DO NOT connect the peripheral device’s power cord into the LOGIQ E9 system.

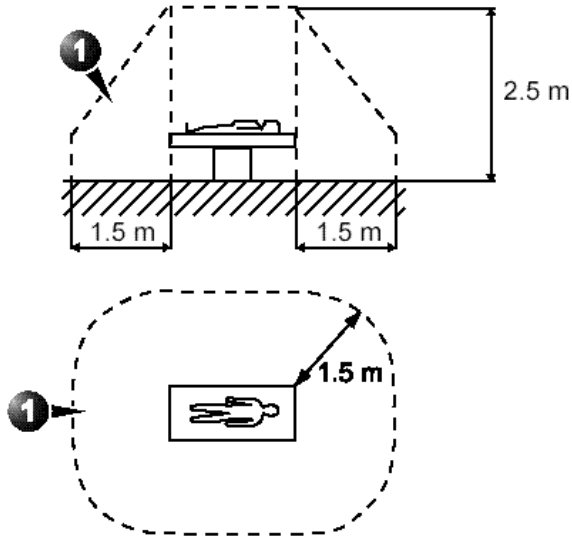


Figure 2-8. Patient Environment

CAUTION

Use a USB printer cable that is less than 3 meters in length.

Chapter 3

After the Exam is Over

Probe Overview, System Presets, DataBackup, Configuring Connectivity, Electronic Documentation, Contact Information, System Data, System Care and Maintenance, and Accessories

Probe Overview

Probe Naming Conventions

Table 3-1: Probe Naming Convention

Real Time 4D	Type	Application	Frequency	Connector Type
“R”	C=Convex L=Linear M=Matrix S=Sector	AB=Abdominal IC=Intracavitary NA=Neonatal SP=Small Parts	“1-5”	D=DLP

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.



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.

Endocavitary Probe Handling Precautions

If the sterilization solution comes out of the endocavitary probe, please follow the cautions below.



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 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 the the sterilant's instruction manual.

Sterilant Exposure from Probe 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 connector before scanning the paitent. If sterilant comes into contact with the patient, refer the the sterilant's instruction manual.

Endocavitary Probe Point of Contact—Refer to the sterilant's instruction manual.

Probe Cleaning Process

Cleaning probes

Perform After Each Use

To clean the probe:

1. 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.
2. Wash the probe with mild soap in lukewarm water. Scrub the probe as needed using a soft sponge, gauze, or cloth to remove all visible residue from the probe surface. Prolonged soaking or scrubbing with a soft bristle brush (such as a toothbrush) may be necessary if material has dried onto the probe surface.



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.

3. Rinse the probe with enough clean potable water to remove all visible soap residue.
4. Air dry or dry with a soft cloth.

Cleaning probes (continued)

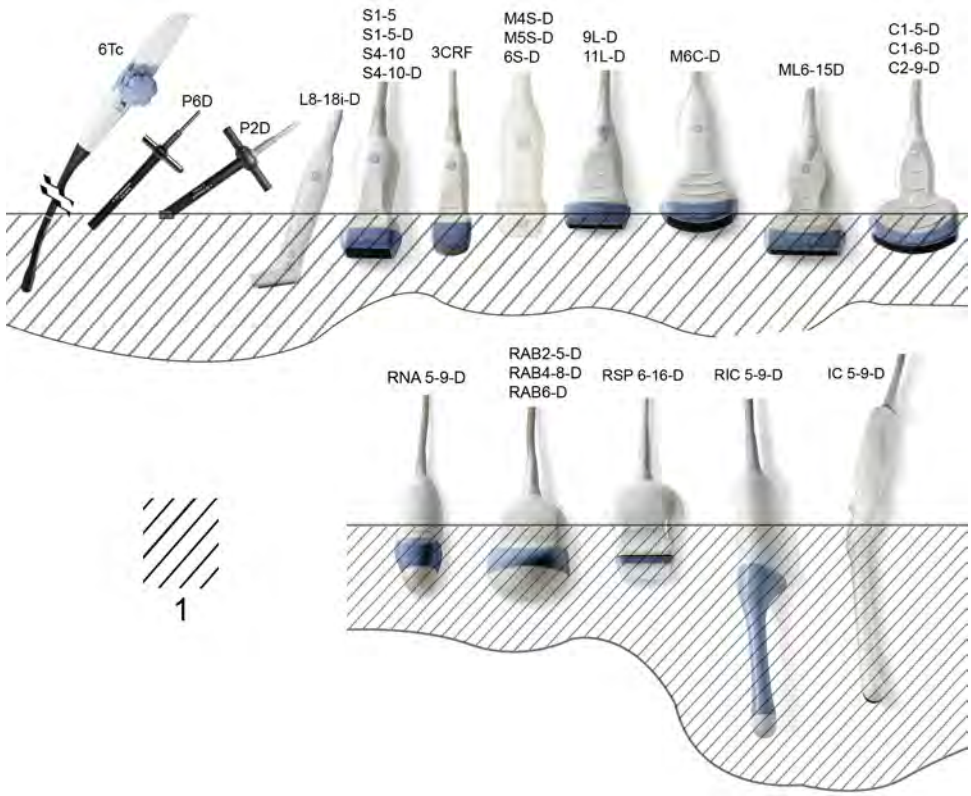


Figure 3-1. Probe Immersion Levels

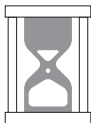
1. Fluid Level

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 3-2: 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.

Disinfecting probes (continued)


CAUTION

Review the probe care card that is packed with each probe.

Table 3-3: Probe Disinfectants

Disinfectant	9L-D/11L-D	ML6-15-D	L8-18i-D	M4S-D	M5S-D	S1-5	S1-5-D	S4-10/S4-10-D	C1-5-D	C1-6-D	C2-9-D	M6C-D	3CRF	IC5-9-D	RNA5-9-D	RAB2-5-D	RAB4-8-D	RAB6-D	RIC5-9-D	RSP6-16-D	6S-D	6Tc	P2D/P6D
Anios					X		X																
Aniosyme DD1																						X	
Anioxyde 1000																						X	
Asepti-Wipes																X	X		X				
Asepti-Wipes II	X	X	X	X					X	X	X	X		X									
Cavi Wipes	X	X	X	X					X	X	X	X		X									
Cidex	X	X	X	X		X		X	X	X	X	X	X	X	X	X	X	X	X	X		X	
Cidex OPA	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		X	
Cidex Plus	X	X	X	X	X	X	X	X	X	X	X	X		X		X	X		X			X	
Cidezymel Enzol					X		X															X	
Cleanisept wipes	X	X	X	X					X	X	X	X		X	X	X	X	X	X	X			
DisOPA																						X	
Gigasept															X			X	X	X			
Gigasept AF														X		X	X		X				
Gigasept FF					X	X	X	X						X	X	X	X	X	X	X			
Gigasept FF neu	X	X	X	X					X	X	X	X	X	X									
Hexanios G+R																						X	
Hibitane		X	X						X	X	X			X									
Incidin Foam																			X				
Korsolex Extra																						X	
Klenzyme					X		X									X	X		X		X	X	
Metricide																						X	

Table 3-3: Probe Disinfectants (Continued)

Disinfectant	9L-D/11L-D	ML6-15-D	L8-18i-D	M4S-D	M5S-D	S1-5	S1-5-D	S4-10/S4-10-D	C1-5-D	C1-6-D	C2-9-D	M6C-D	3CRF	IC5-9-D	RNA5-9-D	RAB2-5-D	RAB4-8-D	RAB6-D	RIC5-9-D	RSP6-16-D	6S-D	6Tc	P2D/P6D
Metricide 14	X	X	X	X	X	X		X	X	X	X	X	X	X	X	X	X	X	X	X			
Metricide OPA Plus	X	X	X	X		X		X	X	X	X	X		X				X					
MetriWipes																X	X		X				
MetriZyme	X	X	X	X	X		X		X	X	X	X		X									
Milton					X	X	X	X															
Nu-Cidex																						X	
PeraSafe	X	X	X	X		X		X	X	X	X	X	X	X	X	X	X	X	X	X		X	
Protex	X	X	X	X					X	X	X	X		X									
RelyOn MDC (Virkon)					X	X	X	X															
Salvanios pH7																						X	
Sani-Cloth Active																		X	X	X			
Sani-Cloth Germicidal																X	X		X				
Sani-Cloth HB	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X			
Sekusept Aktiv																						X	
Sekusept Plus																			X				
Septiwipes	X	X	X	X					X	X	X	X		X	X	X	X	X	X	X			
Sporox					X		X																
Sporox II					X	X	X	X															
Ster Bac Blu														X	X	X	X	X	X	X			
Super Sani-Cloth					X		X																
TD-100 and TD-5																						X	
Transeptic Spray					X	X	X	X					X	X		X	X		X				
Tristel Generator Solution														X		X	X					X	
T-Spray	X	X	X	X	X	X		X	X	X	X	X	X	X	X	X	X	X	X	X			

Table 3-3: Probe Disinfectants (Continued)

Disinfectant	9L-D/11L-D	ML6-15-D	L8-18i-D	M4S-D	M5S-D	S1-5	S1-5-D	S4-10/S4-10-D	C1-5-D	C1-6-D	C2-9-D	M6C-D	3CRF	IC5-9-D	RNA5-9-D	RAB2-5-D	RAB4-8-D	RAB6-D	RIC5-9-D	RSP6-16-D	6S-D	6Tc	P2D/P6D
T-Spray II	X	X	X	X		X		X	X	X	X	X	X	X	X	X	X	X	X	X			
Trophon EPR	X	X		X										X	X	X	X		X	X			
Wavicide-01	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		X	

Disinfecting probes (continued)

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 LOGIQ E9 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

Neurological use on patients with this disease must be avoided. If a probe becomes contaminated, there is no adequate disinfecting means.



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 60°C.
- Inspect the probe prior to use for damage or degeneration to the housing, strain relief, lens and seal. Do not use a damaged or defective probe.

Trophon EPR Probe High-Level Disinfection

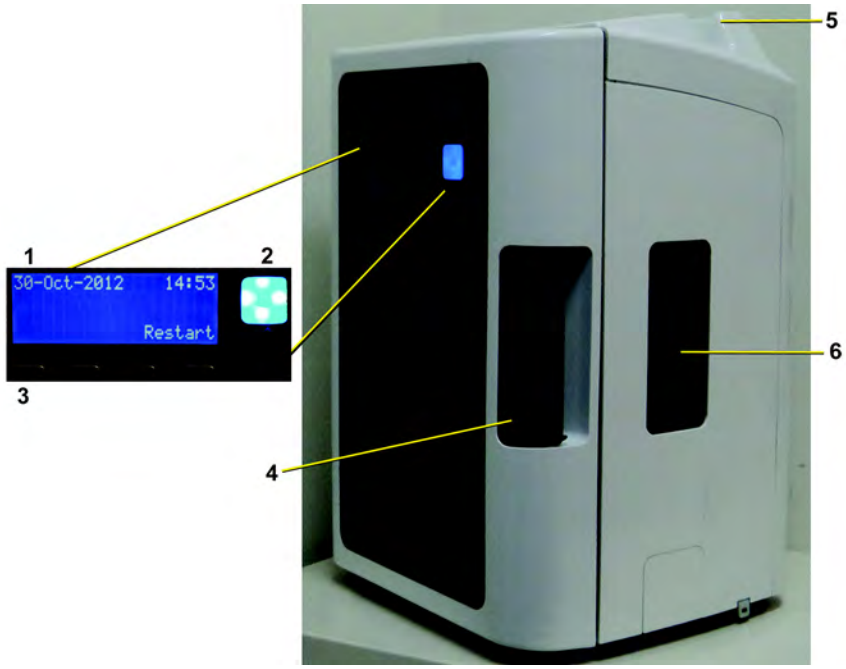


Figure 3-2. Trophon EPR

1. Screen Display
2. Start Button
3. Soft key buttons

1. Chamber door handle
2. Probe cable clamp
3. Cartridge door

CAUTION

Only those individuals previously trained on the Trophon EPR unit may use the device. Refer to the Trophon EPR user documentation for more information on disinfecting approved probes.

Trophon EPR Instructions for Use

Installing the disinfectant cartridge

1. The cartridge door automatically opens when a cartridge needs replacing.
2. Screen message: “Load Cartridge” or “Cartridge Empty, Replace Cartridge Now” displays.
3. Wear disposable gloves and chemical resistant goggles. These should be worn at all times while using the Trophon EPR.
4. Press the soft key button under “Yes” to open the cartridge replacement door.
5. Remove the cartridge lid and insert the bottle on the side of the unit.
6. Rotate the cartridge until it drops into place and cannot rotate any further.
7. Close the cartridge door. Do not use excessive force to accomplish this. The door clicks into place and locks.

Disinfecting probe in Trophon EPR

8. When the screen message reads “Load Probe”, open the chamber door.
9. Clean and rinse the probe. Dry the probe.

NOTE: *The probe must be cleaned, per the manufacturer’s guidelines, and dried before disinfection.*

10. Place Chemical Indicator on the bottom of the device chamber.
11. While holding the probe handle, press the top of the probe into the chamber’s seal. Ensure the probe is straight and not touching either the walls or bottom of the chamber. Strain relief (interface between cable and probe body) must be positioned at the top of the chamber. The tip of the probe must be above the horizontal line marked in the chamber.



Do NOT allow the probe surface or lens to touch the chamber’s wall during the disinfection process. This could cause permanent damage to the probe.

Trophon EPR Instructions for Use (continued)

12. Press the probe's electrical cable into the cable clamp, found at the top of the chamber.
13. Close the chamber door. It will automatically lock.
14. The screen message "Is the probe clean and dry?" appears, select Yes.
15. Press "Start" to begin the disinfecting process.
16. Discard disposable gloves.

Removing the Probe after 7-minute cycle time

1. Wear a new pair of disposable gloves.
2. When "Cycle complete" displays on the screen, open the chamber door.
3. Check the Chemical Indicator color change and refer to the Chemical Indicator.
4. Remove the Chemical Indicator from device and discard.
5. Remove the probe from the Trophon EPR.
6. Wipe the probe prior to use with an absorbent, single-use, dry, lint-free cloth.
7. Remove and discard the disposable gloves.

Coupling gels



WARNING

Do not use unrecommended gels (lubricants). They may damage the probe and void the warranty.

Table 3-4: Probe Gels

Gel	9L-D/11L-D	ML6-15-D	L8-18i-D	M4S-D	M5S-D	S1-5	S1-5-D	S4-10/S4-10-D	C1-5-D	C1-6-D	C2-9-D	M6C-D	3CRF	IC5-9-D	RNA5-9-D	RAB2-5-D	RAB4-8-D	RAB6-D	RIC5-9-D	RSP6-16-D	6S-D	6Tc	P2D/P6D
Aquasonics 100	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X			
Clear Image	X	X	X	X					X	X	X	X		X									
GE Ultrasound Contact Gel															X	X	X	X	X	X			
HAIYIN Gel	X	X	X	X					X	X	X	X		X									
Incidin Foam																			X				
Kendall	X	X	X	X					X	X	X	X		X									
Natural Image					X		X																
Scan	X	X	X	X					X	X	X	X	X	X	X	X	X	X	X	X			
Sonogel	X	X	X	X	X	X		X	X	X	X	X	X	X	X	X	X	X	X	X			
Wavelength	X	X	X	X					X	X	X	X		X									

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

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.

System Presets

Foreign Language Keyboard Setup

Changing the System Language

To change the system language (non-Russian/Greek languages), in Utility--> System--> General, under “Language,” set the Language as the desired language. Save this setting. Reboot the system.

Typing Foreign Characters on the International Keyboard

To type foreign characters, press Alt+Shift to change the keyboard to the international keyboard, then press the Alt GR+appropriate keyboard key.

- [AltGr]+[Q] to type ä
- [AltGr]+[W] to type å
- [AltGr]+[E] to type é
- [AltGr]+[Y] to type ü
- [AltGr]+[I] to type í
- [AltGr]+[P] to type ö
- [AltGr]+[A] to type á
- [AltGr] + [Function Key] + [,] to type ç
- [Shift] + [6] + [a] to type â
- [Shift] + [6] + [e] to type ê
- [Shift] + [6] + [i] to type î
- [Shift] + [6] + [o] to type ô
- [Shift] + [~] + [a] to type ã
- [Shift] + [~] + [n] to type ñ
- [Shift] + [“] + [a] to ä
- [Shift] + [“] + [e] to ë
- [Shift] + [“] + [i] to ï
- [Shift] + [“] + [o] to ö

Keyboard Setup for Russian/Greek Languages

To set up the keyboard for Russian/Greek languages:

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

1. In Utility--> System--> General, set the Language as Russian or Greek. Save this setting, but do not reboot the system yet.

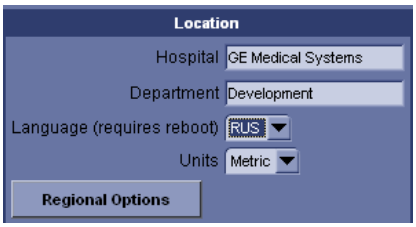


Figure 3-3. Changing the System Language to Russian/Greek

2. Press ***Regional Options***. The “Region and Language” pop-up menu appears. Under “Format:” select “Russian (Russia)”/”Greek (Greece),” press ***Apply***, Press ***OK***.

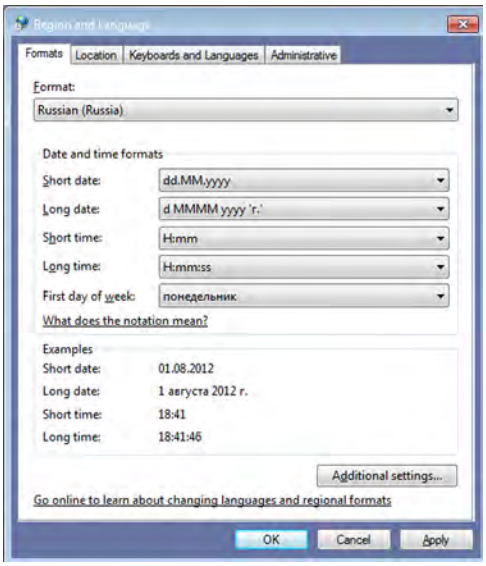


Figure 3-4. Region and Language

Keyboard Setup for Russian/Greek Languages (continued)

3. Select the “Keyboards and Languages” tab. Select the “Change Keyboards” button. The “Text Services and Input Languages” pop-up appears. On the “General Tab” under “Default input language” select “Russian (Russia) - Russian”/”Greek (Greece) - Greek.” In the “Installed Services” section ensure that both “English (United States)” and “Russian (Russia)” both appear. Press Apply. Press OK.

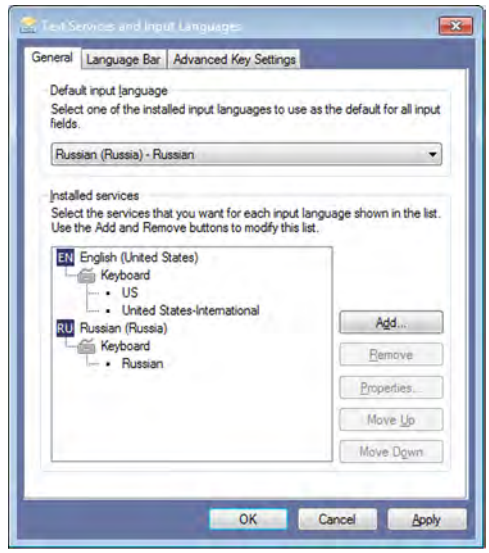


Figure 3-5. Set Language

Keyboard Setup for Russian/Greek Languages (continued)

4. Under “Choose a display language:” select [Russian]/ [Greek]. Press Apply.

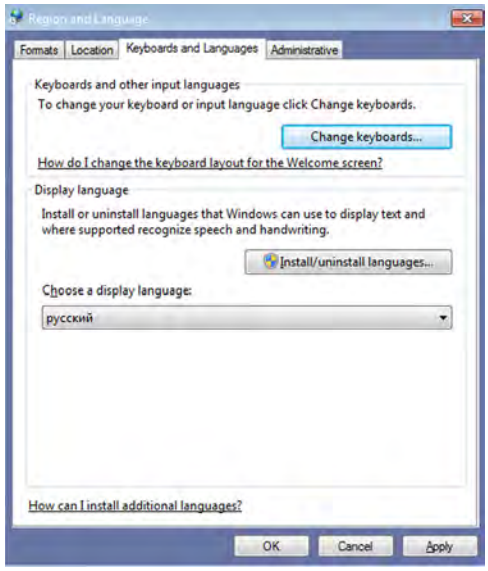


Figure 3-6. Set Language

5. The “Change Display Language” pop-up prompt appears. Press “Cancel.” Press OK.

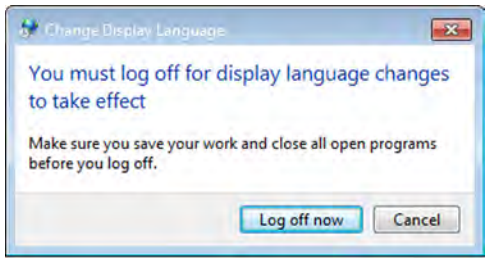


Figure 3-7. Change Display Language

Keyboard Setup for Russian/Greek Languages (continued)

6. Select the “Administrative” tab. In the “Language for non-Unicode programs” section select the “Change system locale...” button. The “Region and Language Settings” pop-up menu appears.

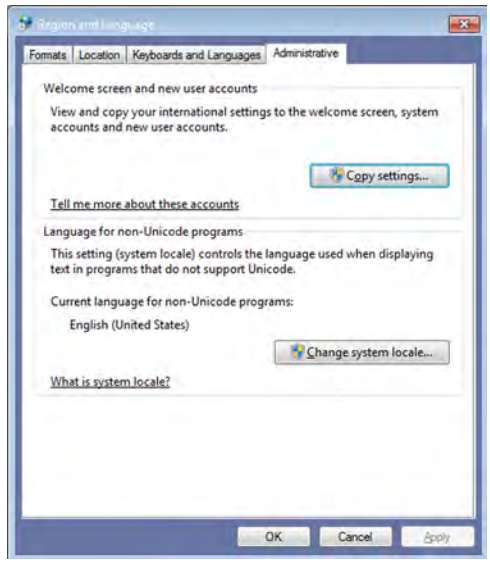


Figure 3-8. Change system locale

7. Under “Current system locale:” select “Russian (Russia)”/ ”Greek (Greece).” Press OK.

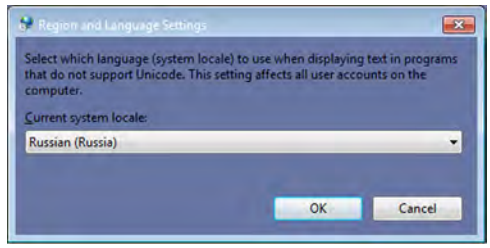


Figure 3-9. Set Language

Keyboard Setup for Russian/Greek Languages (continued)

8. The “Change System Locale” pop-up prompt appears. Press “Cancel.” Press “Close.” The “Change System Locale” pop-up prompt appears again. Press “Cancel” again. Press “Exit.

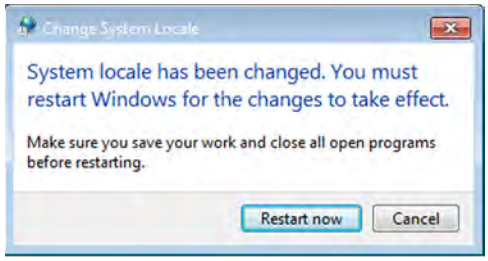


Figure 3-10. Change system locale

9. Reboot the system. When your system restarts, the system appears in the selected language.

*NOTE: To have the settings take effect, you **MUST** turn off the system and turn it back on.*

NOTE: Service password does not work for Greek and Russian language settings. Change the setting to English.

Keyboard Setup for Russian/Greek Languages (continued)

Here is an example of the Russian keyboard:

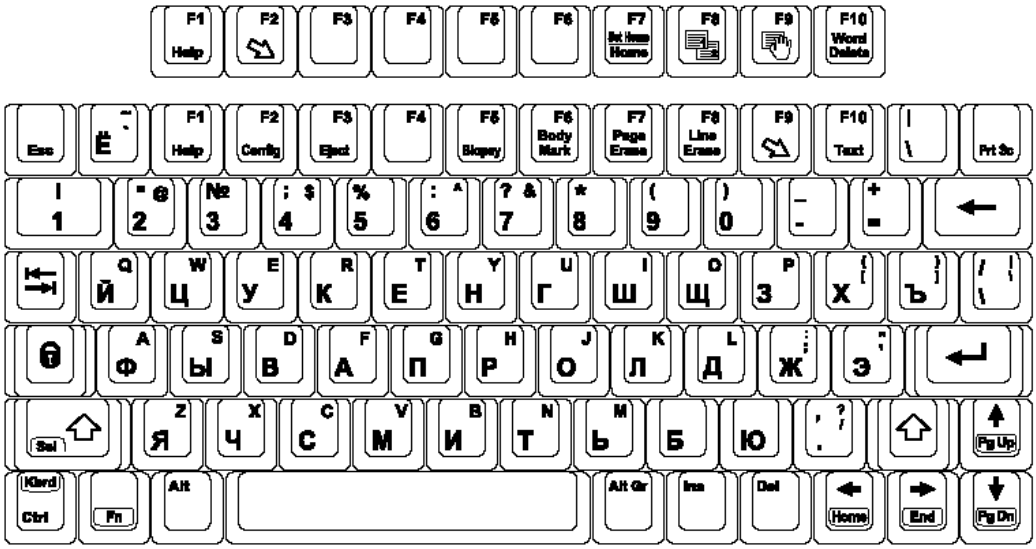


Figure 3-11. Russian Keyboard

Here is an example of the Greek keyboard:

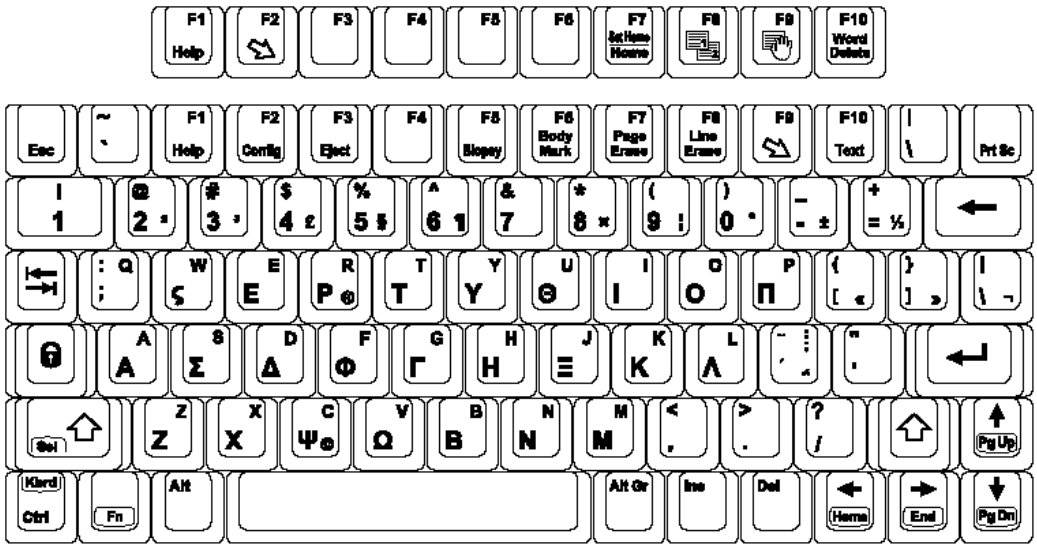


Figure 3-12. Greek Keyboard

Data Backup

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.



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.

GE Healthcare IS NOT responsible for lost data if you do not follow suggested back-up procedures. GE Healthcare WILL NOT aid in the recovery of lost data.

EZBackup and EZMove (continued)



DO NOT use DVD-RAM for EZBackup and EZMove.

Use Medical Grade CD-R, DVD-R, or USB Hard Drive for EZBackup and EZMove.



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.



After copying the image file to the media, EZMove deletes the image file from the Local HD.

EZBackup does not back up the exams which were previously backed up once by EZBackup or Export. If you want to back up those exams by EZBackup again, select “Full Backup Option” on the EZBackup wizard. Even when “Full backup” is selected, the system only backs up the exams within the range specified in the Utility -> System -> Backup/Restore -> Backup Files Older Than in Days preset.



Disconnect the USB HDD when performing EZMove on the system.

- DO NOT use the internal hard drive for long-term image storage. Daily backup is recommended. External storage media is recommended for image archive.
- You need to set up a process for locating images stored to external storage media for easy recall

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 (or reports), and creates a reference between the patient database and the media's volume.

1. Prepare unformatted media or the USB HDD before starting EZBackup/EZMove.

NOTE: BEFORE starting the EZBackup, select "Unlock All" in Utility --> Admin --> Logon.

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: 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.

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).

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

If you uncheck this option, the system only backs up exams which have not yet been backed up.

NOTE: If you update an exam which is already backed up, the exam is also backed up.

EZBackup and EZMove (continued)

NOTE: You do not need to format the media prior to performing an EZBackup/EZMove. You cannot use formatted media for EZBackup/EZMove.

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

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

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.”

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*.
   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 LOGIQ E9 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.

NOTE: You can cancel the backup/move at any time. The system completes backing up the current media and then cancels the operation.

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


CAUTION

Only cancel the backup/move in case of an emergency.

NOTE: This message appears if you press Next without inserting the backup media: “Please insert a blank media...”. Insert the media and continue.

EZBackup and EZMove (continued)

7. The status menu appears. When the backup/move has been completed, press *Next*.

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.*

8. When the backup is complete, the completed wizard page appears. Press *Finish*.
9. Do a patient archive after each EZBackup/EZMove (move).

NOTE: *Use Import to restore EZBackup images.*

We recommend attaching the patient list to the EZBackup/EZMove media. Insert the media and select DICOM CD Read from the Patient Screen for dataflow (if you use a USB drive, select DICOM USB Drive Read). Select any patient and press the left Set key to print the patient list on the digital printer for each CD/DVD.



NEVER restore the patient archive from media made previous to the last move. You can still do a backup/move daily; but ALWAYS do a patient archive backup after each move.



DO NOT use the USB Hard Disk Drive for patient storage. The USB HDD is not considered a permanent storage device.

If you connect the USB HDD to a virus-infected computer, the USB HDD may also be infected with a computer virus.

To Review EZBacked Up/EZMoved Images

You can view backed up media via the Patient Menu or Import.

1. Select the patient on the Patient Menu (on the same system where the backup/move 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 procedure: user-defined configurations

CAUTION

To avoid the risk of overwriting the local patient and report archives on the system to update, DO NOT check Patient Archive when making a backup of configuration settings.

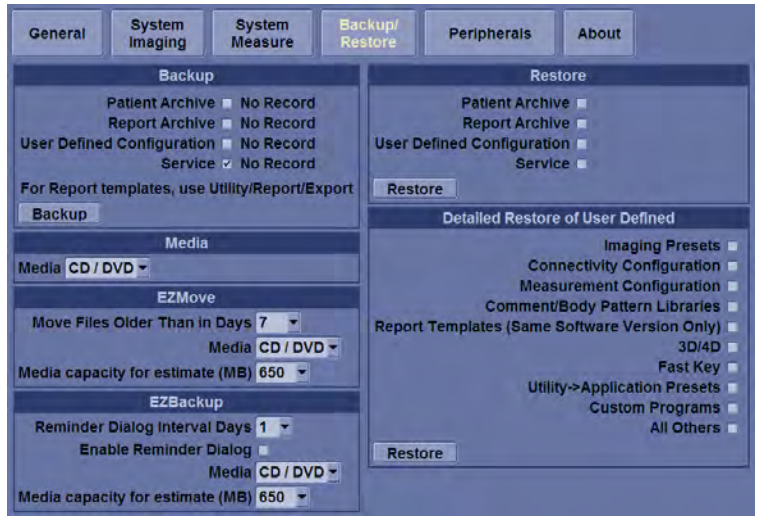


Figure 3-13. System/Backup/Restore Preset Menu

1. Insert media into the media drive.
2. On the Touch Panel, press ***Utility***.
3. On the Utility Touch Panel, press ***System***.
4. On the monitor display, select Backup/Restore.

   The Backup/Restore screen is displayed.

NOTE: *If you are not logged in with administrator privileges, the Operator Login window is displayed. Log on with administrator privileges.*

5. In the Backup list, select User Defined Configuration.
6. In the Media field, select a media.
7. Select Backup.

   The system performs the backup. As it proceeds, status information is displayed on the Backup/Restore screen.
8. After the backup is complete, press ***F3*** to eject the CD.

Restore procedure: patient data


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.

1. Insert the media into the media drive.
2. On the Touch Panel, press ***Utility***.
3. On the Utility Touch Panel, press ***System***.
4. On the monitor display, select Backup/Restore.

   The Backup/Restore screen is displayed.

NOTE: *If you are not logged in with administrator privileges, the Operator Login window is displayed. Log on with administrator privileges.*

5. In the Restore list, select Patient Archive.
6. In the Media field, select the media.
7. Select Restore.

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

Restore procedure: user-defined configurations


CAUTION

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


CAUTION

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

1. Insert the media with the user-defined configurations into the drive.
2. On the Touch Panel, press ***Utility***.
3. On the Utility Touch Panel, press ***System***.
4. On the monitor display, select Backup/Restore.

   The Backup/Restore screen is displayed.

   NOTE: If you are not logged in with administrator privileges, the Operator Login window is displayed. Log on with administrator privileges.
5. In the Restore list, select from the following, depending on which configurations you want to restore:
   - User Defined Configuration

     OR
   - Select the parameters to be restored in the Detailed Restore section.
6. In the Media field, select the media.
7. Select Restore.

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

Configuring Connectivity

Overview

You use Connectivity functionality to set up the connection and communication protocols for the ultrasound system. The following page gives an overview of each of the Connectivity functions. Each function is described in detail in the following pages.

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 video print and 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, and the order of the columns in the examination list on the Patient menu.

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.



You must restart the LOGIQ E9 (shutdown) 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

LOGIQ E9 Security

At GE Healthcare we're committed to providing technologies to help you excel every day. The LOGIQ E9 Ultrasound system is designed with you, your specialty, and your patients in mind offering extraordinary image quality, easy workflow, and expert tools to help you provide the best patient care.

Since the LOGIQ E9 is integrated into your data network, GE wants to ensure that you are comfortable with the proactive measures we are taking to secure the product. Below are some activities and measures that we have performed and implemented to help secure the LOGIQ E9.

1. Only communication ports that are needed for the LOGIQ E9 to operate are enabled. All other operating system communication ports (such as port 4444, which was used by the MSBlast virus) are disabled.

   Ports remaining opened are:

   - Port 104 is used for DICOM communication only.

2. All operating system services that are not used by the system application software (such as DCOM, Windows Messenger Service, and UPnP) are disabled to help ensure that the source of security vulnerabilities is minimized.
3. The operating system is locked down to prevent a user from loading software, opening email, or using a web browser and introducing viruses or Trojan horses to the system.
4. The "auto run" feature is disabled on the system. For instance, when a DVD or USB memory stick that has a program that runs automatically is inserted, the system will not open or run the program.
5. Our Engineering team performs a security scan on the LOGIQ E9 system using the same tools that major organizations and hospital IT organizations use to check for vulnerabilities on their networks. Failures that are detected during this test process are corrected as expediently as possible and are deployed to our installed base customers.

LOGIQ E9 Security (continued)

We have worked diligently to develop a combination of the safety measures 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.

Finally, a few points as to why we do not use Anti-Virus software. The main reasons for not doing so:

- Every Virus scanner is constantly active in the background. Due to the software-intensive operating system of the Ultrasound scanner, all computing resources are required for normal operation of this device. Anti-Virus software activities would have a negative impact on the system performance.
- The operating software of a medical Ultrasound system is part of an FDA-cleared medical device that requires a specific release process. Any update of the Anti-Virus software would mean a change of the system software. Such change would require an extensive release and validation process to help ensure that the Anti-Virus update does not have any impact on the system software performance and stability.

Electronic Documentation

Accessing Documentation Via a Windows PC

To view user documentation on a Windows PC,

1. Insert the media into the media drive.
2. Open the media drive on your desktop.
3. Double click on the ‘gedocumentation.html’ document.
4. Select the item you want to view (click on the blue, underlined link in the File Name column).

To close the window, click on the ‘X’ in the upper, right-hand corner of the browser window.

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

Accessing Documentation on the Ultrasound Scanner Via the media

To access documentation via the media,

1. Select Utility. Select Service. Wait until the logon screen appears.
2. Logon as ‘Operator’ next to Select User Level. Enter the following password: ‘uls’. Press Okay.
3. Select Utilities.
4. Insert the media.
5. Select Common Utilities.
6. Select Scanner Documentation Interface.
7. Scroll to find the document and double click on it to open it.

NOTE: You can search through a document, use hyperlinks in the Table of Contents and Index to locate topics, and navigate via bookmarks.

NOTE: In addition to viewing documentation on the Ultrasound system, the Documentation media can be read on any PC.

To exit, press the ‘X’ in the upper, right-hand corner of the documentation window.

Using Online Help Via F1

Online Help is available via the F1 key. After pressing F1, Help appears. The Help screen is divided into three sections: navigational tools on the top, left portion of the screen (Hide, Back, Forward), help book navigational tools on the left portion of the screen (Contents, Index, Search, Favorites), and the content portion on the right side of the screen where help topics are displayed.

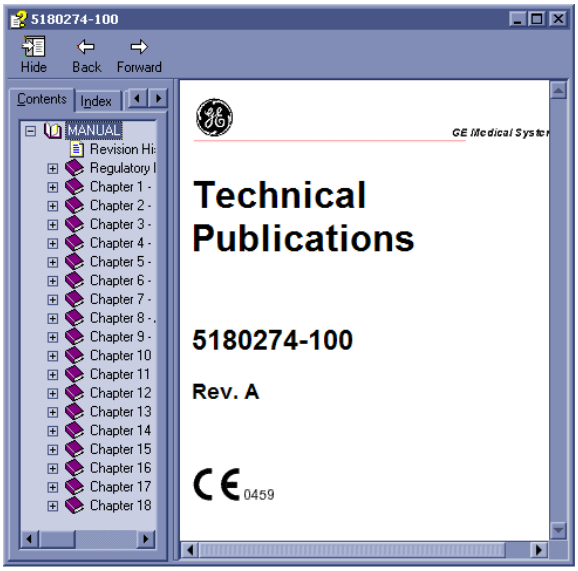


Figure 3-14. Opening Help Screen

Exiting Online Help

To exit Online Help, press the ‘X’ in the upper, right-hand corner of the Online Help window.

Contact Information

Contacting GE Healthcare 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 Healthcare. 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.

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System Data

Features/Specifications

Table 3-5: Physical Attributes

Dimensions and Weight • Height: 1300mm • Width: 585mm • Depth: 830mm • Weight: 140 kg, 309 lb Operator Panel • Height: Maximum, 93 cm; Minimum, 79 cm • Full alphanumeric keyboard • Ergonomic hard key operations • Interactive Back-Lighting • Task lighting • Floating keyboard adjustable in 3 dimensions • LCD touch screen, 10.4 in High Resolution, Color • Integrated recording keys for remote control • User Configurable Layout Electrical Power • Voltage:100 to 240 Vac • Frequency: 50/60 Hz • Power: Max. 1.2 KVA with on-board peripherals	Console Design • 4 Active Probe Ports • Probe connection area designed to allow free movement of legs • KBD/Monitor up-down mechanism (200mm adjustable in height) • On-board storage for peripherals: Black/white printer. • Rear Storage Cover for Peripheral Connectors and Cables • Probe Holder, removable for cleaning and washing • Gel Holder, removable for cleaning and washing • Gel Warmer • Integrated speakers with sub-woofer for premium sound • Wheels. Wheel diameter: 175mm. Rotating flexible wheels with protective cover. Locking Mechanism for wheels. • Integrated Hard Disk Drive (250 GB) • Integrated DVD-R Multi Drive LCD Monitor (19”) • High-Resolution monitor Non Interlace Scan • LCD translation: 350mm horizontal; 120mm vertical; 90 degree swivel • Fold-down and Lock Mechanism for Transport • Resolution 1280 x 1024

Table 3-6: System Overview

Applications
• Abdominal
• Obstetrical
• Gynecological
• Breast
• Small parts
• Vascular
• Peripheral
• Transcranial
• Pediatric and Neonatal
• Musculoskeletal
• Urological
• Cardiac
 	
Scanning Methods
• Electronic Sector
• Electronic Convex
• Electronic Linear
• Mechanical Volume Sweep
 	
Operating Modes
• B-Mode
• M-Mode
• Color Flow (CFM)
• B-Flow (option)
• B-Flow Color (option)
• Extended Field of View (LOGIQView Option)
• Power Doppler Imaging (PDI)
• PW Doppler
• CW Doppler (option)
• Volume Modes-3D/4D
  • 3D Static
  • 4D Real Time (Option)
• Anatomical M-Mode
• Coded Contrast Imaging (Option) [not available in the US]
• Elastography (Option)
	Display Modes
	• Simultaneous Capability [B or CrossXBeam/PW; B or CrossXBeam/CFM or PDI; B/M; B/CrossXBeam; Realtime Triplex Mode (B or CrossXBeam + CFM or PDI/PW)]
	• Selectable alternating Modes [B or CrossXBeam/PW; B or CrossXBeam + CFM (PDI)/PW; B/CW (option)]
	• Colorized Image - Colorized B - Colorized M - Colorized D
	• Time line Display [Independent Dual B or CrossXBeam/PW Display; CW Display; 2 Display Formats; Top/Bottom or Side/Side selectable Format; Size: 1/2: 1/2; 1/3: 2/3 (full format, switchable after freeze); 2 Timeline Methods: Scrolling or Moving Bar
	• Virtual Convex
	• Multi Image Split/Quad Screen [Live and/or Frozen, B or CrossXBeam+B or CrossXBeam/CFM or PDI, PW/M, Independent Cine playback]
	• Zoom: Write/Read/Pan
	
	Transducer Types
	• Sector Phased Array
	• Convex Array
	• Micro convex Array
	• Linear Array
	• Matrix Array
	• Volume probe (4D)
	  • Convex Array
	  • Micro convex Array
	  • Linear Array
	• Split Crystal

Table 3-6: System Overview (Continued)

Standard Features	Options

• Advanced user interface with high resolution 10.4 inch LCD touch screen
• Automatic Optimization
• CrossXBeam
• Speckle Reduction Imaging (SRI-HD)
• Fine Angle Steer
• Coded Harmonic Imaging
• Virtual Convex
• Patient information database
• Image Archive integrated on CD/DVD and Hard Drive
• Advanced 3D
• Raw Data Analysis
• Real-time automatic Doppler calcs
• OB Calcs
• Fetal Trending
• Multi gestational Calcs
• Hip Dysplasia Calcs
• Gynecological Calcs
• Vascular Calcs
• Urological Calcs
• Renal Calcs
• Cardiac Calcs
• inSite ExC Capability
• On-board electronic documentation
	• LOGIQView
	• Coded Contrast Imaging [not available in the US]
	• B Flow (including B Flow Color)
	• Volume Navigation
	• Scan Assistant
	• DICOM 3.0 connectivity
	• Report Writer
	• Real-Time 4D
	• Physiological Input Panel
	• Wireless LAN
	• CW Doppler
	• Tissue Velocity Imaging (TVI)
	• Elastography
	• TV Probe Holder
	• Tomographic Ultrasound Imaging
	• Volume Calculation (VOCAL II)
	• Volume Contrast Imaging (VCI) Static
	• Quantification (Elastography [not available in the US], Color Flow/PDI, Volume, TVI, Contrast)
	• Stress Echo
	• Auto IMT
	• Compare Assistant
	• Breast Productivity Package
	• Thyroid Productivity Package
	• OB Measure Assist
	• Breast Measure Assist
	• Tru3D
	
	Peripheral Options
	• Integrated options for
	  • Digital B/W Printer
	  • DVD Video Recorder
	• Digital Color Printer
	• External USB Printer connection
	• DVI-I output available for compatible devices
	• Console Protective Cover
	• Footswitch with programmable functionality
	• Video Scan Converter
	• S-Video Output

Table 3-7: System Parameters

Controls Available on Freeze or Recall • Max Read Zoom to 8 • B/M/CrossXBeam Mode (Gray Map; TGC, Colorized B and M; Frame Average [Loops only]; Dynamic Range) • PW-Mode (Gray Map; Post Gain; Baseline Shift; Sweep Speed; Invert Spectral Waveform; Compression; Rejection, Colorized Spectrum; Display Format; Angle Correct; Quick Angle Correct, Auto Angle Correct) • Color Flow (Overall Gain [Loops and Stills]; Color Map; Transparency Map; Frame Averaging [Loops only]; Flash Suppression, CFM Velocity Tag, CFM Display Threshold; Spectral Invert for Color/ Doppler) • Automatic Optimization • SRI-HD • CrossXBeam (display non-compounded and compounded image siultaneously in split screen) • 3D Reconstruction from a stored CINE loop • 4D (Gray Map, Colorize; Post Gain; Change display between single, dual, quad sectional or rendered) • Anatomical M-Mode • Anatomical M-Mode on CINE Loop Controls Available While “Live” • Write Zoom • B/M/CrossXBeam-Mode (Gain; TGC; Dynamic Range; Acoustic Output; Transmission Focus Position; Transmission Focus Number; Line Density Control; Sweep Speed for M-Mode; # of Angles for CrossXBeam) • PW-Mode (Gain; Dynamic Range; Acoustic Output; Transmission Frequency; PRF; Wall Filter; Spectral Averaging; Sample Volume Gate for PW-Mode Length and Depth; Velocity Scale; Doppler Audio) • Color Flow (CFM Gain; CFM Velocity Range; Acoustic Output; Wall Echo Filter; Packet Size; Frame Rate Control; CFM Spatial Filter; CFM Frame Averaging; CFM Line Resolution; Frequency/Velocity Baseline Shift)	Scanning Parameters • Digital Beamformer • Imaging Depth: 0-36cm [Minimum: 0-2 cm (Zoom); Maximum: 0-36 cm] • Continuous Dynamic Receive Focus/Continuous Dynamic Receive Aperture • Adjustable Dynamic Range • Adjustable Field of View [FOV] • Image Reverse: Right/ Left • Image Rotation: 0 and 180 degrees Image Storage • Storage Format: DICOM, Export JPEG, WMV (MPEG4), AVI • Storage Devices: USB Memory Stick (64MB to 64GB; CD-R Storage (700MB); DVD-R Storage (4.7GB); Hard Drive Image Storage (~137GB) CINE Memory/Image Memory • 776 MB of CINE Memory • Selectable CINE Sequence for CINE Review • Prospective CINE Mark • Measurements/Calculations & Annotations on CINE Playback • Scrolling timeline memory • Dual Image CINE Display • Quad Image CINE Display • CINE Gauge and CINE Image Number Display • CINE Review Loop • CINE Review Speed • Retrospective CINE • Prospective CINE

Table 3-8: Measurements and Calculations

B-Mode
• Depth and Distance
• Circumference and Area (Ellipse/Trace)
• Volume (Ellipsoid)
• Angle between 2 Lines
• % Stenosis (Area or Diameter)
• Dual B-Mode capability
 	
M-Mode
• M Depth and Distance
• Time
• Slope
• Heart Rate
 	
Doppler Measurements/Calculations
• Velocity
• Time
• Peak Systole
• End Diastole
• Acceleration
• Acceleration Time
• Ratios
  • A/B Ratio (Velocities/Frequency Ratio)
  • Peak Systole/End Diastole (PS/ED Ratio)
  • End Diastole/Peak Systole (ED/PS Ratio)
• Heart Rate
• TAMAX (Time Averaged Maximum Velocity)
• Volume Flow [TAMEAN and Vessel Area]
• PI (Pulsatility Index)
• RI (Resistivity Index)
 	
Vascular Measurements/Calculations
• Carotid, Vertebral, Subclavian Measurements, Auto IMT
• Summary Worksheet
• Summary Report
	Obstetrics Measurements/Calculations
	• Gestational Age Calculation
	• Calculations and Ratios
	• EFW Calculation
	• Growth Percentiles
	• Multi-Gestational Calculation
	• Fetal Qualitative Description (Anatomical Survey)
	• Fetal Environmental Description (Biophysical profile)
	• Programmable OB Tables
	• Fetal Trend Graph
	• Summary Worksheet
	• Summary Report
	
	Gynecology Measurements/Calculations
	• Ovarian, Uterine, Endometrium, Follicular Measurements
	• Summary Worksheet
	• Summary Report
	
	Urology Measurements/Calculation
	• Bladder, Prostate, Renal, Generic, Post-Void Bladder Volume Measurements
	• Summary Worksheet
	• Summary Report
	
	Cardiology Measurements/Calculations
	• Cardiology Measurements and Calculations
	• Summary Worksheet
	• Summary Report

Table 3-9: Probes

• M6C-D Matrix Array Convex Probe (Applications: Abdomen, OB/GYN, Pediatric) • C1-5-D Convex Probe (Applications: Abdomen, OB/GYN) • C1-6-D Convex Probe (Applications: Abdomen, OB/GYN) • C2-9-D Convex Probe (Applications: Abdomen, OB/GYN, Pediatric) • 3CRF Micro-Convex Probe (Applications: Abdomen, OB/GYN) • IC5-9-D Micro Convex Probe (Applications: OB/GYN, Urology) • 9L-D Linear Probe (Applications: Abdomen, Small Parts, Peripheral Vascular, Pediatric, OB/GYN, Musculoskeletal) • 11L-D Linear Probe (Applications: Abdomen, Small Parts, Peripheral Vascular, Musculoskeletal) • ML6-15-D Matrix Array Linear Probe (Applications: Small Parts, Peripheral Vascular, Pediatric, Neonatal, Musculoskeletal) • L8-18i-D Linear Probe (Applications: Small Parts, Peripheral Vascular, Musculoskeletal, Intraoperative) • M4S-D Sector Probe (Applications: Adult Cephalic) • M5S-D Sector Probe (Applications: Cardiac, Adult Cephalic, Abdomen, OB/GYN, Pediatric) • S1-5 Sector Probe (Applications: Abdomen, OB/GYN)	• S1-5-D Sector Probe (Applications: Abdomen, OB/GYN) • S4-10 Sector Probe (Applications: Pediatrics, Neonatal, Pediatric Cardiac) • 6S-D Sector Probe (Applications: Pediatric Cardiac) • 6Tc Transesophageal Probe (Applications: Adult Cephalic) • RNA5-9-D Convex Volume Probe (Applications: Pediatric, Neonatal) • RAB2-5-D Convex Volume Probe (Applications: Abdomen, OB/GYN) • RAB4-8-D Convex Volume Probe (Applications: Abdomen, OB/GYN, Pediatrics) • RAB6-D Convex Volume Probe (Applications: Abdomen, OB, Pediatrics) • RIC5-9-D Convex Volume Probe (Applications: OB/GYN, Urology) • RSP6-16-D Linear Volume Probe (Applications: Small Parts, Peripheral Vascular, Pediatric, Musculoskeletal) • P2D CW Split Crystal Probe (Applications: Cardiac, Peripheral Vascular, Adult Cephalic) • P6D CW Split Crystal Probe (Applications: Cardiac, Peripheral Vascular, Adult Cephalic)

Table 3-10: Biopsy Guides

• Single-Angle, disposable with a reusable bracket • Multi-Angle, disposable with a reusable bracket	• Single-Angle, disposable with a disposable bracket

Table 3-11: Inputs and Outputs Signal

• DVI-I • Audio Stereo Out • S-Video	• Ethernet • Multiple USB 2.0 ports

System Care and Maintenance

Expected Service Life Description

The expected service life for the LOGIQ E9 system and probes is identified in this table:

Table 3-12: Expected Service Life

Equipment / Accessory	Expected Service Life
LOGIQ E9 system	The expected service life for the LOGIQ E9 is at least seven (7) years from the manufacturing date under the provision of regular maintenance by authorized service personnel.
LOGIQ E9 Probes	The expected service life for the LOGIQ E9 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 / Accompanying LOGIQ E9 Instructions for Use.

Inspecting the System

Examine the following on a monthly basis:

- 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.



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.



Electrical Hazard

If any defects are observed or malfunctions occur, do not operate the equipment but inform a qualified service person. Contact a Service Representative for information.

Weekly Maintenance

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

- LCD
- Operator control panel
- B/W Printer
- CD/DVD-R Multi Drive
- Filters (weekly, or as needed)
- Footswitch

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

Table 3-13: Appropriate Cleaning Agents

Cleaning Agent	LCD Monitor (Glass)	LCD Frame (Panel)	System Cabinet	Touch Panel	Operator Controls
Mild, Non-Abrasive Soap and Water	X	X	X	X	X
Ammonia		X	X		X
Bleach (10 to 1 Ratio of 5% Home Bleach)		X	X		X
Hydrogen Peroxide / Hydrogen Peroxide Wipes		X	X		X
Other					T--Spray II Sani-Cloth HB Ammonia Diluted Cidex

Cleaning the system

Prior to cleaning any part of the system:

1. Turn off the system power. If possible, disconnect the power cord. See ‘Power Off’ on *page 1-25 for more information.*

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.

NOTE: The cloth should be damp, not dripping wet.

2. Wipe down the top, front, back, and both sides of the system cabinet.
3. Wipe off excess cleaning agents.

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

Other acceptable cleaning agents are:

- Ammonia
- Bleach (10 to 1 ratio of 5% home bleach)
- Hydrogen Peroxide / Hydrogen Peroxide Wipes

Touch Panel

To clean the Touch Panel:

1. Moisten a soft, non-abrasive folded cloth with a mild, general purpose, non-abrasive soap and water solution.

NOTE: The cloth should be damp, not dripping wet.

2. Wipe down the top, front, back, and both sides of the Touch Panel.
3. Wipe off excess cleaning agents.

LCD

LCD Monitor

To clean the LCD Monitor:

1. Moisten a soft, non-abrasive folded cloth with a mild, general purpose, non-abrasive soap and water solution.

NOTE: The cloth should be damp, not dripping wet.

2. Wipe down the top, front, back, and both sides of the LCD Monitor.
3. Wipe off excess cleaning agents.

NOTE: Never use thinner, benzene, alcohol (ethanol, methanol, or isopropyl alcohol), abrasive cleaners, or other strong solvents, as these may cause damage to the LCD Monitor.

LCD Frame

To clean the LCD frame:

1. Moisten a soft, non-abrasive folded cloth with a mild, general purpose, non-abrasive soap and water solution.

NOTE: The cloth should be damp, not dripping wet.

2. Wipe down the top, front, back, and both sides of the LCD Frame.
3. Wipe off excess cleaning agents.

Other acceptable cleaning agents are:

- Ammonia
- Bleach (10 to 1 ratio of 5% home bleach)
- Hydrogen Peroxide / Hydrogen Peroxide Wipes

NOTE: DO NOT scratch or press on the panel with any sharp objects, such as pencils or pens, as this may result in damage to the panel.

Operator Controls

Cleaning Agents

ONLY use the following cleaners on the LOGIQ E9 Operator Panel:

- Palmolive Dishwashing Liquid (manufactured by Colgate-Palmolive)
- Sani Wipes (Sani-Cloth HB, green cap) Alcohol-free (manufactured by Micorgen Inc.)
- T-Spray II (manufactured by Pharmaceutical Innovations, Inc.)
- Ammonia
- Bleach (10 to 1 ratio of 5% home bleach)
- Hydrogen Peroxide / Hydrogen Peroxide Wipes

DO NOT USE:

- T-Spray I (Original T-Spray)
- SaniCloth Plus (red cap)
- Any cleaning/disinfecting solution containing Alcohol.

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 or Cidex in a normal diluted form for cleaning/disinfecting the operator panel.

Cleaning Instructions

To clean the operator control panel:

1. Lock the Operator Panel controls via the Keyboard Lock rotary on the Utility Touch Panel.

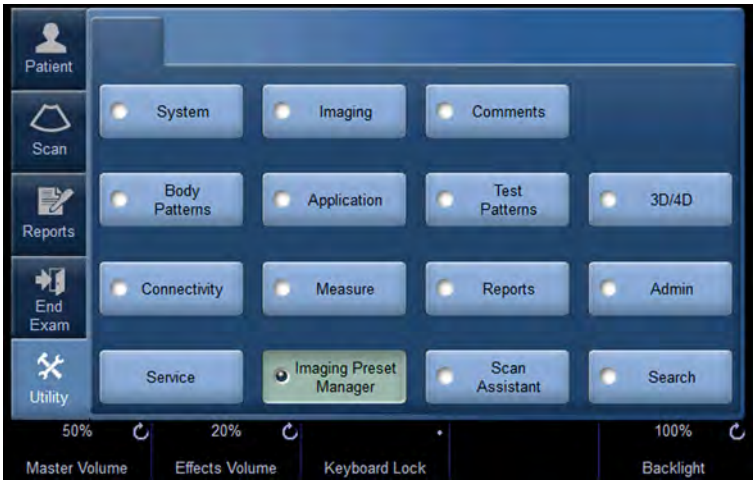


Figure 3-15. Utility Touch Panel

NOTE: After pressing Keyboard Lock, the following pop-up message appears.



Figure 3-16. Keyboard Locked Warning

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

CD/DVD Discs

To clean medical grade CD/DVD discs:

- If the disc is dirty, you can clean it with a commercially available dust removal spray. Be careful not to scratch the disc when wiping it off.

NOTE: CD type cleaner cannot be used.



HINTS

Keeping your media disc in an original media case or caddy all the time will prevent it from becoming dirty or damaged.

Footswitch

To clean the footswitch:

1. Disconnect the footswitch from the LOGIQ E9.
2. Moisten a soft, non-abrasive folded cloth with a mild, general purpose, non-abrasive soap and water solution.

NOTE: The cloth should be damp, not dripping wet.

3. Wipe the external surfaces of the unit then dry with a soft, clean, cloth.

Other Maintenance

Manually Moving the Operator Panel Up/Down

The LOGIQ E9 is equipped with an automatic Operator Panel up/down, left/right, forward/backward control. But if the system is powered down when you need to lower the Operator Panel, you can use the manual release handle located at the back of the unit to manually move the Operator Panel up/down.

To move the Operator Panel up/down using the manual control,

1. Locate the manual release handle which extends through the air vent at the back of the LOGIQ E9.



Figure 3-17. Manual release handle

2. Move the manual release handle to the left with one hand while pushing up/down on the Operator Panel to position it.

For information on resetting the Park Lock, see ‘Park Lock Reset’ on *page 1-22*.

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 quarterly (once every three months).

CAUTION

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

Locating

The LOGIQ E9 has two air filters which need to be cleaned. The top air filter (A) is located on the back of the LOGIQ E9 below the power cord and the bottom air filter (B) is located underneath the LOGIQ E9.

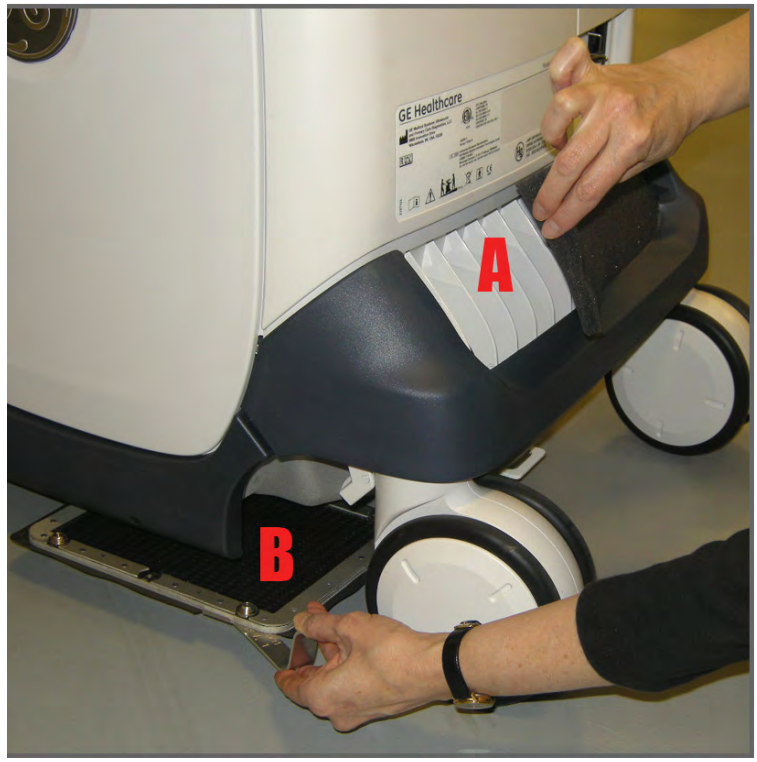


Figure 3-18. Location of Air Filters

Cleaning the Air Filters (continued)

Cleaning

To clean the top air filter,

1. Gently remove the filter cover. Pull the cover out and away from the LOGIQ E9. Set it down.
2. Remove the foam filter.
3. Clean the foam filter with soap and water. Let dry.
4. Replace the filter.
5. Replace the filter cover. Position it back into place on the back of the LOGIQ E9.

The bottom filter is held in place with magnets. To clean the bottom air filter,

1. You need to kneel down on the floor to access the bottom filter. Locate the metal handle extending from the air filter on the bottom of the LOGIQ E9.
2. You may need two hands to remove this filter. One hand is used to pull on the piece of cloth that extends from the filter and the other hand is used to wedge a finger just under a corner of the filter. In this step, firmly take hold of the metal handle that extends from the filter.
3. Position your other hand at a corner of the filter and wedge a finger between the filter and the bottom of the LOGIQ E9.
4. Pull down on the filter with the finger that is wedged between the filter and the LOGIQ E9 while pulling on the metal handle that extends from the filter at the same time to remove the filter.
5. Clean this filter with soap and water. Let dry.
6. Reposition the filter at the bottom of the LOGIQ E9.

Assistance

Supplies/Accessories



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

Not all features or products described in this document may be available or cleared for sale in all markets.

Contact the distributor, GE affiliate or sales representative for approved peripherals. For HCATs, contact your sales person. For 2million/5million number part numbers, these are service replacement part numbers that may be either new or refurbished. To order these, contact CARES in the US, or call service in Europe and Asia.

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

Peripherals

Table 3-14: Peripherals and Accessories

Accessory	Part Number / HCAT
Sony B/W Printer Model UP-D897	5171608 / H41392LZ
Sony Color Printer Model UP-D23MD	2401985 / H4903JS
Sony Color Printer Model UP-D25MD	5389822 / H4911JT
Sony Color Printer Model UP-D55	5116559 / H4904PA
Canon PIXMA MP610 Digital Printer	
HP470 Report Printer	5322258 / H4908RP
HP470 Report Printer USB Cable	5315370

Console

Table 3-15: Console Accessories

Accessory	Part Number / HCAT
Protective Cover	H4913DC
Remote Display with Adapter	H4910SM
LOGIQ E9 Technical Course	H4908TC
Swedish Keyboard	H4908SY
Norwegian Keyboard	H4908NY
Greek Keyboard	H4908GY
Russian Keyboard	H4908RY
Power Cord - North American	H4000ZA / 5148381
Power Cord - Argentina	H4000ZH / 5148381-9
Power Cord - Europe	H4000ZB / 5148381-3
Power Cord - UK-Ireland	H4000ZD / 5148381-4
Power Cord - Switzerland	H4000ZL / 5148381-7
Power Cord - Denmark	H4000ZE / 5148381-8
Power Cord - Israel	H4000ZJ / 5148381-10
Power Cord - Japan	H4000ZK / 5148381-2
Power Cord - China	H4000ZC / 5148381-5
Power Cord - Australia	H4000ZG / 5323129
Power Cord - India	H4000ZF / 5148381-11
Probe Holder Insert, Small Probes	H4911P

NOTE: For best results, GE recommends using high quality medical or professional grade CDs or DVDs.

Volume Navigation

Table 3-16: Volume Navigation

Accessory	Part Number / HCAT
Volume Navigation Stand	H4908NS / 5268740
Volume Navigation On-Board Stand	H4913NP
Volume Navigation Bracket Starter Kit	H4908NK
2-Bracket Biopsy with V Nav Starter Kit (C1-5-D and ML6-15-D)	H4910NK
IC5-9-D V Nav Bracket	H4908NF
3CRF V Nav Bracket	H40452LK
L8-18i-D V Nav Bracket	H4908NH
9L-D V Nav Bracket	H4908NB
C1-5-D V Nav Bracket	H40432LF
M5S-D V Nav Bracket	H4908NM
S1-5 V Nav Bracket	H4908ND
ML6-15-D V Nav Bracket	H40432LK
S4-10 V Nav Bracket	H4908NN
RIC5-9-D V Nav Bracket	H4908NG
C2-9-D / C1-6-D V Nav Bracket Starter Kit	H4913NK
C1-5-D V Nav Bracket Starter Kit	H4913NL
V Nav Needle Tracker Starter Kit	H4910NT
V Nav Needle Virtual Tracker Starter Kit	H4910NY
V Nav eTRAX 18/20g Starter Kit	H4913NT
Virtual Tracker Sensor	H4911NG
V Nav Probe Sensor	H4913PS
V Nav Needle Tracking Storage Insert	H4913NS
V Nav Upgrade to Needle Tracking Kit	H4910NS
V Nav Active Tracker (Omni TRAX) Starter Kit	H4913AT
V Nav Flat Transmitter	H4913NF

V Nav Shelf Load Description

Shelf load for the V Nav wire shelf on the V Nav Stand is 10 lbs.

ECG Accessories

Table 3-17: ECG Accessories

Accessory	Part Number / HCAT
ECG Cables, IEC, AHA Style for Americas	H4910EC
ECG Cables, IEC Style	H4911JC
ECG Cables IEC Style - Short	H44012LK
ECG Cable Kit	H45521AL

Probes

Table 3-18: Probes and Accessories

Probe	HCAT Global P/N Japan P/N	Biopsy Guide	Biopsy Guide HCAT	V Nav Capable	V Nav Bracket HCAT
3CRF Micro Convex	H40442LP	Single Angle, Disposable with a Reusable Bracket Multiline Starter Kit Multi Biopsy Multi Spare Screw Multi 13, 14, 15G Multi 16, 17, 18, 19G Multi 20, 21, 22, 23G	H40442LR H78122PA H40452LP H40452LR H40452LS H40452LT H40452LW	Yes	H40452LK
C1-5-D Convex	H40452LE	Multi Angle, Disposable with a Reusable Bracket	H40432LE	Yes	H40432LF H4913NL (Starter Kit)
C1-6-D Convex	H40472LT	Starter Kit	H4913BB	Yes	H4913NK (Starter Kit)
C2-9-D Convex	H40462LN	Multi Angle, Disposable with a Reusable Bracket	H4913BB	Yes	H4913NK (Starter Kit)
M6C-D Matrix Array Convex	H40432LM	Multi Angle, Disposable with a Reusable Bracket	E8385RF	No	N/A
IC5-9-D Micro Convex Intracavitary	H40442LK	Single Angle Disposable with a Plastic Bracket or Reusable with a Stainless Steel Bracket	E8385MJ H40412LN IC59_TR5 IC59_RU	Yes	H4908NF
S1-5 Sector	H4908SC	Multi Angle, Disposable with a Reusable Bracket	H4908SD	Yes	H4908ND
S1-5-D Sector	H4913SD	Multi Angle, Disposable with a Reusable Bracket	H4908SD	Yes	H4908ND
S4-10 Sector	H4908SN	Not Available	N/A	Yes	H4908NN

Table 3-18: Probes and Accessories (Continued)

Probe	HCAT Global P/N Japan P/N	Biopsy Guide	Biopsy Guide HCAT	V Nav Capable	V Nav Bracket HCAT
S4-10-D Sector	H45302LA	Not Available	N/A	Yes	H4908NN
M4S-D Sector	H40442LN	Not Available	N/A	No	N/A
M5S-D Sector	H45551NH	Not Available	N/A	Yes	H4908NM
6S-D Sector	H45021RR	Not Available	N/A	No	N/A
L8-18i-D	H40452LL	Not Available	N/A	Yes	H4908NH
9L-D Linear	H40442LM	Multi Angle, Disposable with a Reusable Bracket	H4906BK	Yes	H4908NB
11L-D Linear	H40432LN	Multi Angle, Disposable with a Reusable Bracket	H40432LC	No	N/A
ML6-15-D Matrix Array Linear	H40452LG	Multi Angle, Disposable with a Reusable Bracket	H40432LJ	Yes	H40432LK
RAB2-5-D 4D Convex Volume	H48651MN	Single Angle, Disposable with a Reusable Bracket Single Angle, Reusable	H4601AE H48621W	No	N/A
RAB4-8-D 4D Convex Volume	H48651MP	Same Brackets as RAB2-5-D	H46701AE H48621W	No	N/A
RAB6-D 4D Convex Volume	H48681MG	Not Available	N/A	No	N/A
RIC5-9-D 4D Convex Volume Intracavitary	H48651MS	Single Angle, Reusable	H46721R	Yes	H4908NG
RNA5-9-D 4D Convex Volume	H48651MY	Single Angle, Disposable with a Reusable Bracket Single Angle, Reusable	H46701AF H468651DG	No	N/A

Table 3-18: Probes and Accessories (Continued)

Probe	HCAT Global P/N Japan P/N	Biopsy Guide	Biopsy Guide HCAT	V Nav Capable	V Nav Bracket HCAT
RSP6-16-D 4D Linear Volume	H48651MR	Single Angle, Disposable with a Reusable Bracket Single Angle, Reusable Starter Kit	H47001AD H46721W H46701AD	No	
P2D CW Split Crystal Pencil Probe	H4830JE	Not Available	N/A	No	N/A
P6D CW Split Crystal Pencil Probe	H4830JG	Not Available	N/A	No	N/A
6Tc Trans-esophageal Probe	H45551ZD	Not Available	N/A	No	N/A

Options

Table 3-19: Options

Option	Part Number / HCAT
LOGIQView	H4908LW
DICOM	H4908DM
Report Writer	H4908RW
Realtime 4D	H4908D
4D with VCI	H4908MD
VOCAL II (Volume Calculation)	H4908HL
Contrast Imaging (Not available in the USA)*	H4908C
Volume Contrast Imaging (VCI)	H4908HM
Volume Navigation, v.2	H4913NA
Volume Navigation with Stand	H4908N
Volume Navigation with On-Board Stand	H4913NP
Volume Navigation without Stand	H4908NA
Scan Assistant	H4908SA
Tomographic Ultrasound Imaging	H4908TM
DVR	H4913DR
Footswitch, USB	H46732LF
ECG Module	H4910EG
Continuous Wave (CW)	H4911C
Wireless Lan (WLAN)	H4913WL
Elastography	H4910E
Elastography + QAnalysis	H4911EC
Auto IMT	H4910MT
Tissue Velocity Imaging (TVI)	H4910TY
LOGIQ E9 On-Board Scan Converter	H4913SC
Quantification	Elastography: H4911EN (N/A in the USA) B, Color, and PDI Mode: H4911CN
Stress Echo	H4911SE
Video Scan Converter	H4911SC

Table 3-19: Options (Continued)

Option	Part Number / HCAT
B-Flow	H4913BF
Compare Assistant	H4913CM
Breast Productivity Package	H4913BP
Thyroid Productivity Package	H4913TP
OB Measure Assistant	H4913AM
Breast Measure Assistant	H4913AB
LOGIQ E9 Advanced Probes	H4913AP
3-DLP Port Relay Board	H4913DL
*The LOGIQ E9 is designed for compatibility with commercially available Ultrasound contrast agents. Because the availability of these agents is subject to government regulation and approval, product features intended for use with these agents may not be commercially marketed nor made available before the contrast agent is cleared for use. Contrast-related product features are enabled only on systems for delivery to an authorized country or region of use.	

Gel

Table 3-20: Gel

Accessory	Units
Thermasonic Gel Warmer	Holds three plastic bottles (250ml or 8 oz)
Aquasonic 100 Scan Gel	5 liter jug
	250 ml plastic bottles (12/case)
Scan Ultrasound Gel	8 oz plastic bottles (12/case)
	1 gallon plastic jug
	Four 1-gallon plastic jugs

Disinfectant

Table 3-21: Disinfectant

Accessory	Units
Cidex Activated Dialdehyde	16/1 quart bottles
	4/1 gallon bottles
	2/2.5 gallon bottles

Ultrasound Probe and Cord Sheath Sets

Table 3-22: Probe and Cord Sheath Sets

Accessory	Units
Sterile Ultrasound Probe Sheath Set	20 Per Set
Sterile Ultrasound Cord Sheath Set	20 Per Set
Sanitary Rectal/Vaginal Probe Cover	20 Per Set
Sterile Combination Probe and Cord Cover Set	12 Per Set
Sterile Ultrasound Probe Sheath Set for Wide (2.5 and 3.5) Aperture Sector Probes	20 Per Set

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.



CAUTION

For USA only:

Federal law restricts this device to use by, or on the orders of, a physician.

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.



Improper use can result in serious injury. The use of the system outside the descibed 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 Healthcare if needed.

Disregarding information on safety is considered abnormal use.



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



The concerns listed 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 users, as a diagnostic tool. They are explicitly not to be regarded as the sole, irrefutable basis for clinical diagnosis. Users are encouraged to study the literature and reach their own professional conclusions regarding the clinical utility of the system.

The user 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.



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.



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.

The use of damaged 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.



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.



CAUTION

Do not use with Defibrillator.

This equipment does not have a defibrillator approved applied part.

Scanner and electrosurgical units



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 while operating the ESU. Where contact cannot be avoided, as in the case of TEE monitoring during surgery, make sure the transducer is not located between the ESU active and dispersive electrodes and keep the ESU cables away from the transducer cable.

ALARA



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.

Training

It is recommended that all users receive proper training in applications before performing them in a clinical setting. Please contact the local GE representative for training assistance.

ALARA training is provided in the Medical Ultrasound Safety booklet shipped in the eDOCs kit. The ALARA education program for the clinical end-user covers basic ultrasound principles, possible biological effects, the derivation and meaning of the indices, ALARA principles, and examples of specific applications of the ALARA principle.

Equipment and Personnel Safety

The concerns listed below can seriously affect the safety of equipment and personnel during a diagnostic ultrasound examination.

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


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 serviceable components inside the console. Refer all servicing to 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.
- In North America, a 220-240V installation requires the use of a center-tapped AC power source.

Related Hazards (continued)



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 LOGIQ E9.



WARNING

The LOGIQ E9 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.



DANGER

The concerns listed below can seriously affect the safety of equipment and personnel during a diagnostic ultrasound examination.



Explosion Hazard

Risk of explosion if used in the presence of flammable anesthetics.

Related Hazards (continued)


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

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 while operating the ESU. Where contact cannot be avoided, as in the case of TEE monitoring during surgery, make sure the transducer is not located between the ESU active and dispersive electrodes and keep the ESU cables away from the transducer cable.


CAUTION

Peripheral devices that use their own AC power source CANNOT be attached to the LOGIQ E9. DO NOT connect the peripheral device's power cord into the LOGIQ E9 system.

Use a USB printer cable that is less than 3 meters in length.


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.

Related Hazards (continued)


CAUTION

When you move the Control Panel up/down with the monitor, place BOTH hands on the Control Panel. Touching other moving parts other than the Control Panel may cause personal injury.


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.


CAUTION

Do not unpack the LOGIQ E9. This must be performed by qualified service personnel only.

Related Hazards (continued)



To avoid skin burns in surgical use, do not place ECG electrodes in the current path between the Electrosurgical Unit (ESU) active and dispersive electrodes. Keep ESU cables away from ECG leads.



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.



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 -> Backup/Restore. Enable the following checkboxes under Backup:
   - Patient Archive
   - Report Archive
   - User defined configuration
   - Service



DO NOT load non-system software on the system computer.

Material Safe Data

Rubber part

Material: EPDM

Where Used: Probe holder/Gel holder/Keyboard bumper/Front and Rear Foot Pedal/System bumper at the four corners

Related Hazards (LCD Monitor)



- **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 LCD/LCD arm in transport position.
- The LCD 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 LCD panel has a fixed life span. When the screen becomes dark or begins to flicker, contact a qualified Service Representative for information.

Related Hazards (Volume Navigation)



DO NOT use the Volume Navigation feature on any patient relying on life-sustaining electronic equipment, such as a pacemaker or defibrillator.

Classifications

Type of protection against electric shock

Class I Equipment (*1)

Degree of protection against electric shock

Type BF Applied part (*2) (for PCG, Probes marked with BF symbol)

Type CF Applied part (*3) (for ECG marked with CF symbol)

Continuous Operation

System is Ordinary Equipment (IPX0)

Footswitch is IPX8

1. Class I Equipment

EQUIPMENT in which protection against electric shock does not rely on BASIC INSULATION only, but includes an earth ground. This additional safety precaution prevents exposed metal parts from becoming LIVE in the event of an insulation failure.

2. Type BF Applied Part

TYPE BF APPLIED PART providing a specified degree of protection against electric shock, with particular regard to allowable LEAKAGE CURRENT.

Table 4-2: Type BF Equipment

	Normal Mode	Single fault condition
Patient leakage current	Less than 100 microA	Less than 500 microA

3. Type CF Applied Part

TYPE CF APPLIED PART providing a degree of protection higher than that for Type BF Applied Part against electric shock particularly regarding allowable LEAKAGE CURRENTS.

Table 4-3: Type CF Equipment

	Normal Mode	Single fault condition
Patient leakage current	Less than 10 microA	Less than 50 microA

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 4.2, Notice upon Installation of Product.

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)



CAUTION

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) unless intended for use with this system, in the vicinity of this equipment as it may cause performance outside the published specifications.

Keep power to these devices turned off when near this equipment.

Medical staff in charge of this equipment is required to instruct technicians, patients and other people who may be around this equipment to fully comply with the above regulation.

Portable and mobile radio communications equipment (e.g. two-way radio, cellular/cordless telephones, wireless computer networks) should be used no closer to any part of this system, including cables, than determined according to the following method:

Table 4-4: 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

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 Healthcare or ones designated by GE Healthcare. 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 Healthcare. 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 Option Installation 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 LOGIQ E9 to image recording and other devices or communication networks.

Peripherals used in the patient environment

The LOGIQ E9 has been verified for overall safety, compatibility and compliance with the following image recording devices:

- Sony UP-D897 Digital Printer
- Sony UP-D23 Digital Printer
- Sony UP-D25 Digital Printer
- Sony UP-D55 Digital Printer
- Canon PIXMA MP610 Digital Printer
- HP470 Report Printer
- DVR
- Drive Bay (for Tru3D and Volume Navigation)
- USB 2.0 Flash Drive (Memory Stick)
- Hard Disk Drive

The LOGIQ E9 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.

A Wireless LAN option is available.

The LOGIQ E9 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 60601-1-1.

Peripherals used in the patient environment (continued)

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 IEC60601-1-1. Everyone who connects additional equipment to the signal input part or signal output part of the LOGIQ E9 system configures a medical system, and is therefore responsible to ensure that the system complies with the requirements of the valid version of IEC60601-1-1. If in doubt, consult the technical service department or your local GE Healthcare representative.

General precautions for installing an alternate on-board device would include:

1. The added device must have appropriate safety standard conformance and CE Marking.
2. The total power consumption of the added devices, which connect to the LOGIQ E9 and are used simultaneously, must be less than or equal to the rated supply of the LOGIQ E9.
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 60601-1-1.
6. Electromagnetic emissions and immunity of the combination must conform to IEC/EN 60601-1-2.

Peripherals used in the patient environment (continued)

General precautions for installing an alternate off-board, remote device or a network 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 60601-1-1.



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 60601-1-1 by the installer. Equipment modifications and possible resulting malfunctions and electromagnetic interference are the responsibility of the owner.

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 4-5: 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.

Declaration of Immunity (continued)

Table 4-6: Declaration of Immunity

Immunity Type	Equipment Capability	Regulatory Acceptable Level	EMC Environment and Guidance
IEC 61000-4-2 Static discharge (ESD)	± 9 kV contact ± 12 kV air	± 9 kV contact ± 12 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: 
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	< 50_T (> 95% dip) for 0.5 cycle; 400_T (60 0ip) for 5 cycles; 700_T (30 0ip) for 25 cycles; < 50_T (>95% dip) for 5 sec	< 50_T (> 95% dip) for 0.5 cycle; 400_T (60 0ip) for 5 cycles; 700_T (30 0ip) for 25 cycles; < 50_T (>95% dip) for 5 sec	
IEC 61000-4-8 Power frequency (50/60 Hz) magnetic field	6 A/m	6 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	
IEC 61000-3-2 Harmonic Disturbance Emissions	IEC Limits	230Vac	
IEC 61000-3-3 Voltage Fluctuations Emissions	IEC Limits	230Vac 50Hz, 100Vac 50Hz	
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.			

Essential performance

The essential performance of the ultrasound unit is:

- The ability to display B-mode image as input for diagnosis.
- The ability to display M-mode image as input for diagnosis.
- The ability to display Doppler-mode image as input for diagnosis.
- The ability to display Color Flow-mode image as input for diagnosis.
- The display of acoustic power indexes as an aid for safe use of ultrasound diagnostic (MI,TIS,TIB,TIC).

Patient Environmental Devices



Figure 4-1. Patient Environmental Devices

1. Front Panel (Signal I/O Port, Power On/Off, USB Ports)
2. Peripheral Devices
   DVD Multi Drive (CD, DVD, DVR),
   Patient I/O (ECG, CW Probe Port),
   V Nav Connectors
3. Network/Disk Indicators, USB Ports
4. Probe Ports (4)
   Probe Ports with CW Option (5)
5. Imaging Probes
6. Wireless LAN
7. Power In/Out
   Power Line (AC~)
   Ground Line
   Power Cable with Protective Earth
8. Signals I/O Port (USB Ports, Ethernet Connector, Audio In/Out, DVI Port Connector, S-Video Connector)

Acceptable Devices

The Patient Environmental devices shown on the previous page are specified to be suitable for use within the PATIENT ENVIRONMENT.



DO NOT connect any probes or accessories without approval by GE within the PATIENT ENVIRONMENT.

See ‘Peripheral Update for EC countries’ on *page 4-24 for more information.*

Unapproved Devices



DO NOT use unapproved devices.

If devices are connected without the approval of GE, the warranty will be INVALID.

Any device connected to the LOGIQ E9 must conform to one or more of the requirements listed below:

1. IEC standard or equivalent standards appropriate to devices.
2. The devices shall be connected to PROTECTIVE EARTH (GROUND).

Accessories, Options, Supplies



Unsafe operation or malfunction may result. Use only the accessories, options and supplies approved or recommended in these instructions for use.

Acoustic Output



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.

When the “Auto Freeze Time (probe selection required)” preset is selected on the Utility -> System -> System Imaging screen, the system auto freezes after the time specified (2, 5, 10, 15 or 30 minutes, 1 or 2 hours) of scanning if it detects no change in the image.

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 display starts at a value of 0.0 and increments in steps of 0.1 The MI display values between 0 and 0.4 increment in steps of 0.01 and for values greater than 0.4, increments in steps of 0.1.

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.

Display precision is ±0.1 and accuracy is ±50%. Accuracy of the power output displayed value on the Touch Panel is ±10%.

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 LOGIQ E9 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 ***New Patient*** is selected.

To modify acoustic output, adjust the Power Output level on the Touch Panel.

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 4-7: Label Icons

Label/Icon	Purpose/Meaning	Location
Identification and Rating Plate 	Manufacturer's name and address	• Rear Panel • Rating Plate • Probes
Identification and Rating Plate 	Date of manufacture	• Rating Plate • Probes
	Serial Number	• Rating Plate • Probes
	Catalog Number	• Rating Plate • Probes
Type/Class Label	Used to indicate the degree of safety or protection.	• Rear Panel
	United States only Prescription Requirement label	• Rear Panel
	CE Mark The CE Mark of Conformity indicates this equipment conforms with the Council Directive 93/42/EEC.	• Rear Panel • Probes

Table 4-7: Label Icons (Continued)

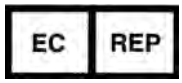
Label/Icon	Purpose/Meaning	Location
	Authorized European Representative address	• Rear Panel
	Use two people to transport system on inclines. This label also indicates the system weight.	• Rear Panel
IP Code • IPX8 • IPX7	Indicates the degree of protection provided by the enclosure per IEC60 529. Can be used in operating room environment.	• Footswitch • Probes
	Type BF Applied Part (man in the box) symbol is in accordance with IEC 60417-5333.	• Probe Connector Panel • Probes
	Type BF Applied Part (man in the box with paddle) symbol is in accordance with IEC 60417-5334.	• Probes
	Type CF Applied Part (heart in the box) symbol is in accordance with IEC 60878-02-03.	• CW Probe Connector • Patient Cardiac Connectors • Probes
	Type CF Defib-Proof Applied Part (heart in the box with paddle) symbol is in accordance with IEC 60878-02-06.	• ECG Connector • Probes
	“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.	• Rear Panel • Inside of Console • Rear of the LCD monitor • Probes
	“General Warning Sign”	• Rear Panel • Patient Cardiac and ECG Connectors • Peripheral/Accessory Connector Panel • Probe Connector Panel • Circuit Breaker Panel • Inside of Console • Probes

Table 4-7: Label Icons (Continued)

Label/Icon	Purpose/Meaning	Location
	"Warning" - Dangerous voltage" (the lightning flash with arrowhead) is used to indicate electric shock hazards.	• Rear Panel • Inside of Console • Circuit Breaker Panel
	"Mains OFF" indicates the power off position of the mains power breaker.	• Circuit Breaker Panel
	"Mains ON" indicates the power on position of the mains power breaker.	• Circuit Breaker Panel
	"ON" indicates the power on position of the power switch. **CAUTION:** This Power Switch **DOES NOT ISOLATE** Mains Supply.	• Power On/Off Switch
	"Protective Earth" indicates the protective earth (grounding) terminal.	• Inside of 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	• Circuit Breaker Panel
	Alternating Current symbol is in accordance with IEC 60878-01-14.	• Rear Panel • Rating Plate

Table 4-7: Label Icons (Continued)

Label/Icon	Purpose/Meaning	Location
	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 • Probes
	To avoid injury, **DO NOT** place a finger, hand or any object below the operator panel when it is lowered.	• Movable up/down Operator Panel support as the Operator Panel is lowered. Label hidden when in down position.
	GOST Symbol. Russia Regulatory Country Clearance.	• Rear Panel
	This product consists of devices that may contain mercury, which must be recycled or disposed of in accordance with local, state, or country laws. Within this system the backlight lamps in the monitor display contain mercury.	• Rear Panel
	ETL Listing Mark Monogram	• Rear Panel
	The product has been tested and approved in UL Laboratories, based on UL and CSA standards, through mutual approval activities.	• Footswitch
	Non-Ionizing Electromagnetic Radiation	• Rear Panel, on LOGIQ E9 equipped with Wireless LAN
	ISO 7010 - P007 Volume Navigation Pacemaker Warning	• V Nav Transmitter

Table 4-7: Label Icons (Continued)

Label/Icon	Purpose/Meaning	Location
	Indicates the presence of hazardous substance(s) above the maximum concentration value. Maximum concentration values for electronic information products, as set by the People's Republic of China Electronic Industry Standard SJ/T11364-2006, include the hazardous substances of lead, mercury, hexavalent chromium, cadmium, polybrominated biphenyl (PBB), and polybrominated diphenyl ether (PBDE). "20" indicates the number of years during which the hazardous substance(s) will not leak or mutate so that the use of this product will not result in any severe environmental pollution, bodily injury, or damage to any assets.	• China Rating Plate
	Indicates the presence of hazardous substance(s) above the maximum concentration value. Maximum concentration values for electronic information products, as set by the People's Republic of China Electronic Industry Standard SJ/T11364-2006, include the hazardous substances of lead, mercury, hexavalent chromium, cadmium, polybrominated biphenyl (PBB), and polybrominated diphenyl ether (PBDE). "10" indicates the number of years during which the hazardous substance(s) will not leak or mutate so that the use of this product will not result in any severe environmental pollution, bodily injury, or damage to any assets.	• Probes
	How to lower LCD prior to transport	• Rear of the LCD monitor
	How to lock Operator Panel prior to transport	• Rear of the LCD monitor

Table 4-7: Label Icons (Continued)

Label/Icon	Purpose/Meaning	Location
	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.	• Rear of the LCD monitor
	DO NOT push the system. Use the handle to push/pull the system, e.g., DO NOT use the LCD. Failure to do so may cause serious injury or system damage.	• Rear of the LCD monitor • Rear of On-board V Nav Stand

Warning Label Locations



Figure 4-2. Rear Panel Label Location

Warning Label Locations (continued)

Table 4-8: Rear Panel Label Explanations

1. Manufacturer's name and address
2. Prescription Device (For U.S.A. Only)
3. ETL Label: 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.
4. CISPR Emissions Label
5. Authorized European Representative address
6. Country-specific labels
7. This machine should be used in compliance with law. Some jurisdictions restrict certain uses, such as gender determination. (shown for country specific label)
8. RoHS Label–China systems only (shown for country specific label)
9. Non-Ionizing Electromagnetic Radiation
10. "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.
11. Possible shock hazard. Do not remove covers or panels. No user serviceable parts are inside. Refer servicing to qualified service personnel.
12. The equipment weighs approximately 135 kg (298 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.
13. WEEE symbol
14. BF Applied Part
15. The CE Mark of Conformity indicates this equipment conforms with the Council Directive 93/42/EEC.
16. Mercury Warning Label
17. GOST Mark - 220V system only–Russia (shown for country specific label)
18. Identification and Rating Plate–USA/Asia 120V console
19. Identification and Rating Plate–Europe/Asia/ USA 220V console
20. Identification and Rating Plate–China
21. Identification and Rating Plate– Korea

Warning Label Locations (continued)

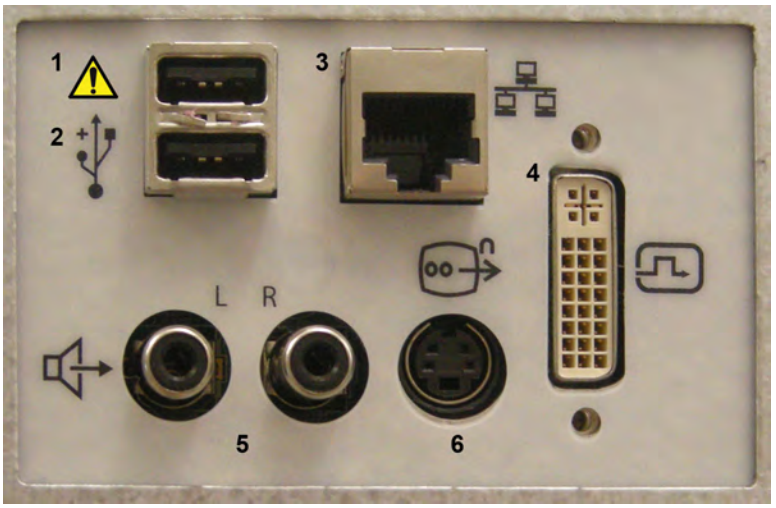


Figure 4-3. Peripheral/Accessory Connector Panel

Table 4-9: Accessory/Connector Panel Explanations

1. USB Ports
2. Ethernet Connection
3. Possible shock hazard. Do not remove covers or panels. No user serviceable parts are inside. Refer servicing to qualified service personnel.
4. DVI Port Connector
5. Audio In/Out
6. S-Video

Warning Label Locations (continued)

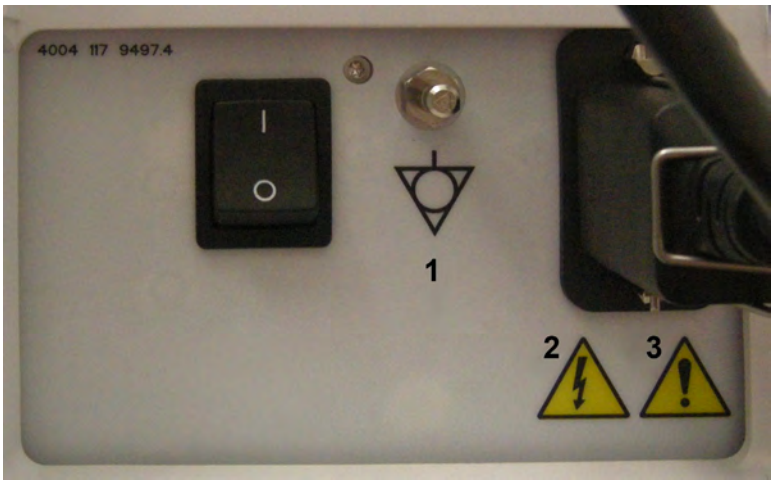


Figure 4-4. Circuit Breaker Panel

1. Signal ground point label **CAUTION**: This is only for “FUNCTIONAL GROUNDING”, NOT “PROTECTIVE EARTH”. *NOTE: Grounding reliability can only be achieved when this equipment is connected to a receptacle marked “Hospital Only” or “Hospital Grade”. (For U.S.A., Canada, Japan)*
2. “Warning” - Dangerous voltage” (the lightning flash with arrowhead) is used to indicate electric shock hazards.
3. Possible shock hazard. Do not remove covers or panels. No user serviceable parts are inside. Refer servicing to qualified service personnel.

Warning Label Locations (continued)



Figure 4-5. Rating Plate–USA/Asia 120V console



Figure 4-6. Caution Label on the LCD Monitor



Figure 4-7. Footswitch Label

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