GE Healthcare

Technical Publications

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Rev. 10

CE 0197

Venue 40 Basic User Manual

R1.x.x, R2.0.x, R3.x.x

Operating Documentation

Regulatory Requirement

Venue 40 complies with regulatory requirements of the following European Directive 93/42/EEC concerning medical devices.

CE 0197

This manual is a reference for the Venue 40. It applies to all versions of the R1.x.x, R2.0.x, R3.x.x software for the Venue 40 ultrasound system.

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Revision History

Reason for Change

REV	DATE (YYYY/MM/DD)	REASON FOR CHANGE
Rev. 1	2008/09/18	Initial Release
Rev. 2	2009/02/05	Update UI and software functions.
Rev. 3	2009/03/10	Update Utility settings.
Rev. 4	2009/09/15	Add 4C-SC probe
Rev. 5	2010/06/15	Add L8-18i-SC probe, software update to R2.0.x.
Rev.6	2011/06/15	Add E8CS-SC probe information, footswitch information, OB measurement information and software update to R3.x.x.
Rev.7	2011/07/07	Update OB worksheet function
Rev.8	2012/01/05	Update to identify which features are only available for R3.x.x
Rev.9	2012/02/17	Update to add a caution for Estimated Fetal Weight.
Rev.10	2012/09/10	Update cTUVus certification mark

List of Effective Pages

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

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Regulatory Requirements

Conformance Standards

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

- According to 93/42/EEC Medical Device Directive, this is Class IIa Medical Device.
- According to IEC/EN 60601-1,
  - Equipment is Class I, Type B with BF Applied Parts.
  - Docking Station/Cart is Class I.
- According to CISPR 11,
  - Equipment is Group 1, Class A ISM Equipment.
  - Docking Station/Cart is Group 1, Class A ISM Equipment
- According to IEC60529, the footswitch rate is IP X8 (MKF 2 1S/1S-MED HID GP 26)

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 Equipment, 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/EN 60601-1-6 (Usability), EN1041 (Information supplied with medical devices).
  - IEC 60601-2-37 Medical electrical equipment. Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment.
  - IEC 61157 Declaration of acoustic output parameters.
- 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 UD3, 2004).
- 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: 221ABBZX00092000

- CHINA

Table of Contents

Chapter 1

Introduction/Safety

This chapter consists of information concerning indications for use/contraindications, how this documentation is organized. Also includes the safety and regulatory information pertinent for operating this ultrasound system.

System Overview

Attention

This manual contains necessary and sufficient information to operate the system safely.

Read and understand all instructions in this manual before attempting to use the Venue 40 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.

Documentation

Venue 40 documentation consists of three manuals:

- The Basic User Manual (TRANSLATED) provides information needed by the user to operate the system safely. It describes the basic functions of the system, safety features, operating modes, measurements/calculations, probes and user care and maintenance.

NOTE: Screen examples are for reference only.

NOTE: Probe information displayed on screen examples does not necessarily reflect the probes available on your ultrasound system. Please refer to the Probes chapter for a listing of available probes and features.

- The Quick Card (TRANSLATED) provides descriptions of basic system features and operation. It is intended to be used in conjunction with the Basic User Manual in order to provide the information necessary to operate the system safely.
- The Release Notes (TRANSLATED) provide precautions and instructions that supplement the Basic User Manual.
- The Advanced Reference Manual (ENGLISH ONLY) contains data tables, such as OB and Acoustic Output tables.

The Venue 40 manuals are written for users who are familiar with basic ultrasound principles and techniques. They do not include sonographic training or detailed clinical procedures.

Principles of Operation

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

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

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

Indications for Use

The Venue 40 is intended for use by a qualified physician for ultrasound evaluation. Specific clinical applications and exam types include:

- Fetal/OB
- Abdominal
- GYN
- Urology
- Pediatric
- Small Organ (including breast, testes and thyroid)
- Neonatal Cephalic
- Adult Cephalic (Transcranial)
- Cardiac (including Adult and Pediatric)
- Peripheral Vascular
- Musculoskeletal Conventional
- Musculoskeletal Superficial
- Thoracic (fluid, Pleural and motion detection)
- Interventional guidance
- Non vascular (including Nerve Block)
- Intraoperative
- Transvaginal*

NOTE: ** R3.x.x only.*

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

Contraindication

The Venue 40 ultrasound system is not intended for ophthalmic use or any use causing the acoustic beam to pass through the eye.

Prescription Device

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

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 1-1: Potential Hazards

Icon	Potential Hazard	Usage	Source
	• Patient/user infection due to contaminated equipment.	• Cleaning and care instructions • Sheath and glove guidelines	ISO 7000 No. 0659
	• Electrical micro-shock to patient, e.g., ventricular	• Probes • ECG, if applicable • Connections to back panel	
	• Patient injury or tissue damage from ultrasound radiation.	• ALARA, the use of Power Output following the ‘as low as reasonably achievable’ principle	
	• Risk of explosion if used in the presence of flammable anesthetics.	• Flammable anesthetic	
	• 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 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 Medical Systems if needed.

The equipment user is obligated to be familiar with these concerns and avoid conditions that could result in injury.

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.

If the Venue 40 needs to be sent for repair, ensure that any patient information is erased from the storage device. In case that any patient information is still residing on the Venue 40, GE will contact the customer and request for urgent collection of that patient information. GE will keep this patient information in a secure environment for a maximum period of 1 month. All patient information will be permanently deleted at that point.

If PHI (Patient Healthcare Information) data needs to be sent to GE employees for service purposes, GE will ascertain agreement from the customer. The patient information shall only be transferred by approved service processes, tools and devices restricting access, protecting or encrypting data where required, and providing traceability in the form of paper or electronic documents at each stage of the procedure while maintaining compliance with cross-border restrictions information transfers.

Related Hazards (continued)

Diagnostic information

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.

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.

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 are the sole responsibility of the user. The user must consider contraindications for the use of a calculation or chart as described in the scientific literature. The diagnosis, decision for further examinations and medical treatment must be performed by qualified personnel following good clinical practice.

Related Hazards (continued)

Mechanical hazards

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. Become familiar with all instructions and precautions provided with special purpose probes.


Electrical Hazard

A damaged probe can also increase the risk of electric shock if conductive solutions come in contact with internal live parts. Inspect probes often for cracks or openings in the housing and holes in and around the acoustic lens or other damage that could allow liquid entry. Become familiar with the probe's use and care precautions outlined in *Probes and Biopsy*.


CAUTION

Ultrasound transducers are sensitive instruments which can easily be damaged by rough handling. Take extra care not to drop transducers and avoid contact with sharp or abrasive surfaces. A damaged housing, lens or cable can result in patient injury or serious impairment or operation.


CAUTION

Ultrasound can produce harmful effects in tissue and potentially result in patient injury. Always minimize exposure time and keep ultrasound levels low when there is no medical benefit. Use the principle of ALARA (As Low As Reasonably Achievable), increasing output only when needed to obtain diagnostic image quality. Observe the acoustic output display and be familiar with all controls affecting the output level. See the *Bioeffects section* of the *Acoustic Output chapter* in the *Advanced Reference Manual* for more information.

Related Hazards (continued)

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 by GE Application Specialists. 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

Related Hazards

WARNING

If any defects are observed or malfunctions occur, stop operating the equipment and perform the proper action for the patient.

There are no user serviceable components inside the console. Refer all servicing to the Repair Center.

WARNING

Only approved and recommended peripherals and accessories should be used.

All peripherals and accessories must be securely mounted to the Venue 40 or Docking Station/Cart.

WARNING

Venue 40 is not intended to be used as a storage device; backup of the Patient and image Database is your institution's responsibility.GE is NOT responsible for any lost patient information or for lost images.

DANGER

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

Related Hazards (continued)

Electrical Hazard

To avoid injury:

- Do not remove protective covers. No user serviceable parts are inside. Refer servicing to qualified service personnel.
- 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.

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.

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

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

CAUTION

DO NOT use high-frequency surgical equipment with the Venue 40.

General Caution

CAUTION

Standard maintenance must be performed by authorized service personnel the lifetime of the product (7 years).

CAUTION

Proceed cautiously when crossing door or elevator thresholds with Docking Cart. Use the handle to push/pull the system, e.g., do not use the Venue40. Failure to do so may cause serious injury or system damage.

CAUTION

The maximum capacity load is 8kg for the Printer Shelf (1) and 2kg for the Accessories Shelf (2), refer to the following figure.

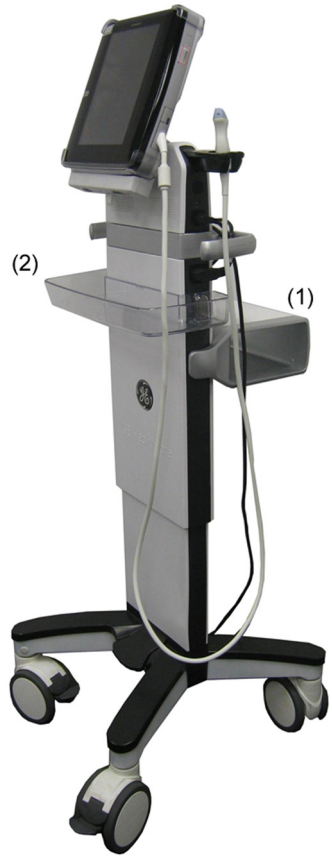


Figure 1-1. Capacity Load

Device Labels

Icon Description

The following table describes the purpose and location of safety labels and other important information provided on the equipment.

Table 1-2: Label Icons

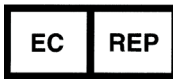
Label/Icon	Purpose/Meaning	Location
Identification and Rating Plate 	• Manufacture's name and address • Date of manufacture • Model and serial numbers • Electrical ratings (Volts, Amps, phase, and frequency)	AC Adapter Label. 'Warning label locations' on page 1-33
Type/Class Label	Used to indicate the degree of safety or protection.	
IP Code (IPX8) IPX8: MKF 2 1S/1S-MED HID GP26	Indicates the degree of protection provided by the enclosure per IEC60529. IPX8 can be used in an operating room environment.	
	Authorized European Representative address	
	United States only Prescription Requirement label	
	Type BF Applied Part (man in the box) symbol is in accordance with IEC 60878-02-03.	Beside the probe connector
	General Warning	Various
	"Consult accompanying documents" is intended to alert the user to refer to the operator manual or other instructions when complete information cannot be provided on the label.	Various

Table 1-2: Label Icons

Label/Icon	Purpose/Meaning	Location
	“CAUTION” - Dangerous voltage” (the lightning flash with arrowhead) is used to indicate electric shock hazards.	Various
	“ON” indicates the power on position of the power switch. **CAUTION:** This Power Switch **DOES NOT ISOLATE** Mains Supply.	See the Console Overview section for location information.
	“Protective Earth” indicates the protective earth (grounding) terminal.	Inside of AC adapter with docking station
	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.	Bottom of Venue 40
	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.	• Bottom of Venue 40 • Rear panel of Docking Station

Table 1-2: Label Icons

Label/Icon	Purpose/Meaning	Location
 Pb/Cd/Hg	The separate collection symbol is affixed to a battery, or its packaging, to advise you that the battery must be recycled or disposed of in accordance with local or country laws. The letters below the separate collection symbol indicate whether certain elements (Pb=Lead, Cd=Cadmium, Hg=Mercury) are contained in the battery. To minimize potential effects on the environment and human health, it is important that all marked batteries that you remove from the product are properly recycled or disposed. For information on how the battery may be safely removed from the device, please consult the service manual or equipment instructions. Information on the potential effects on the environment and human health of the substances used in batteries is available at this url: http:// www.gehealthcare.com/euen/ weee-recycling/index.html	Battery Pack if contains Pb/Cd/ Hg
	No hazardous substance, above the maximum concentration value, is present. 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)	Bottom

Table 1-2: Label Icons

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). "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.	Rating Plate
	GOST symbol: Russia Regulatory Country Clearance.	Rating Plate Note: Only after Russian regulatory registration is complete, this label will be located on the console rating plate.
	Utilize additional care and personnel when moving on steep inclines (>5 degrees) or loading into vehicle for transport.	Rating Plate of Docking Cart
	Do not put anything weighed over 5kg on the shelf.	Printer shelf of Docking Cart
	Do not push the system	Back of Docking Cart
	Do not step on the system	Base chassis covers of Docking Cart

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 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.

EMC Performance (continued)

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.

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.

EMC Performance (continued)

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

Table 1-3: 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

General Notice

1. Designation of Peripheral Equipment Connectable to This Product.

   The equipment indicated in Chapter 6 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)

Peripheral Update for EC countries

The following is intended to provide the users in EC countries with updated information concerning the connection of the Venue 40 to image recording and other devices or communication networks.

Peripheral used in the patient environment

The Venue 40 has been verified for overall safety, compatibility and compliance with the following on-board image recording devices:

- Sony UP-D897 B/W Printer
- SanDisk USB Memory Stick 4GB
- Transcend Class 6 SDHC card 8GB
- Transcend Compact Card Reader P5
- Edimax Wireless Network Card
- Footswitch MKF2 1S/1S-MED HID GP26

The Venue 40 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.

CAUTION

The connection of equipment or transmission networks other than as specified in the user instructions can result in an electric shock hazard or equipment malfunction. Substitute or alternate equipment and connections requires verification of compatibility and conformity to IEC/EN 60601-1-1 by the installer. Equipment modifications and possible resulting malfunctions and electromagnetic interference are the responsibility of the owner.

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. There must be adequate mechanical mounting of the device and stability of the combination.
3. Risk and leakage current of the combination must comply with IEC/EN 60601-1.
4. Electromagnetic emissions and immunity of the combination must conform to IEC/EN 60601-1-2.

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 1-4: Declaration of Emissions

Guidance and manufacturer's declaration - electromagnetic emissions		
The system is intended for use in the electromagnetic environment specified below. The user of the system should assure that it is used in such an environment.		
Emission Type	**Compliance**	**Electromagnetic Environment**
RF Emissions CISPR 11	Group 1	This system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	This system is suitable for use in all establishments, other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: WARNING: This system is intended for use by healthcare professionals only. This system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the system or shielding the location.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/Flicker Emissions IEC 61000-3-3	Complies	

Declaration of Immunity

This system is suitable for use in the following environment. The user must assure that the system is used according to the specified guidance and only in the electromagnetic environment listed.

Table 1-5: Declaration of Immunity

Immunity Type	Equipment Capability	Regulatory Acceptable Level	EMC Environment and Guidance
IEC 61000-4-2 Static discharge (ESD)	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. Mains power quality should be that of a typical commercial and/or hospital environment. If the user requires continued operation during power mains interruptions, it is recommended that the system be powered from a UPS or a battery. NOTE: UT is the a.c. mains voltage prior to application of the test level. Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial and/or hospital environment. Separation distance to radio communication equipment must be maintained according to the method below. Interference may occur in the vicinity of equipment marked with the symbol:  Image degradation or interference may occur due to conducted RF noise on the equipment mains power supply or other signal cable. Such interference is easily recognized and distinguishable from patient anatomy and physiological waveforms. Interference of this type may delay the examination without affecting diagnostic accuracy. Additional mains/ signal RF isolation or filtering may be needed if this type interference occurs frequently.
IEC 61000-4-4 Electrical fast transient/burst	± 2 kV for mains ± 1 kV for SIP/ SOP	± 2 kV for mains ± 1 kV for SIP/SOP	
IEC 61000-4-5 Surge Immunity	± 1 kV differential ± 2 kV common	± 1 kV differential ± 2 kV common	
IEC 61000-4-11 Voltage dips, short interruptions and voltage variations on mains supply	< 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	3 A/m	3 A/m	
IEC 61000-4-6 Conducted RF	3 V_{RMS} 150 kHz - 80 MHz	3 V_{RMS} 150 kHz - 80 MHz	
IEC 61000-4-3 Radiated RF	3 V/m 80 MHz - 2.5 GHz	3 V/m 80 MHz - 2.5 GHz	
NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people. If noise generated from other electronic equipment is near the probe's center frequency, noise may appear on the image. Good power line isolation is required.			

Patient Environmental Devices

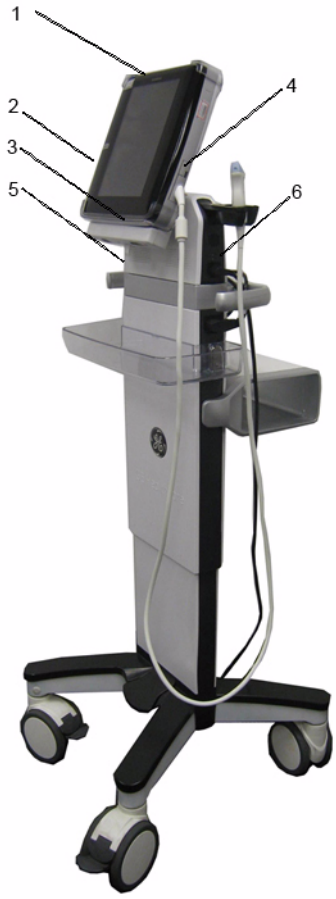


Figure 1-2. Patient Environmental Devices

1. Top side of Venue 40: SD Card socket
2. Left side of Venue 40: Lithium-ion battery port
3. Bottom of Venue 40: Docking Port
4. Right side of Venue 40: Probe port
5. Left side of Docking Station/Cart:
   - 1 Sync USB port
   - 1 Standard USB port
   - 1 DVI port
   - 1 LAN port
6. Right side of Docking Station/Cart: AC Power input socket

Acceptable Devices

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

CAUTION

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

See ‘Peripheral Update for EC countries’ on *page 1-25 for more information.*

Unapproved Devices

CAUTION

DO NOT use unapproved devices.

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

Any device connected to the Venue 40 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

CAUTION

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

Acoustic Output

Located on the upper right section of the system display monitor, the acoustic output display provides the operator with real-time indication of acoustic levels being generated by the system. See the *Acoustic Output chapter* in the *Advanced Reference Manual* for more information. This display is based on NEMA/AIUM Standards for Real-time Display of Thermal and Mechanic Acoustic Output Indices on Diagnostic Ultrasound Equipment.

Acoustic Output Display Specifications

The display consists of three parts: Thermal Index (TI), Mechanical Index (MI), and a relative Acoustic Output (AO) value. Although not part of the NEMA/AIUM standard, the AO value informs the user of where the system is operating within the range of available output.

The TI and MI are displayed at all times. The TI and MI display starts at a value of 0.0 and 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.

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.

Acoustic Output Display Specifications (continued)

Changing the Thermal Index Type

You can select the displayed TI type on Utility -> Imaging. This preset is application dependent so each application could specify a different TI type.

TI display accuracy is ±50%. MI display accuracy is ±30%.

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 chapter.

Always observe the Acoustic Output display for possible effects.

Best practices while scanning

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.

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 Venue 40 initiates scanning at a reduced default output level. This reduced level is preset depends upon the exam application and probe selected.

To modify acoustic output, use the stylus to adjust the Power Output level on the screen. There are three levels of Power Output, H (High), L (Low) and M (Medium)

Warning label locations

Venue 40 warning labels are provided in English.

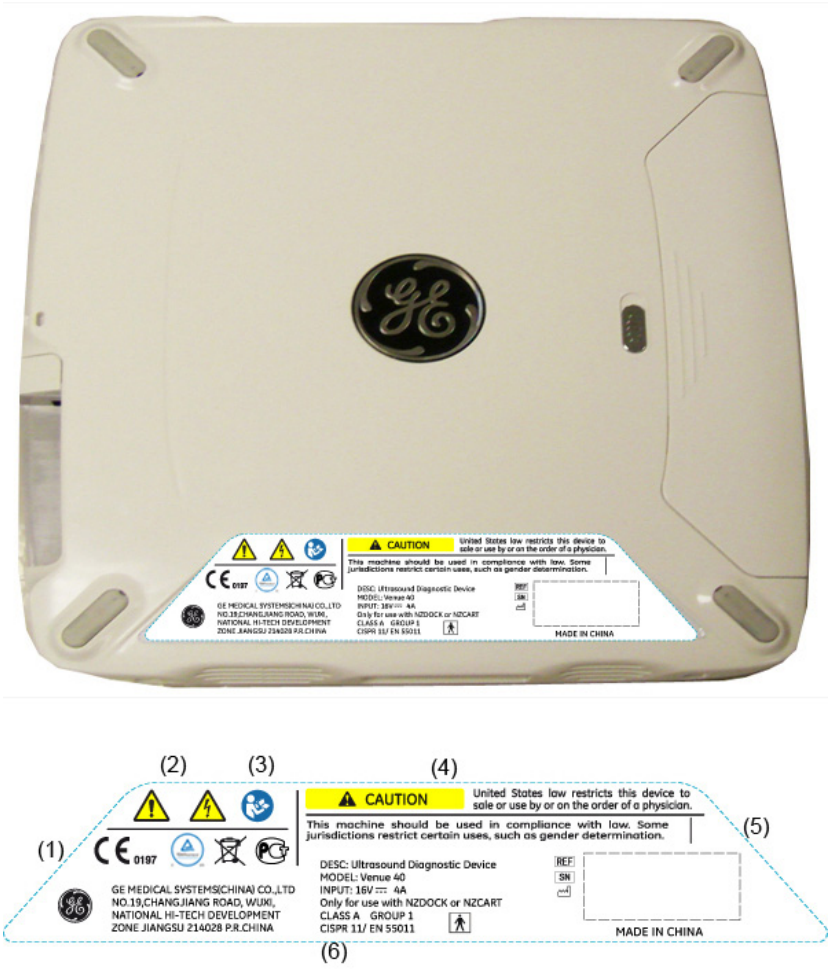


Figure 1-3. Label location explanations

Table 1-6: Label Location Explanations

1. The CE Mark of Conformity indicates this equipment conforms with the Council Directive 93/42/EEC.
2. Possible shock hazard. Do not remove covers or panels. No user serviceable parts are inside. Refer servicing to qualified service personnel.
3. “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.
4. Prescription Device (For U.S.A. Only)
5. Warning of Gender Determination
6. CISPR **CAUTION**: The Venue 40 conforms to the CISPR11, Group 1, Class A of the international standard for Electromagnetic disturbance characteristics.

Warning label locations (continued)

Table 1-7: Rating Plate Explanations

	**Date of manufacture:** The date could be a year, year and month, or year, month and day, as appropriate. See ISO 8601 for date formats.
	**Catalog or model number**
	**Serial number**
	Direct Current: For products to be powered from a DC supply
	Input
	Only for use with Docking Cart or Docking Station
	Description

Warning label locations (continued)

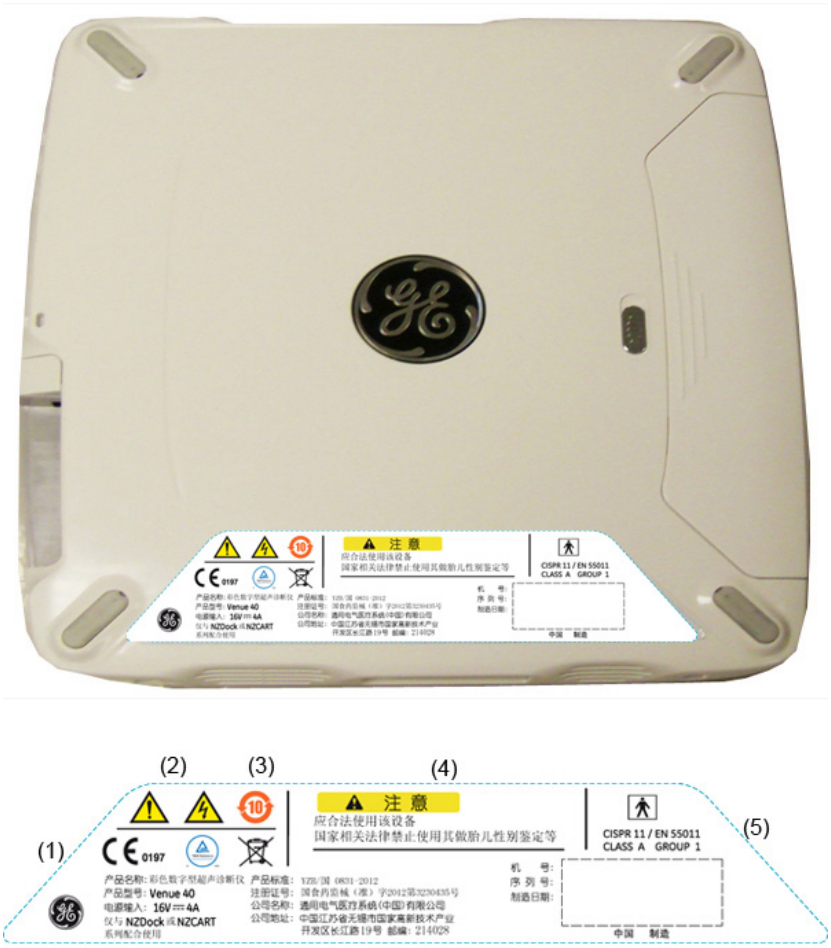


Figure 1-4. Venue40 Rating Plate (China only)

Warning label locations (continued)

Figure 1-5. Venue40 Rating Plate (Korean only)

Warning label locations (continued)

Figure 1-6. Docking Station Label

Figure 1-7. Docking Station Label (China only)

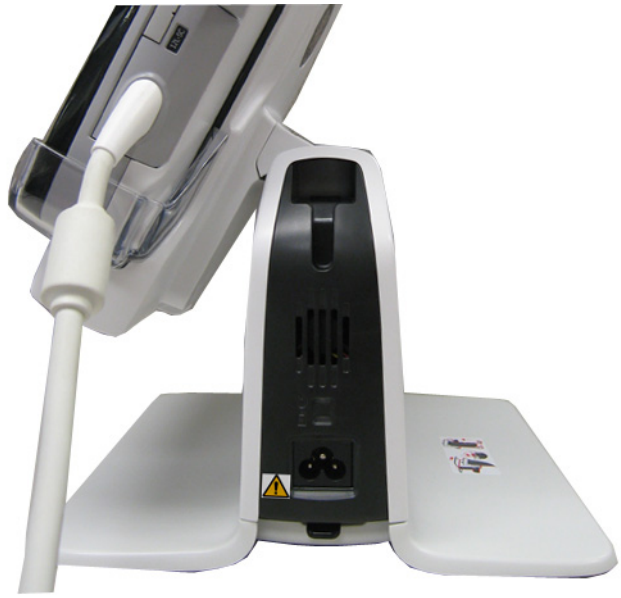


Figure 1-8. Docking Station label location (continued)

Warning label locations (continued)

Figure 1-9. Docking Cart warning label

Figure 1-10. Docking Cart label location (continued)

Warning label locations (continued)

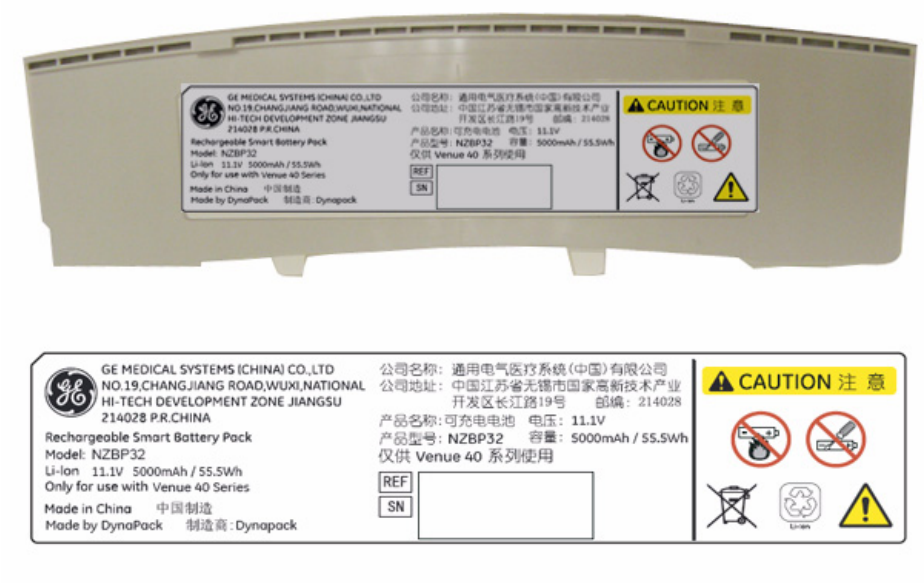


Figure 1-11. Battery Label

Table 1-8: Icons Explanations

	Keep the battery away from fire and other heat sources.
	Do not disassemble or alter the battery.
	The battery can be recharged.

Chapter 2

Preparing the System for Use

Describes the site requirements, console overview, system positioning/transporting, powering on the system, adjusting the display monitor, probes and operator controls.

Site Requirements

Introduction

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

The Venue 40 does not contain any operator serviceable internal components. Ensure that unauthorized personnel do not tamper with the unit.

Perform regular preventive maintenance. See ‘System Care and Maintenance’ on page 6-5 for more information.

Maintain a clean environment. Turn off, and if possible, disconnect the system before cleaning the unit. See ‘Cleaning the system’ on page 6-6 for more information.

Before the system arrives

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 6 amp circuit breaker for 220-240 VAC or a 10 amp circuit breaker for 100-120 VAC.

NOTE: *This is for the Docking Station/Docking Cart.*

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

  Precautions include:

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

Environmental Requirements

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

Table 2-1: System Environmental Requirements

	Operational	Storage	Transport
Temperature	10 - 40 degrees C 50 - 104 degrees F	-5 - 50 degrees C 23 - 122 degrees F	-5 - 50 degrees C 23 - 122 degrees F
Humidity	30 - 75% non-condensing	10 - 90% non-condensing	10 - 90% non-condensing
Pressure	700 - 1060hPa	700 - 1060hPa	700 - 1060hPa

Acclimation Time

After being transported, the unit requires one hour for each 2.5 degree increment its temperature is below 10 degree C or above 40 degree C.

Table 2-2: System Acclimation Time Chart

Degree C	60	55	50	45	40	35	30	25	20	15	10
Degree F	140	131	122	113	104	95	86	77	68	59	50
hours	8	6	4	2	0	0	0	0	0	0	0

Degree C	5	0	-5	-10	-15	-20	-25	-30	-35	-40
Degree F	41	32	23	14	5	-4	-13	-22	-31	-40
hours	2	4	6	8	10	12	14	16	18	20

Console Overview

Console graphics

The following are illustrations of the console:

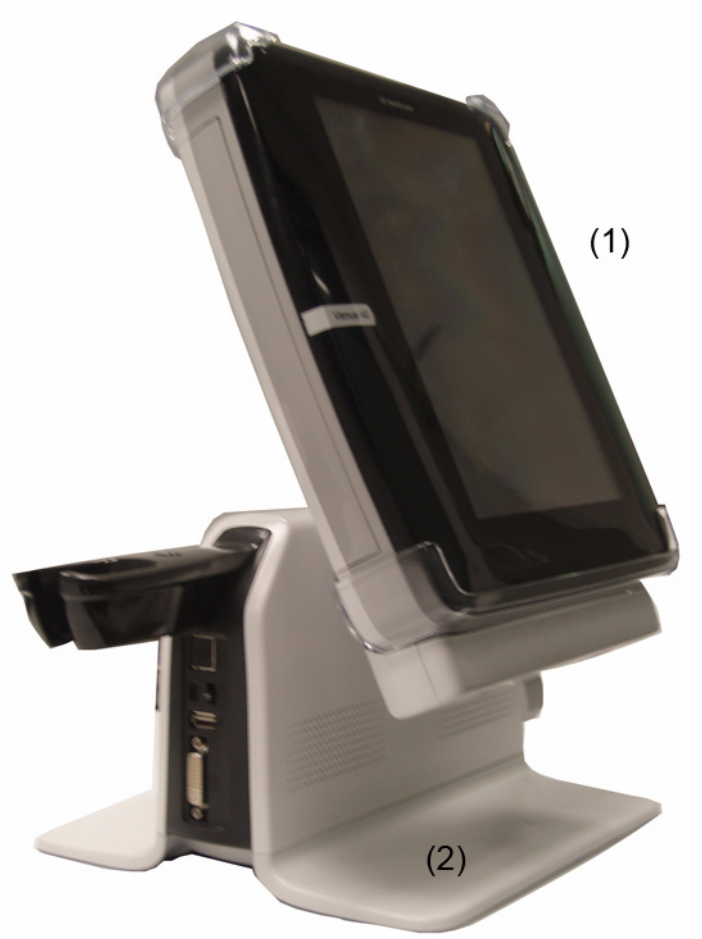


Figure 2-1. Venue 40 system (with docking station)

1. Venue 40
2. Docking station

Console graphics (continued)

Figure 2-2. Venue 40 views

1. Battery
2. SD Cart Socket
3. Docking Port
4. Probe port

CAUTION

Do not push objects into air vents of system. Doing so can cause fire or electric shock by shorting out interior components.

Console graphics (continued)

Docking Cart

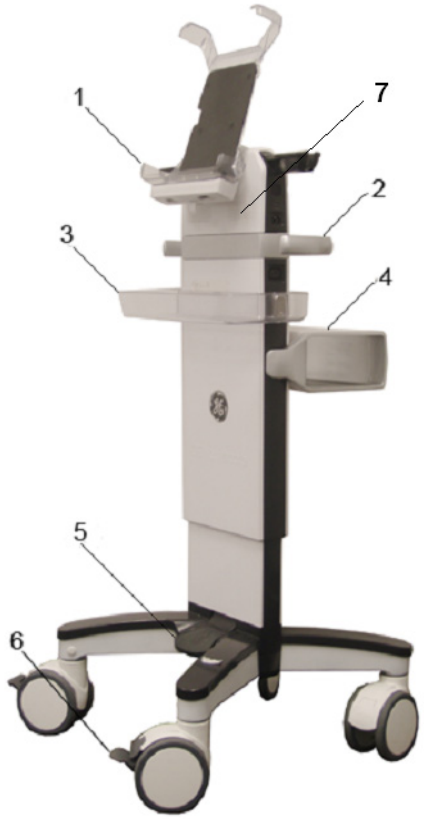


Figure 2-3. Docking Cart

1. Docking
2. Cart Handle
3. Plastic shelf - for accessories and disposals
4. Printer shelf (option)
5. Pedal
6. Wheels brake pedal - for Cart brakes
7. Stereo speaker

Battery

The lithium ion battery provides power when an AC power source is not available. A battery in the battery bay is standard with the Venue 40. Lithium ion batteries last longer than conventional batteries and do not require replacement as often. You can expect one hour of battery life with a single fully charged battery.

The lithium ion technology used in your Venue 40's battery is significantly less hazardous to the environment than the lithium metal technology used in some other batteries (such as watch batteries). Used batteries should not be placed with common household waste products. Contact local authorities for the location of a chemical waste collection program nearest you.

NOTE: The battery is designed to work with Venue 40 systems only. Only use the batteries authorized by GE.

- The battery has a safety device. Do not disassemble or alter the battery.
- Charge the batteries only when the ambient temperature is between 0 and 40 degrees C (32 and 104 degrees F) and discharge the batteries between 0 and 40degrees C (32 and 104 degrees F).
- Do not short-circuit the battery by directly connecting the negative terminals with metal objects.
- Do not heat the battery or discard it in a fire.
- Do not expose the battery to temperature over 50 degrees C (122 degrees F). Keep it away from fire and other heat sources.
- Do not charge the battery near a heat source, such as a fire or heater.
- **Do not leave the battery in direct sunlight.**
- Do not pierce the battery with a sharp object, hit it, or step on it.
- Do not use a damaged battery.
- Do not solder a battery.
- Do not connect the battery to an electrical power outlet.

Battery (continued)

If the Venue 40 is not being used on a monthly basis, the battery needs to be removed during the lengthy non-use period.

To avoid the battery bursting, igniting, or fumes from the battery causing equipment damage, observe the following precautions:

- Do not immerse the battery in water or allow it to get wet.
- Do not put the battery into a microwave oven or pressurized container.
- If the battery leaks or emits an odor, remove it from all possible flammable sources.
- If the battery emits an odor or heat, is deformed or discolored, or in a way appears abnormal during use, recharging or storage, immediately remove it and stop using it. If you have any questions about the battery, consult GE or your local representative.
- Short term (less than one month) storage of battery pack:
    - Store the battery in a temperature range between 0 degrees C (32 degrees F) and 50 degrees C (122 degrees F).

Battery (continued)

- Long term (3 months or more) storage of battery pack:
  - Store the battery in a temperature range between -20 degrees C (-4 degrees F) and 45 degrees C (113 degrees F)
  - Upon receipt of the Venue 40 and before first time usage, it is highly recommended that the customer performs one full discharge/charge cycle. If the battery has not been used for >2 months, the customer is recommended to perform one full discharge/charge cycle. It is also recommended to store the battery in a shady and cool area with FCC (full current capacity).
  - One Full Discharge/Charge Cycle Process:

    1. Full discharge of battery to let the Venue 40 automatically shut down.

    2. Charge the Venue 40 to 100% FCC (full current capacity).

    3. Discharge of Venue 40 for complete shut down (takes one hour for discharge).
  - When storing packs for more than 6 months, charge the pack at least once during the 6 month timeframe to prevent leakage and deterioration in performance.
- Use only GE recognized batteries.

Battery (continued)

View current battery status

When the system is running, there is a battery icon in the upper right corner of the screen. It's current capacity in percent appears "current capacity (unit: percent)".

Figure 2-4. Battery icon

When the battery is charging

If the battery is charging, the following icon displays:

Figure 2-5. Battery charging

Battery power low warning

If the battery is in use and the battery power is low, the battery icon becomes orange, with a warning message: "The battery is critical, the system will shutdown in one minute." displays.

Figure 2-6. Low battery power warning

AC power only/Battery charging complete

If the battery is fully charged or the system is using AC Power only, the following icon displays:

Figure 2-7. AC Power only or battery charging complete

Battery (continued)

Battery Replacement

1. Lay the Venue 40 face down on a stable, smooth surface to avoid scratching the LCD.
2. Pull off the battery cover and remove the battery pack.

Figure 2-8. Battery replacement

NOTE: Battery can be replaced on Docking Station/Docking Cart.

View battery capacity

Press the button on the battery; a green LED indicates the remaining battery capacity.

Figure 2-9. View battery capacity

Peripheral/Accessory Connection

Peripheral/Accessory Connector Panel of Docking Station/Cart

Venue 40 System peripherals and accessories can be properly connected using the side panels of the Docking Station/Cart.

CAUTION

Each outer (case) ground line of peripheral/accessory connectors are **Earth Grounded**.

Signal ground lines are Not Isolated.

CAUTION

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

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

Peripheral/Accessory Connector Panel of Docking Station/Cart (continued)

Figure 2-10. Docking Connector Panel

Docking Station provides DC power to Venue 40 and charging function to battery.

1. Probe Holder (Holder on each side)
2. AC power Indicator
3. Battery charging indicator
4. AC Power input socket
5. Sync USB Port (for PC connection)
6. Standard USB Port (for peripherals connection)
7. DVI port (for external monitor connection)
8. LAN port

CAUTION

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

Peripherals Connection

1. Insert the SD Card with the labeled side facing the front to the SD Card Socket on top of the system.

Figure 2-11. Insert SD Card

2. Connect the USB cable from the printer to the USB port of Docking Station/Cart. Connect the printer's power cord and power on the printer.

Figure 2-12. B/W Printer Connection

Peripherals Connection (continued)

3. Connect the USB Memory Stick to the USB port of Docking Station/Cart.

Figure 2-13. USB Memory Stick Connection

4. Connect the external monitor to the DVI port of the Docking Station/Cart.

Figure 2-14. DVI Connection

Peripherals Connection (continued)

5. Connect the Wireless Network Card to the USB port of the Docking Station/Cart.

Figure 2-15. Wireless Network Card Connection

6. Connect the footswitch to the USB port of the Docking Station/Cart (R3.x.x only)

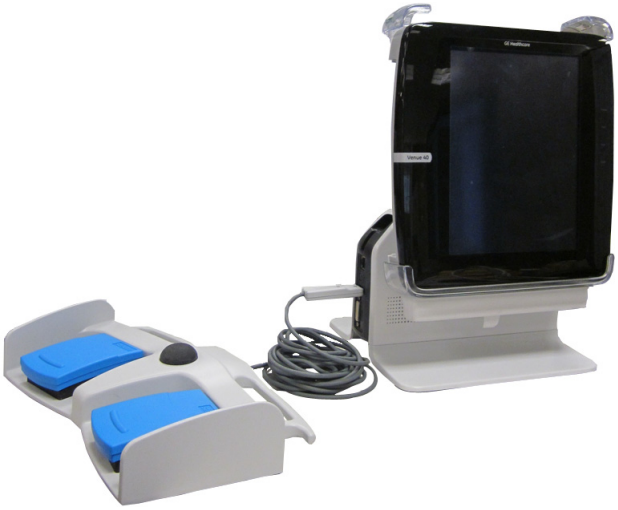


Figure 2-16. Footswitch Connection

Mount Venue 40 to Docking Station/Cart

1. Place the Docking Station and system on a stable surface.
2. Carefully pick up the system. Align the port on the Venue 40 with the docking port and carefully push into place.

Figure 2-17. Mount to Docking Station/Docking Cart

Mount Venue 40 to Docking Station/Cart (continued)

3. Press the locking lever down until it locks in place.

Figure 2-18. Mount to Docking Station/Docking Cart

Release Venue 40 from the Docking Station/Cart

1. Pull the release trigger. The locking lever pops up and the Venue 40 can be removed.

Figure 2-19. Release system from Docking Station/Docking Cart

WARNING

Please make sure to turn off the Venue 40 before releasing it from the Docking Station/Cart, or it may crash.

System Positioning/Transporting

Moving the System

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

Before moving the system

1. Shut down the Venue 40.
2. Unplug the Docking Station/Docking Cart power cord (if the system is plugged in).
3. Release the Venue 40 from the Docking Station/Docking cart.
4. Store all probes in their original cases or in soft cloth or foam to prevent damage.
5. Store sufficient gel and other essential accessories in the special storage case.

When moving the system

CAUTION

To avoid possible injury and equipment damage:

- Do not let the system strike walls or door frame.
- Limit movement to a slow careful walk.

NOTE: When moving the Docking Cart, be sure the path is clear. Limit movement to a slow careful walk.

NOTE: Make sure the console is locked in place to avoid damaging the system due to a fall.

NOTE: Utilize additional care when moving on steep inclines (>5 degrees) or loading into vehicle for transport.

Cable management

WARNING

To avoid the cables catching on external devices, please ensure the power cord and probe cables are wrapped properly, not extended beyond sides of Docking Cart and out of the way for portables.

- Place probes securely in proper probe holders. Wrap the probe cables around the probe hooks on sides of the Docking Cart.
- Place the probe connector which is not used in the disposal shelf.
- Wrap the power cord around the power cable hook at the rear panel of the Docking Cart.

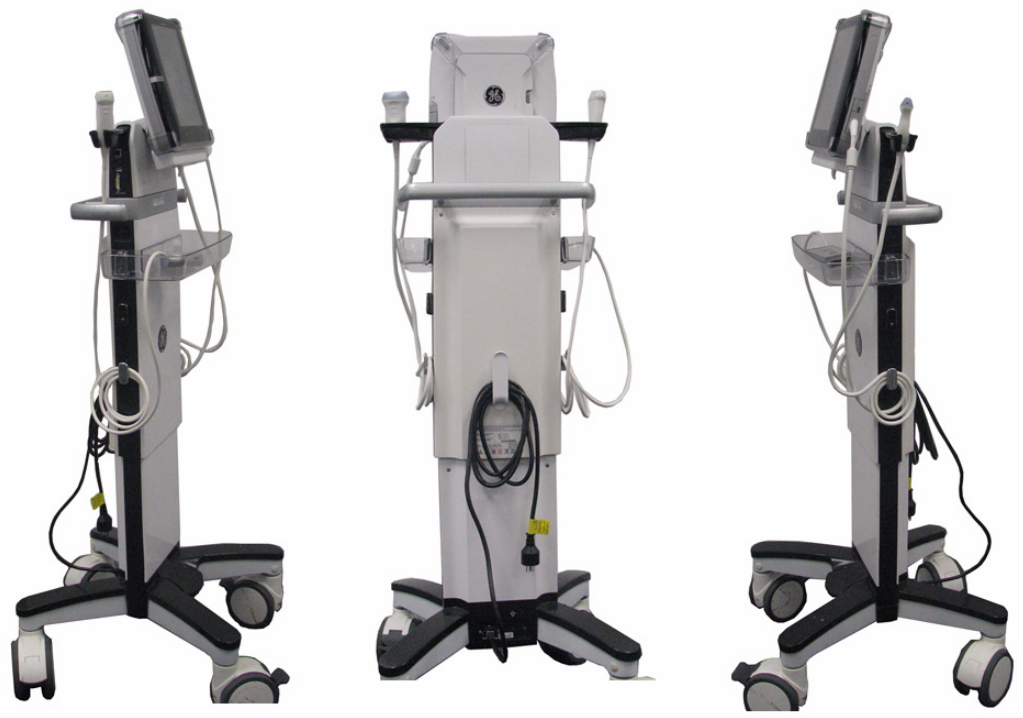


Figure 2-20. Cable management

Transporting the System

Use extra care when transporting the system using vehicles. In addition to the instructions used when moving the system (See ‘Moving the System’ on *page 2-21 for more information.*), also perform the following:

1. Ensure that the system is firmly secured while inside the vehicle.
2. Secure system with straps or as directed otherwise to prevent motion during transport.

Attaching the Security Cable

To ensure that the Venue 40 is not removed from the premises, please attach the security cable.

1. Wrap the cable around an imovable object.
2. Insert the lock into the security slot at the back side of the Venue 40.

Figure 2-21. Insert the security lock

NOTE: Be sure that the security lock is rotated to the unclocked position.

Attaching the Security Cable (continued)

3. Rotate the key to the locked position.

Figure 2-22. Security cable attached

Powering the System

Connecting and Using the System

To connect the Docking Station/Docking Cart to the electrical supply:

1. Ensure that the wall outlet is of the appropriate type.
2. Push the power plug securely into the wall outlet.

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

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

DO NOT use the Venue 40 on plastic foam, paper or similar type surfaces. The system could overheat and slow down. Ensure that the Venue 40 is on a sturdy, heat resistant surface.

To avoid risk of fire, the system power must be supplied from a separate, properly rated outlet. See ‘Before the system arrives’ on *page 2-3 for more information.*

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

To help assure grounding reliability, connect to a “hospital grade” or “hospital only” grounded power outlet.

Connecting and Using the System (continued)

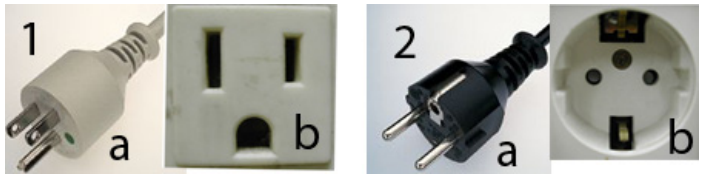


Figure 2-23. Example Plug and Outlet Configurations

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

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

Power On

Press the ***Power On/Off*** switch on top of the system to turn on/off the system.

Figure 2-24. Power On/Off Switch Location

LED

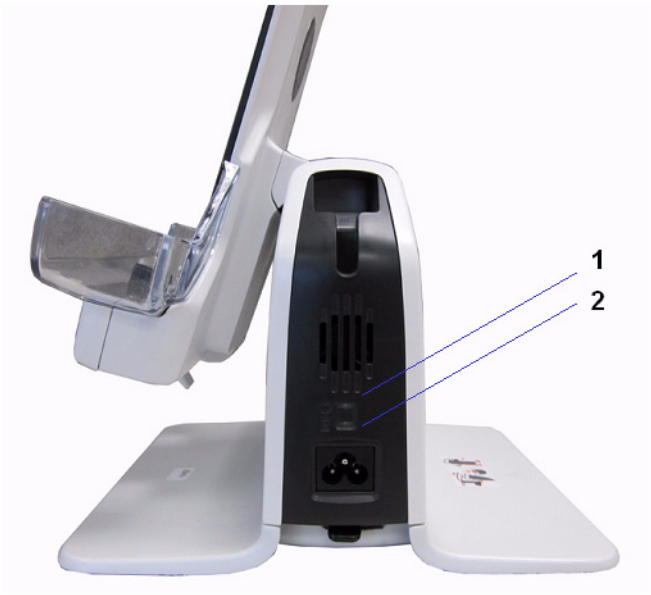


Figure 2-25. LED Indicators (Docking station/Cart)

Figure 2-26. LED Indicators(Venue 40)

1. Indicates AC power status. When the Docking Station/Cart is connecting to AC power, the LED is lit.

   Color: Green

2. Indicates battery status. When the battery is charging, the LED is lit.

   Color: Green

3. Indicates power status. After pressing the Power On/Off switch, the system power is on and this LED is lit.

   Color: Green

Power Off the System

To power off the system:

1. Lightly press the **Power On/Off** switch on top 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.

The shutdown process takes a few seconds.

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

2. Disconnect the probes.

   Clean or disinfect all probes as necessary. Store them in their shipping cases to avoid damage.

3. Disconnect AC power cord from the power outlet.

NOTE: Disconnect the AC adapter plug on the Docking cart/Docking Station from the outlet to ensure the system is disconnected from the power source.

Adjusting the Display Monitor

Tilt LCD monitor

The LCD monitor position on the Docking Station/Cart can be adjusted for easy viewing.

- Tilt the LCD monitor for the optimum viewing angle. The maximum angle is 45.

Figure 2-27. LCD Monitor adjustment

Adjusting the Docking Cart

- To adjust the height of Docking Cart, hold the handle with both hands, step on the pedal and adjust the height.

Figure 2-28. Adjust Docking Cart height

CAUTION

When the cart handles are used for power cable management, the sudden raising of the cart to a higher position may cause the AC plug to break.

CAUTION

When adjusting the cart while scanning, the power cord and wheels may become entangled causing cable damage.

CAUTION

Damage to the probe cable may result if the brake pedal catches the cable and pulls it tight against the base leg. This puts stress on the probe and connector while in the holder.

Brightness

Adjusting the LCD monitor's brightness is one of the most important factors for proper image quality.

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. Click **Patient**, select **Utility**, select **Brightness**.

NOTE: The brightness of the LCD monitor's Brightness should be set first. Once set, this should not be changed unless the brightness of your scanning environment changes.

Probes

Introduction

Only use approved probes.

All imaging probes can be connected into the probe port of the Venue 40.

Refer to the *Probes* chapter.

Selecting probes

- Always start out with a probe that provides optimum focal depths and penetration for the patient size and exam.
- Begin the scan session using the default Power Output setting for the probe and exam.

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.

To connect a probe:

1. Place the probe's carrying case on a stable surface and open the case.
2. Carefully remove the probe and unwrap the probe cord.
3. DO NOT allow the probe head to hang free. Impact to the probe head could result in irreparable damage.

   Inspect the probe before and after each use for damage or degradation to the housing, strain relief, lens, seal 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. Align the connector with the probe port and carefully push into place.

Figure 2-29. Connect probe to Venue 40

Connecting the Probe (continued)

5. Carefully position the probe cord so it is free to move and is not resting on the floor.
6. When the probe is connected, it is automatically activated.

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:

- Do not bend the cable acutely

Deactivating the Probe

When deactivating the probe, the probe is automatically placed in standby mode.

To deactivate a probe:

1. Ensure the Venue 40 is in freeze mode. If necessary, press the ***Freeze*** key.
2. Gently wipe the excess gel from the face of the probe.
3. Carefully slide the probe toward the probe holder on the docking station. Ensure that the probe is placed gently in the probe holder.

Disconnecting the Probe

1. Press to pop up the connector locking lever.

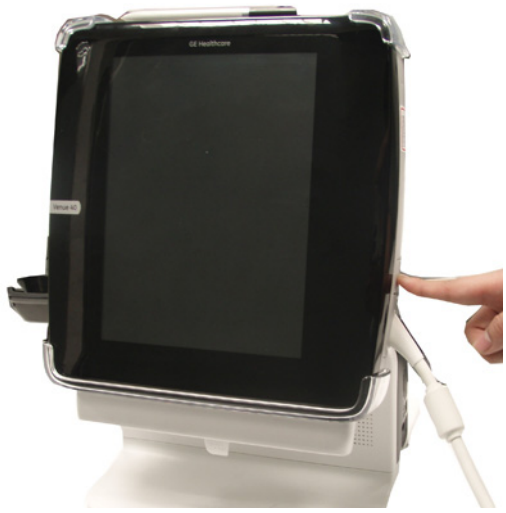


Figure 2-30. Pop up connector locking lever

2. Pull the probe and connector straight out of the probe port.

Figure 2-31. Disconnect probe from Venue 40

3. Carefully slide the probe and connector away from the probe port.
4. Ensure the cable is free.
5. Be sure that the probe head is clean before placing the probe in its storage box or a wall hanging unit.

Transporting Probes

When transporting a probe a long distance, store it in its carrying case.

Storing the Probe

It is recommended that all probes be stored in the provided carrying case or in the wall rack designed for probe storage.

1. First place the probe connector into the carrying case.
2. Carefully wind the cable into the carrying case.
3. Carefully place the probe head into the carrying case. DO NOT use excessive force or impact the probe head.

Stylus

Precautions


CAUTION

Do not apply any excessive pressure during operation, which may shorten the life of the stylus. The recommended tip force during operation is 4.90N max. While the stylus is not in use, do not keep the tip pressed.


CAUTION

Do not use or store the stylus in a place where excessive changes in temperature may occur such as in a car under direct sunlight.


CAUTION

Do not use or store the stylus in moisture and humid environments. If any water enters the stylus or condensation occurs, it may cause the stylus to malfunction.

Do not locate the stylus close to a magnet, it will cause the stylus to malfunction.


CAUTION

Do not subject the stylus to shock or vibration. If the stylus is subjected to repeated dropping, it may cause the stylus to malfunction or deteriorate the performance of tip feel. Do not keep the tip switch pressed while the stylus is not in use.


CAUTION

Do not attempt to disassemble the stylus. Disassembling the stylus may change the calibration setting or shorten lifecycle of the stylus.


CAUTION

Do not use an excessive amount of violate liquids such as alcohol for the purpose of cleaning or disinfection.

Using stylus

Stylus is used for touch panel operation.

Use the stylus to select the menu and controls shown on the screen.

Attaching the stylus to the system

The stylus can be attached to the system,

1. Thread the looped end of the stylus strap through the stylus strap post on side of the Venue 40.

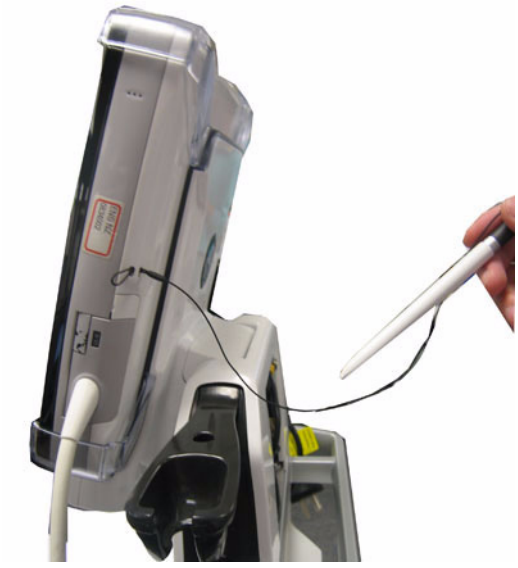


Figure 2-32. Connect stylus to Venue 40

Attaching the stylus to the system (continued)

2. Thread the stylus through the loop.

Figure 2-33. Thread through loop

3. Place the stylus on the top of the system or in the hole of probe holder.

Figure 2-34. Stylus attached to Venue 40

CAUTION

To avoid damaging the system due to a fall, never lift/hold the system with the stylus

Operator Controls

Control Panel Map

Controls are grouped together by function for ease of use.

Figure 2-35. Venue 40 Control panel

1. **Freeze** used to stop the acquisition of ultrasound data and freeze the image in system memory. Pressing Freeze a second time continues live image data acquisition.
2. **Save** used to save the image or cine loops.
3. **Gain** used to 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.
4. **Depth** used to control the image display depth.

NOTE: There is only 1 depth key in R1.x.x system.

Control Panel Map (continued)

5. Five function keys, located at bottom of the system, vary according to different modes of operation.

Use only fingers, gloved fingers or stylus to operate on the system, never use any sharp tools to avoid scratching the LCD.

Do NOT use metal tools or probe cables to touch hard keys, it may result in mis-operation.

Monitor Display

Monitor Display

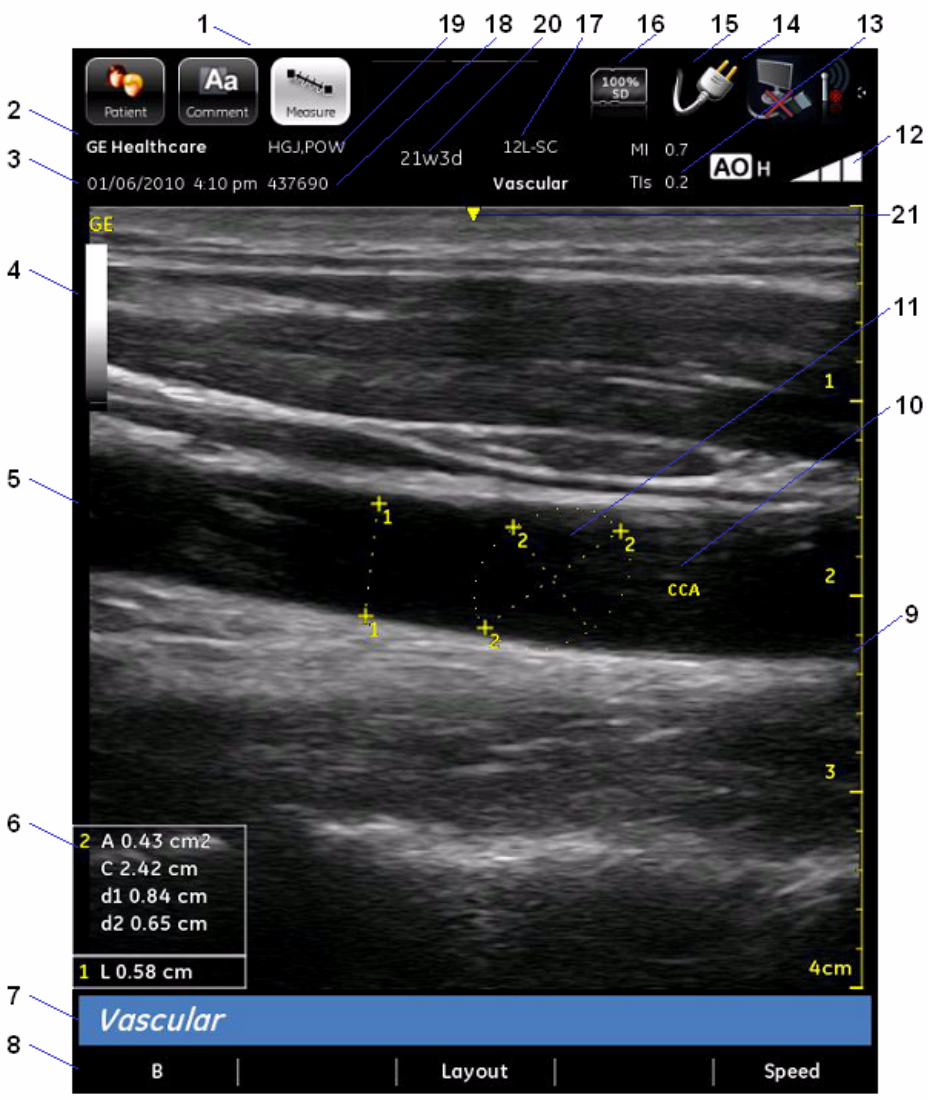


Figure 2-36. Monitor Display

Monitor Display (continued)

1. Function selection icons
2. Institution/Hospital Name
3. Date, Time
4. Gray/Color bar
5. Image area
6. Measurement result window
7. Package
8. Image controls
9. Depth scale
10. Annotation
11. Measurement calipern
12. Gain
13. Acoustic output information
14. Network connection status*
15. Battery status
16. Storage device status
17. Probe and application
18. Patient ID
19. Patient name
20. Gestational age**
21. Center line mark**

*NOTE: R2.0.x, R3.x.x only
**NOTE: R3.x.x only

Chapter 3

Performing an Exam

Describes how to perform an exam, how to annotate, measure and store the images.

Performing an Exam

Overview

An typical exam includes the following:

- Begin a new exam
- Image scanning
- Measurements
- Annotations
- Image management

Begin a new exam

Introduction

Begin an exam by entering new patient information.

The operator should enter as much information as possible, such as:

1. Patient ID
2. Patient name

The patient's name and ID number is retained with each patient's image and transferred with each image during archiving or hard copy printing.

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.

Beginning a New Patient

Select **Patient** using the stylus to display the Patient screen on the monitor.

Enter new patient information. Exit patient screen to begin the exam. At the end of each exam, all patient data, annotations, measurement and image will be stored in the patient files.

NOTE: The patient ID can be typed with the soft keyboard or automatically created by pressing AutoID.

*NOTE: You can also scan without entering any patient data.**See 'Scanning without entering any patient data' on page 3-7 for more information.*

Patient Screen

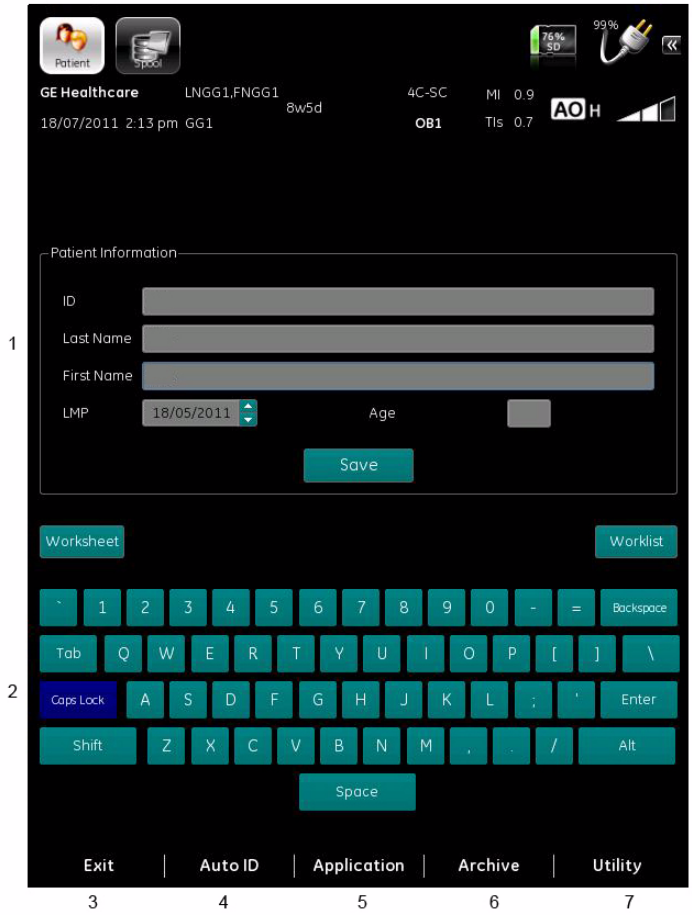


Figure 3-1. Patient Screen

1. Patient Information
2. Soft Keyboard
3. Exit
4. Auto ID
5. Application
6. Archive
7. Utility

Patient Screen (continued)

The Patient Screen details are:

1. Patient Information
   - Patient ID, select Auto ID to automatically generate patient ID.

NOTE: Use only alphanumeric characters for the patient ID.

NOTE: Patient information cannot be saved without a patient ID.

   - 2nd ID

     2nd ID is used to add additional information of the patient, such as Citizen ID.

NOTE: To enable/disable 2nd ID field, go to Utility --> Setting.

   - Patient Name–Last Name and First Name

NOTE: Only use periods, spaces, dashes and alphanumeric characters for the Patient Name.

NOTE: The length of the Last Name and First Name should be no longer than 16 characters.

NOTE: Patient information can be highlighted and edited with stylus.

   - Save, select Save to save patient information
   - Worklist, select Worklist to select the desired patient from the worklist server.

NOTE: Worklist function is not available on software version R1.x.x.

   - Worksheet, select Worksheet to enter into worksheet page.

NOTE: Worksheet function is only available on OB1 and OB2/3 application on software version R3.x.x.

   - LMP: Last Menstrual Period; enter the date that the patient started her last menstrual period, the format is the same as system time format, which can be set in Utility -> General -> Time Format.

NOTE: LMP is only available on OB1 and OB2/3 application on software version R3.x.x.

   - Age: patient age

NOTE: Age is only available on OB1 and OB2/3 application on software version R3.x.x.

Patient Screen (continued)

2. Soft Keyboard - Select with stylus to type text.
3. Exit - Press to exit patient screen.
4. Auto ID - Press to generate patient ID automatically, select Application (if not automatically selected) and exit to live scan.
5. Application - Press to choose presets of different applications.
6. Archive - Press to view patient information and images under storage device.
7. Utility - Press to display the system configuration page.

Scanning a New Patient

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

1. Select **Patient**. The patient screen is displayed.
2. Fill in patient information.
3. Select Save to save the patient information. A specific patient folder is created under the storage device.

   Or

   Select Worklist to select the desired patient from worklist server.
4. Select the Application (if not automatically selected). Perform the exam.
5. Store data to patient files.

Scanning without entering any patient data

To scan a patient without entering any patient data:

1. Scan the patient and press Store to save images/videos.
2. Patient images are stored in the storage device, refer to 'Image Storage' on *page 3-80*

Image Scanning

B Mode

Intended Use

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

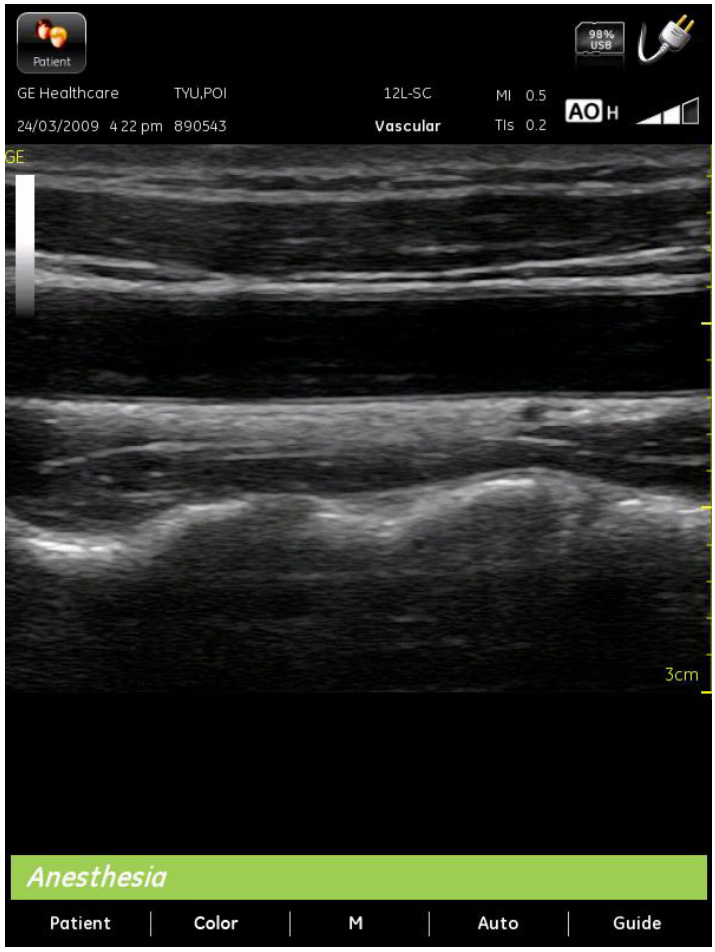


Figure 3-2. B-Mode

B-Mode Controls

Figure 3-3. B Mode Top Menu for R1.x.x and R2.0.x

Figure 3-4. B Mode Top Menu for R3.x.x

Table 3-1: B-Mode Controls

Controls	Affect on Image
Freeze	Freeze real-time scan and allows you to measure and print the image.
Store	Save the images or CINE loops to the storage device.
Gain	Makes images brighter or darker.
Depth	Press to increase or decrease scanning depth.
PDI/Color/M	Switch to PDI/Color Flow/M mode, different option for different packages.
Auto	Tissue image optimization ON/Off.
Guide	Show needle guides.
Mode*	Switch to PDI/Color Flow/M mode, different option for different packages.
B-Steer+*	Press to slant the B-Mode linear image left or right to get more information without moving the probe. The B-Steer+ function only applies to linear probes.
*NOTE: R3.x.x only	

M Mode (R2.0.x, R3.x.x only)

Intended Use

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

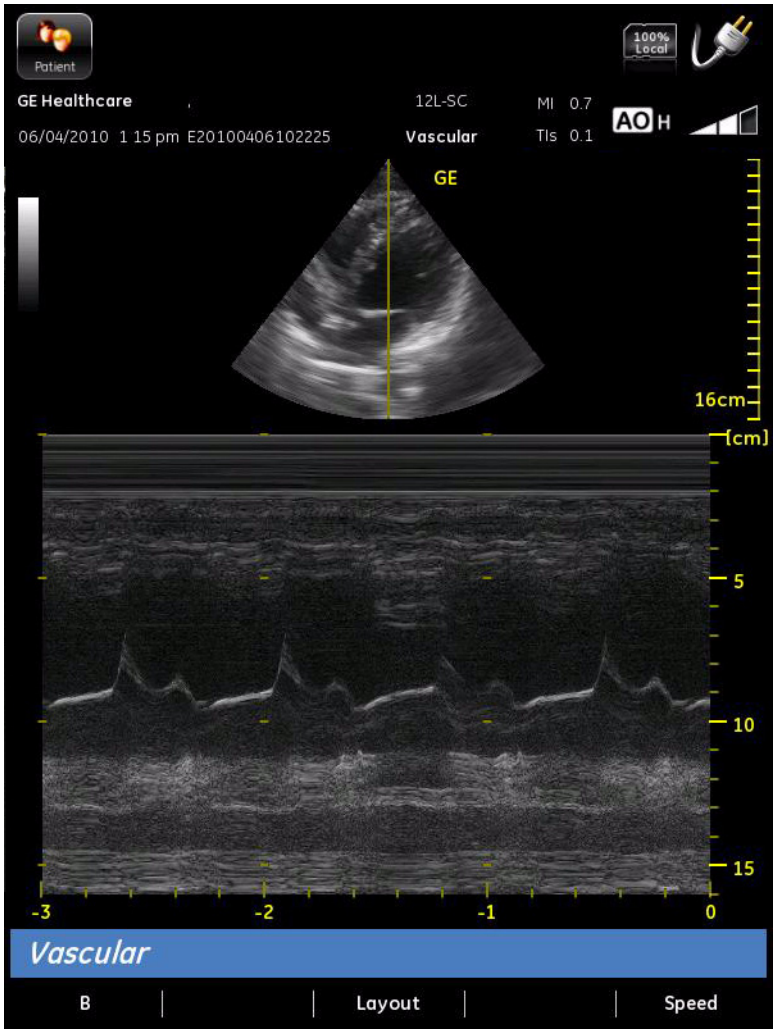


Figure 3-5. M-Mode

M Mode Controls

Figure 3-6. M Mode Top Menu

Table 3-2: M-Mode Controls

Controls	Affect on Image
B	Switch to B Mode.
Layout	Changes the horizontal/vertical layout between B-Mode and M-Mode.
Speed	Changes the speed at which the timeline is swept.

Color Flow Mode

Intended Use

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

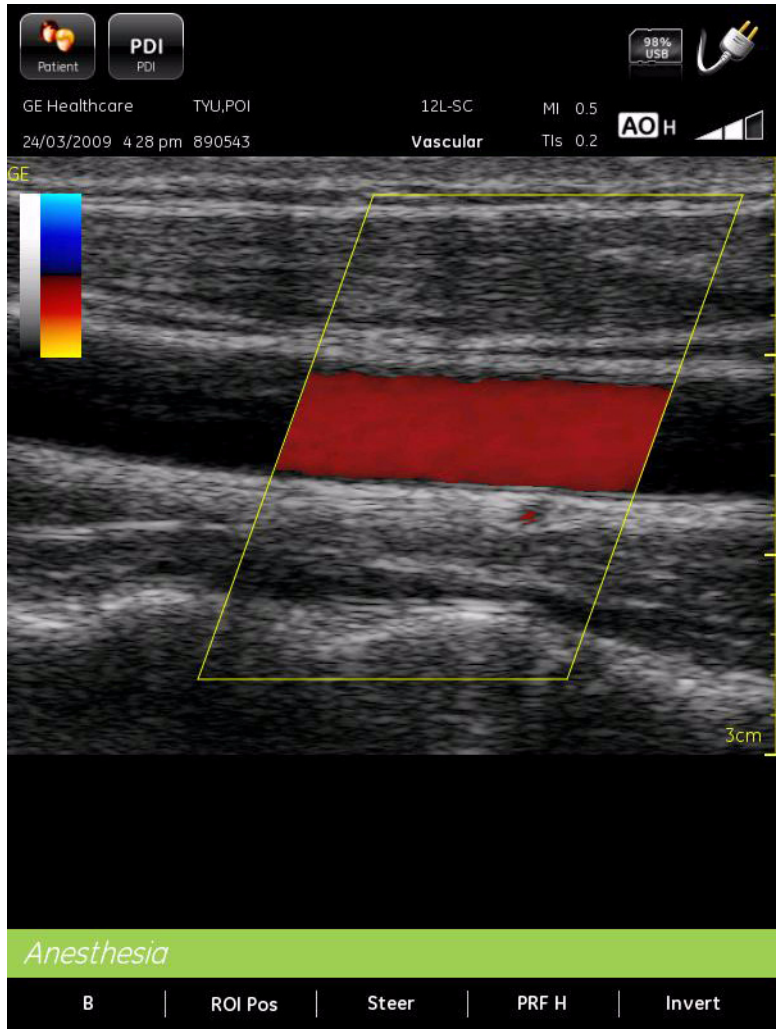


Figure 3-7. Color Flow Mode

Color Flow Mode Controls

Figure 3-8. Color Flow Mode Top Menu

Table 3-3: Color Flow Mode Controls

Controls	Affect on Image
B	Switch to B-Mode
PDI	Switch to PDI-Mode
ROI Pos*	Adjust the ROI position
Steer	Slant linear image to left/center/right, only available on linear probes
Invert	Lets you view blood flow from a different perspective
PRF H/M/L	Increases/decreases the PRF on the color bar
*NOTE: R2.0.x, R3.x.x only	

Power Doppler Imaging (PDI)

Intended Use

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.

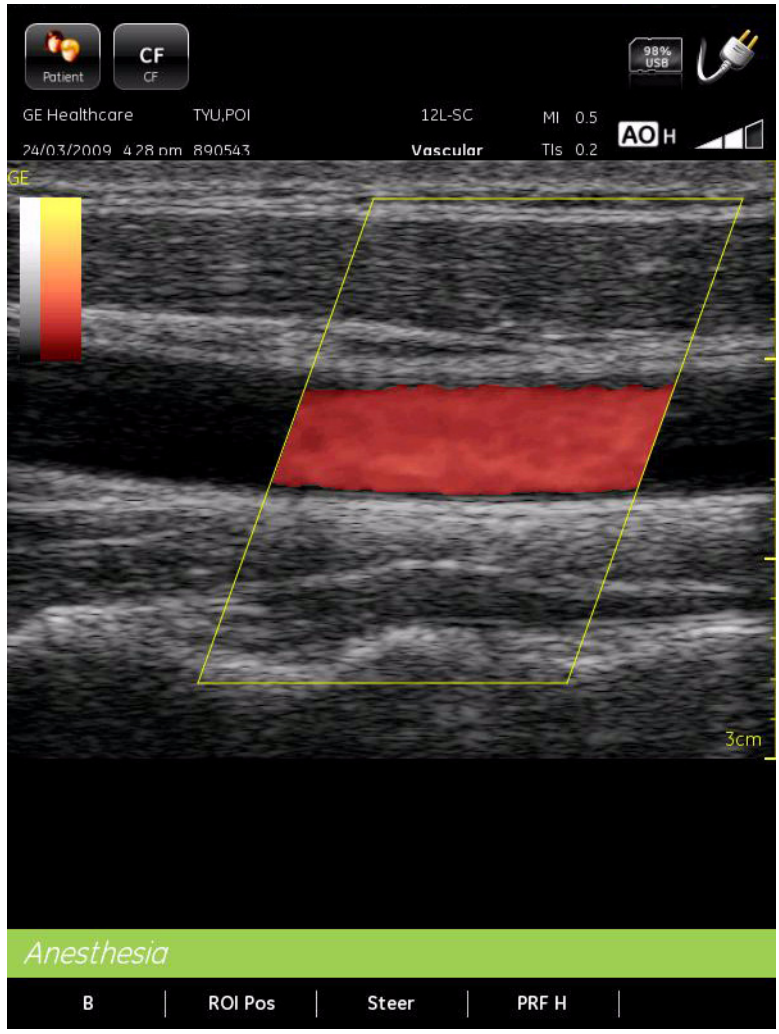


Figure 3-9. PDI Mode

PDI mode controls

Figure 3-10. PDI-Mode Top Menu

Table 3-4: PDI Mode Controls

Controls	Affect on Image
B	Switch to B-Mode
Color	Switch to Color Flow-Mode
ROI Pos*	Adjust the ROI position
Steer	Slant linear image to left/center/right, only available on linear probes.
PRF H/M/L	Increases/decreases the PRF on the color bar.
*NOTE: R2.0.x, R3.x.x only	

Measurements

Introduction

Measurements 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

B-Mode Measurements

Two basic measurements can be made in B-Mode.

- Distance
- Circumference and Area
  - Ellipse Method

NOTE: Measurements are only available in frozen mode.

NOTE: Circumference and Area measurement is not available on software version R1.1.x.

Distance Measurement

To make a distance measurement:

1. Press **Freeze**.
2. Select **Measure**, select **General** tab, select **Distance**.

Figure 3-11. Measurements: B-Mode

3. Select using the stylus to place the first caliper.

Distance Measurement (continued)

4. Select with the stylus to place the second caliper, the result displays in the measurement result window.

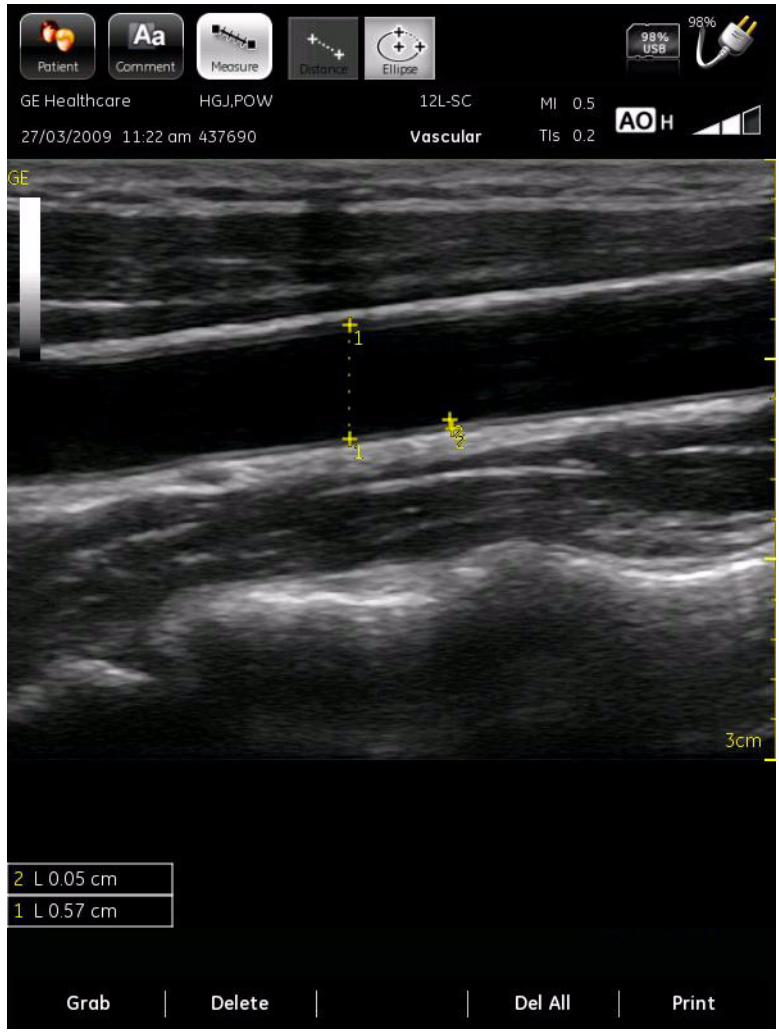


Figure 3-12. Distance Measurement: B-Mode

5. Measurements are numbered besides the calipers.

NOTE: Only 5 measurements are allowed at the same time.

Circumference and area (ellipse) measurement (R2.0.x, R3.x.x only)

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

1. Press **Freeze**.
2. Select **Measure**, select **General** tab, select **Ellipse**.
3. Select using the stylus to place the first caliper.
4. Select with the stylus to place the second caliper, the result displays in the measurement result window.

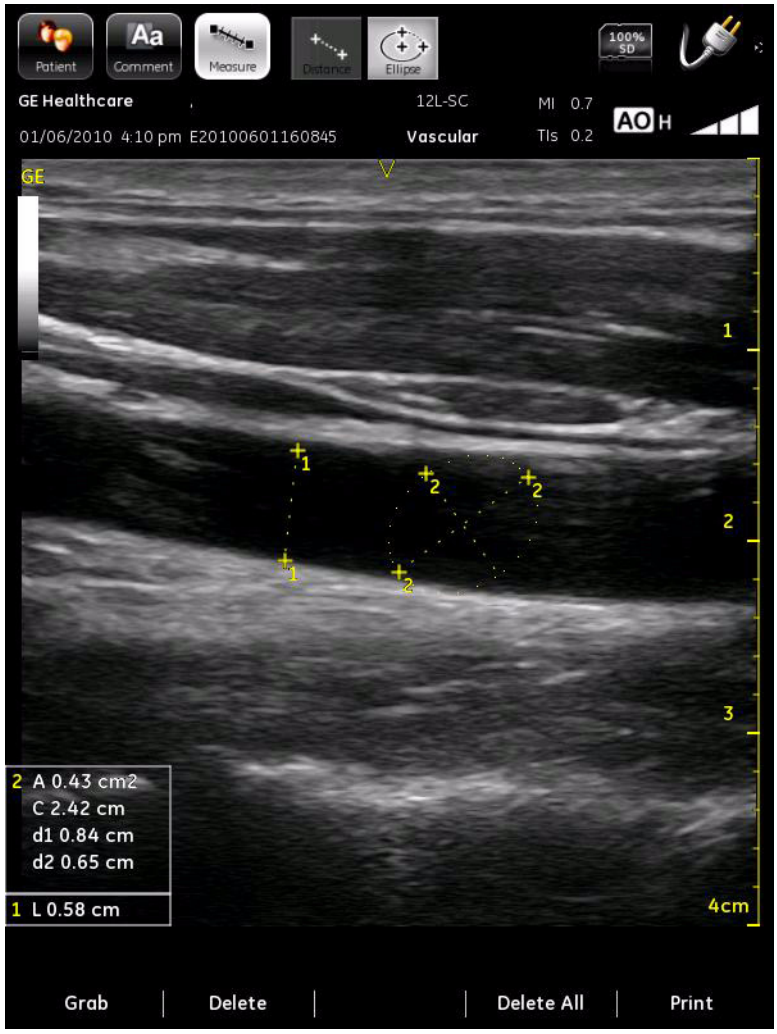


Figure 3-13. Ellipse Measurement: B-Mode

5. Measurements are numbered besides the calipers.

NOTE: Only 5 measurements are allowed at the same time.

Measurement Controls

Figure 3-14. Measurement controls

Table 3-5: Measurement Controls

Controls	Affect on Image
Grab	Toggle among measurements
Delete	Delete the selected measurement
Del All	Delete all measurements
Print	Print the image with measurements

M-Mode Measurements (R2.0.x, R3.x.x only)

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

- Tissue Depth (Distance)
- Heart Rate

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

To make a distance measurement:

1. Press **Freeze**.
2. For software version R2.0.x:
   Select **Measure**, select **Tissue Depth**, select  .
   For software version R3.x.x:
   Select **Measure**, select **General** tab, select **Depth**.

Figure 3-15. Measurements: M-Mode

Tissue Depth (continued)

3. Select using the stylus to place the first caliper.
4. Select with the stylus to place the second caliper, the result displays in the measurement result window.

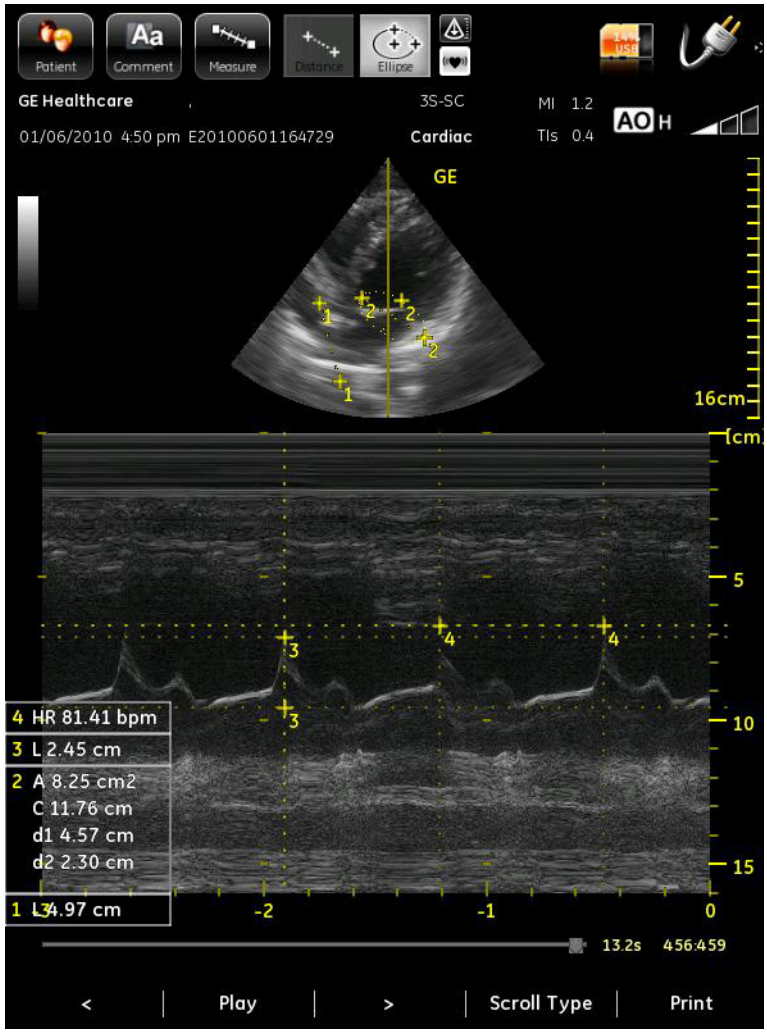


Figure 3-16. Measurement: M-Mode

5. Measurements are numbered besides the calipers.

NOTE: Only 5 measurements are allowed at the same time.

Heart Rate

To measure time and velocity between two points:

1. Press **Freeze**.
2. For software version R2.0.x:
   Select **Measure**, select **Heart Rate**, select  .
   For software version R3.x.x:
   Select **Measure**, select **General** tab, select **Heart Rate**
3. Select using the stylus to place the first caliper.

Heart Rate (continued)

4. Select with the stylus to place the second caliper, the result displays in the measurement result window.

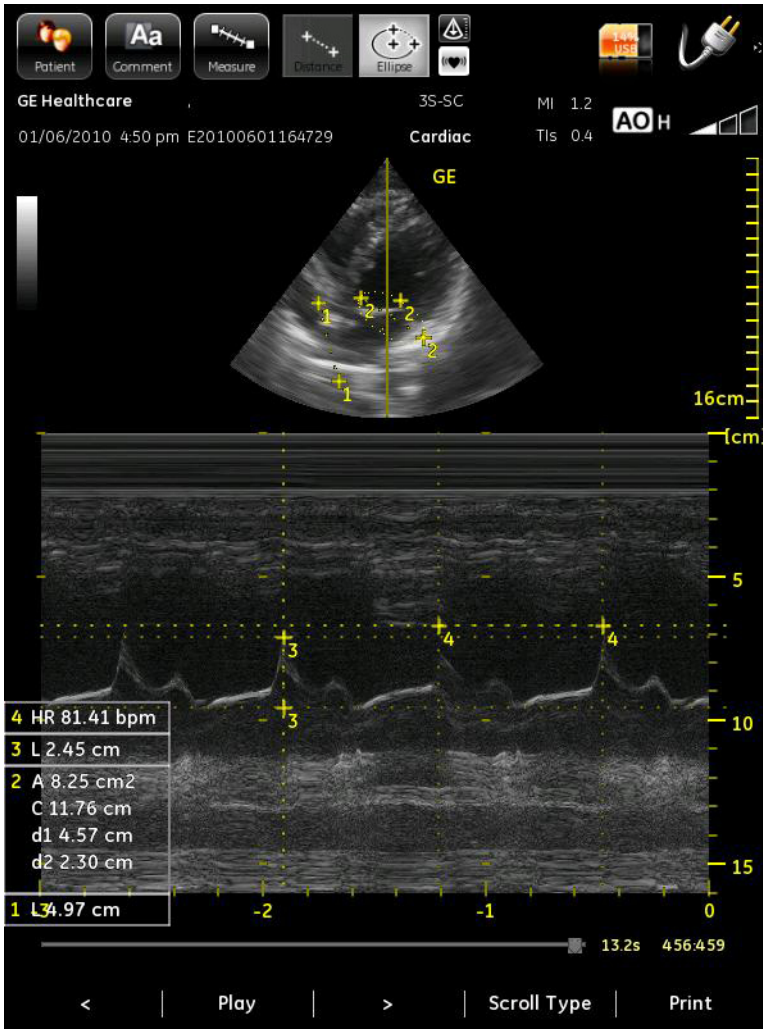


Figure 3-17. M-Mode Measurements - Heart Rate

5. Measurements are numbered besides the calipers.

NOTE: Only 5 measurements are allowed at the same time.

Measurement Controls

Figure 3-18. Measurement controls

Table 3-6: Measurement Controls

Controls	Affect on Image
Grab	Toggle among measurements
Delete	Delete the selected measurement
Del All	Delete all measurements
Print	Print the image with measurements

Obstetrics Measurements (R3.x.x only)

The following pages describe how to make OB measurements.

Out of Range - If the system indicates that a measurement is out of range (OOR), it means one of the following:

- The measurement is out of the normal range based on the gestational age that is calculated from the LMP. The system determines OOR from the ultrasound age compared to the gestational age. The gestational age is calculated from the last menstrual period.
- The measurement is outside of the range for the data used in the calculation. That means that the measurement is either less than or more than the range of measurements used to determine fetal age based on the measurement.

NOTE: Calculation formulas are listed in the Advanced Reference Manual.

NOTE: The Obstetrics measurement could be configured in Utility->Measure.

NOTE: Obstetrics measurement is only available on OB1 and OB2/3 application on software version R3.x.x.

CAUTION

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

Abdominal Circumference (AC)

USA ● Europe ● Tokyo ○ Osaka ● ASUM ●

To measure abdominal circumference, make an ellipse measurement.

1. Press **Freeze**.
2. Select **Measure**, select the **Obstetrics** tab, select **AC**.

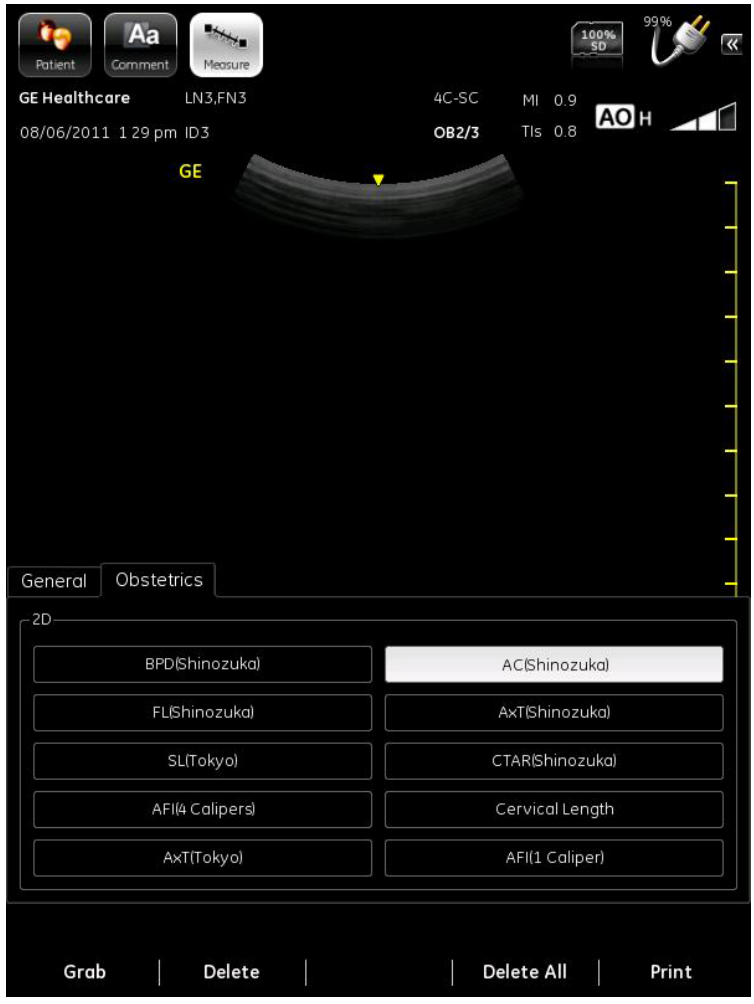


Figure 3-19. Measurements: Obstetrics

Abdominal Circumference (AC) (continued)

3. Select using the stylus to place the first caliper.
4. Select with the stylus to place the second and third caliper, the result displays in the measurement result window.

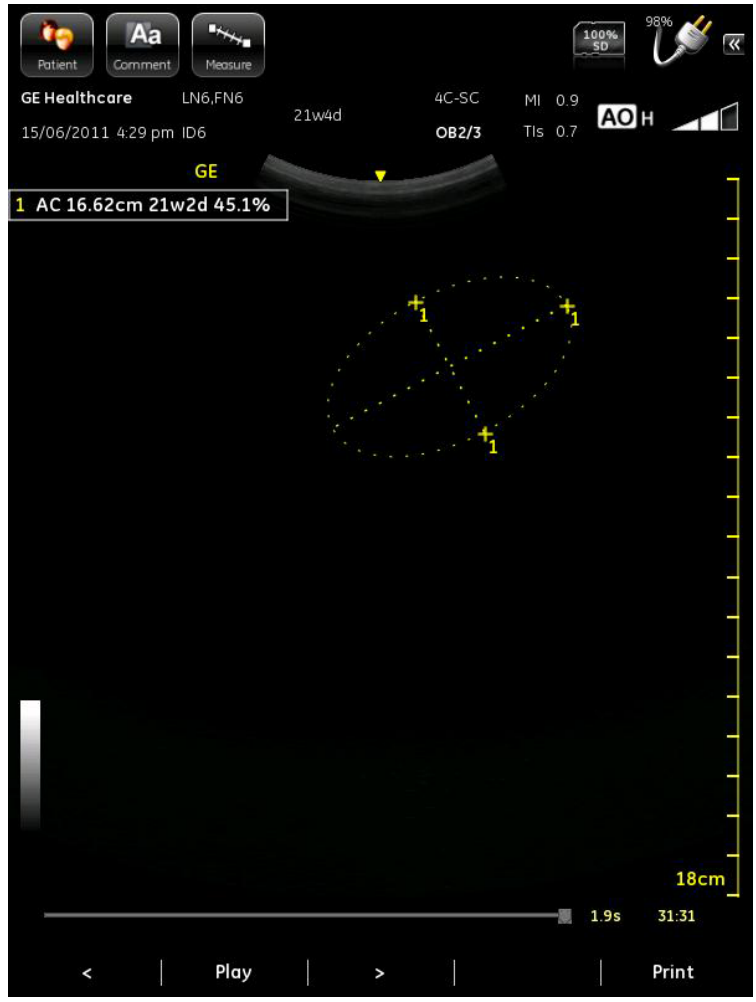


Figure 3-20. OB Measurement: AC

5. Measurements are numbered besides the calipers.

NOTE: Only 5 measurements are allowed at the same time.

Biparietal Diameter (BPD)

USA Europe Tokyo Osaka ASUM

To measure biparietal diameter, make one distance measurement:

1. Press **Freeze**.
2. Select **Measure**, select the **Obstetrics** tab, select **BPD**.
3. Select using the stylus to place the first caliper.
4. Select with the stylus to place the second caliper, the result displays in the Measurement result window.

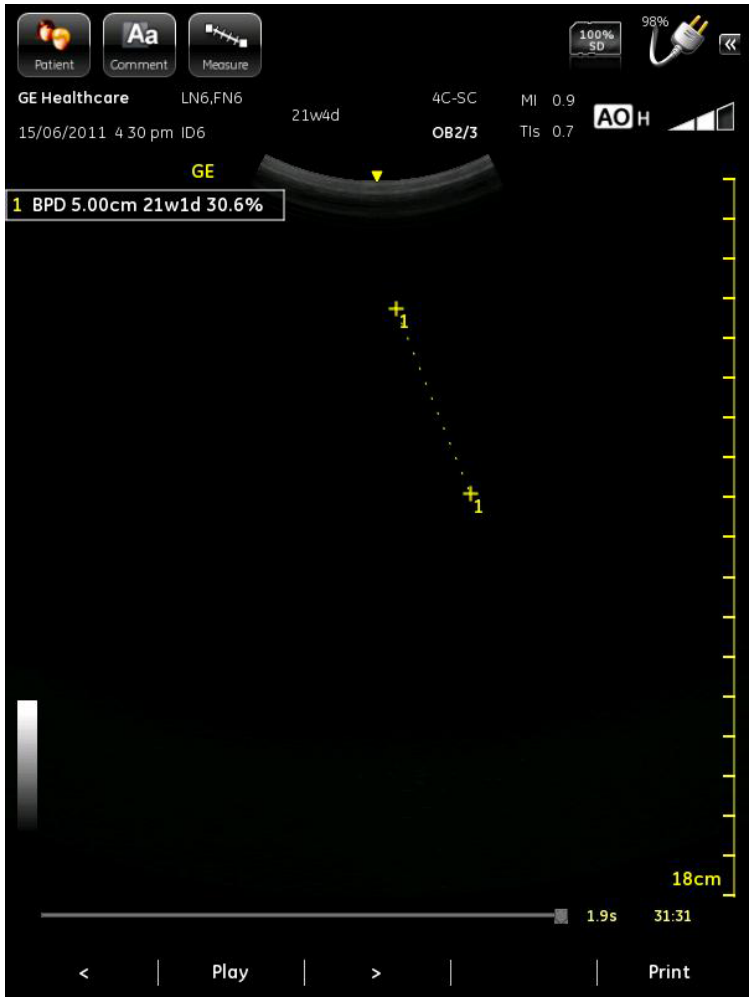


Figure 3-21. OB Measurement: BPD

5. Measurements are numbered besides the calipers.

NOTE: Only 5 measurements are allowed at the same time.

Femur Length (FL)

USA Europe Tokyo Osaka ASUM

To measure femur length, make one distance measurement:

1. Press **Freeze**.
2. Select **Measure**, select the **Obstetrics** tab, select **FL**.
3. Select using the stylus to place the first caliper.
4. Select with the stylus to place the second caliper, the result displays in the Measurement result window.

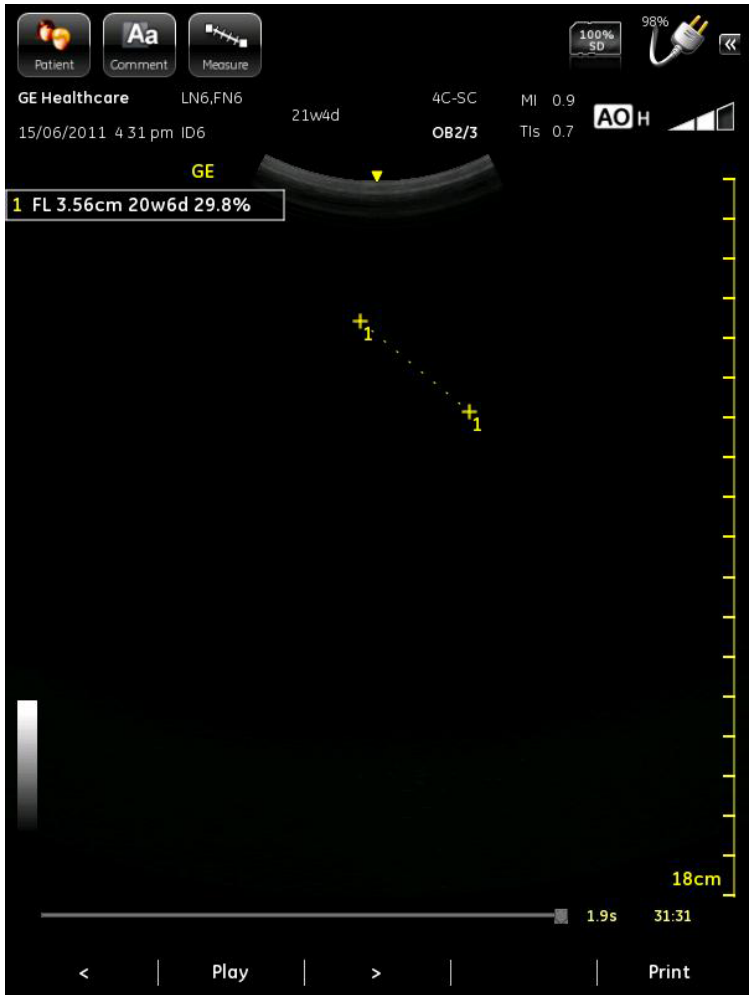


Figure 3-22. OB Measurement: FL

5. Measurements are numbered besides the calipers.

NOTE: Only 5 measurements are allowed at the same time.

Humerus Length (HL)

USA ● Europe ● Tokyo ○ Osaka ● ASUM ●

To measure humerus length, make one distance measurement:

1. Press **Freeze**.
2. Select **Measure**, select the **Obstetrics** tab, select **HL**.
3. Select using the stylus to place the first caliper.
4. Select with the stylus to place the second caliper, the result displays in the Measurement result window.

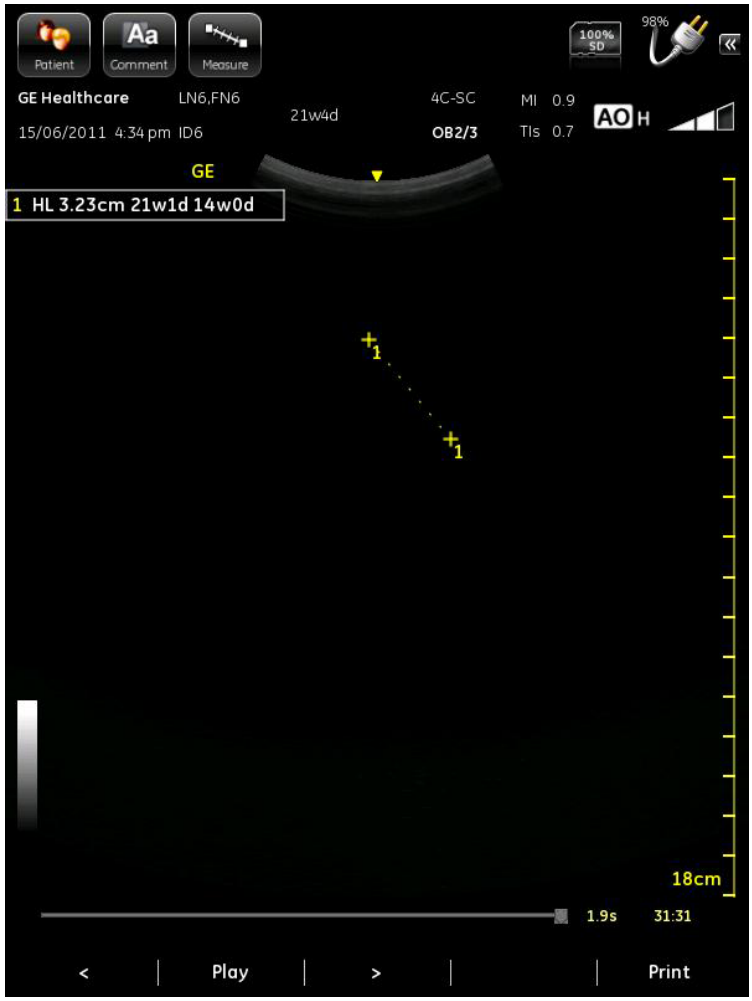


Figure 3-23. OB Measurement: HL

5. Measurements are numbered besides the calipers.

NOTE: Only 5 measurements are allowed at the same time.

Cervical Length

USA Europe Tokyo Osaka ASUM

To measure cervical length, make one distance measurement:

1. Press **Freeze**.
2. Select **Measure**, select the **Obstetrics** tab, select **Cervical Length**.
3. Select using the stylus to place the first caliper.
4. Select with the stylus to place the second caliper, the result displays in the Measurement result window.

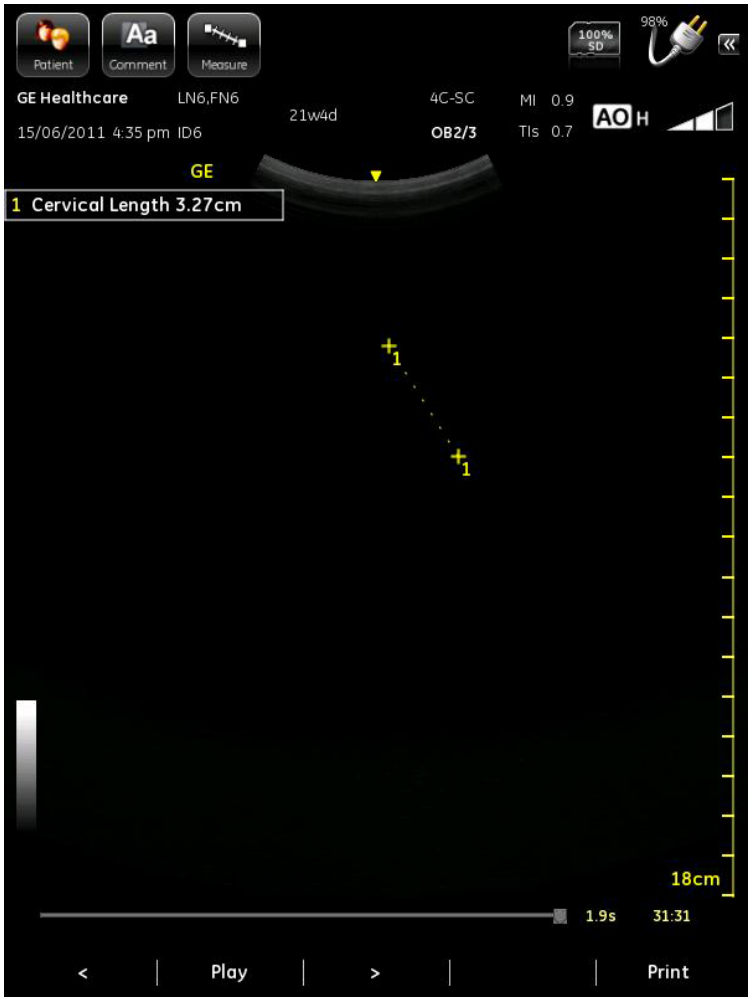


Figure 3-24. OB Measurement: Cervical Length

5. Measurements are numbered besides the calipers.

NOTE: Only 5 measurements are allowed at the same time.

Crown Rump Length (CRL)

USA Europe Tokyo Osaka ASUM

To measure crown rump length, make one distance measurement:

1. Press **Freeze**.
2. Select **Measure**, select the **Obstetrics** tab, select **CRL**.
3. Select using the stylus to place the first caliper.
4. Select with the stylus to place the second caliper, the result displays in the Measurement result window.

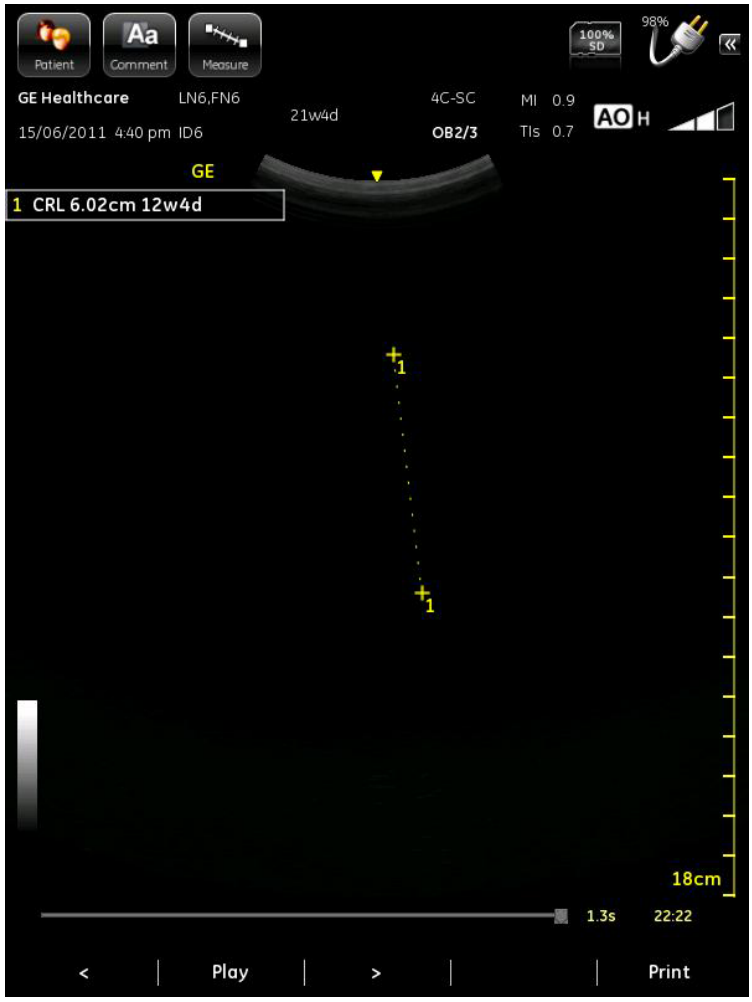


Figure 3-25. OB Measurement: CRL

5. Measurements are numbered besides the calipers.

NOTE: Only 5 measurements are allowed at the same time.

Gestational Sac (GS)

To calculate the gestational sac, make one or three distance measurements.

GS(1 Caliper)

To make a GS(1 Caliper) measurement:

1. Press **Freeze**.
2. Select **Measure**, select the **Obstetrics** tab, select **GS(1 Caliper)**.
3. Select using the stylus to place the first caliper.
4. Select with the stylus to place the second caliper, the result displays in the Measurement result window.

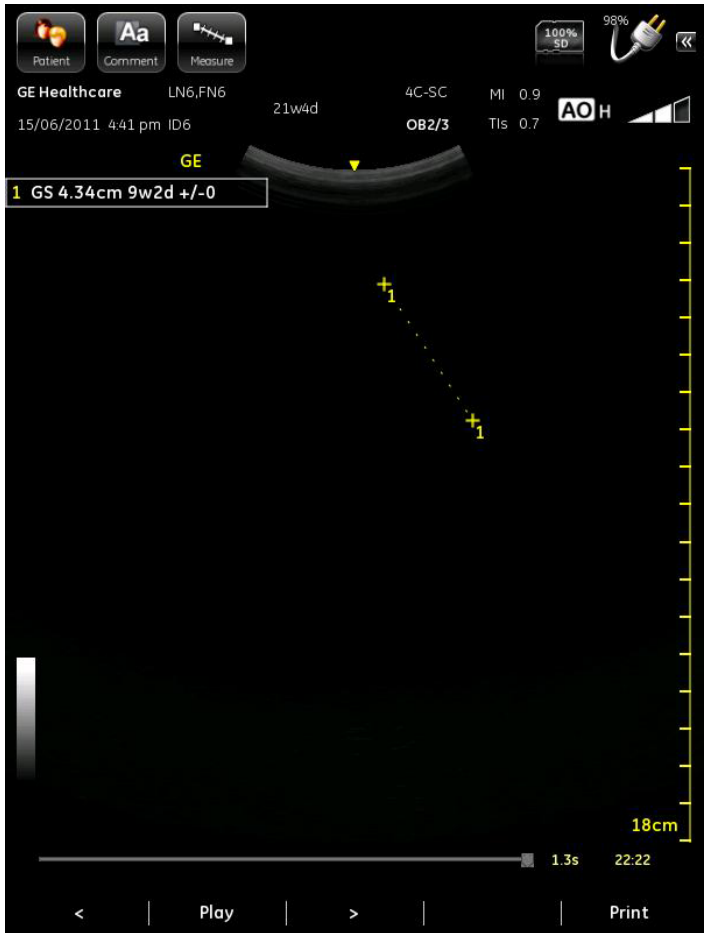


Figure 3-26. OB Measurement: GS -1 Caliper

5. Measurements are numbered besides the calipers.

GS(3 Calipers)

To make a GS(3 Calipers) measurement:

1. Press **Freeze**.
2. Select **Measure**, select the **Obstetrics** tab, select **GS(3 Calipers)**.
   a. Select using the stylus to place the first caliper.
   b. Select with the stylus to place the second caliper, the result displays in the Measurement result window.
3. To make the second and the third distance measurement, repeat steps a-b twice.

   After you complete the third distance measurement, the system displays the gestational sac measurement in the Result Window.

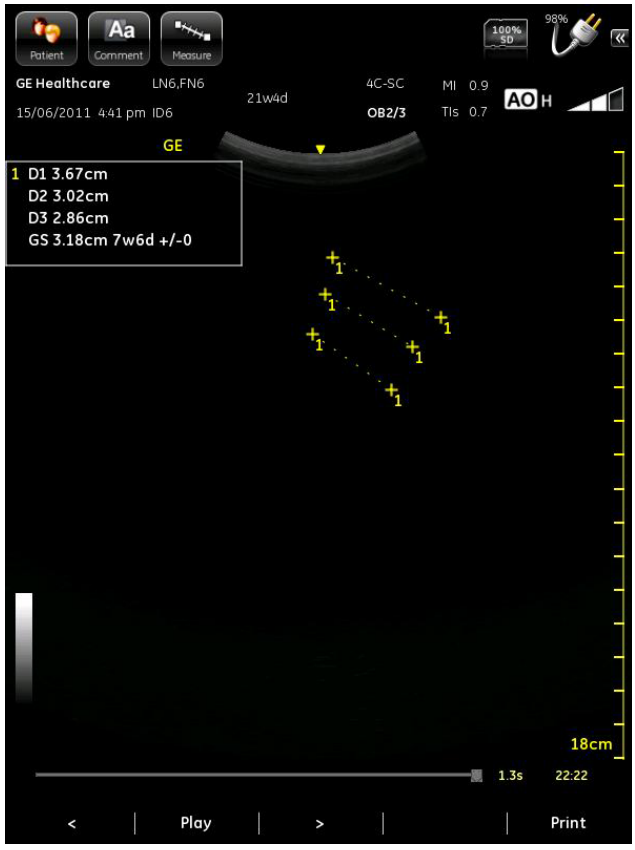


Figure 3-27. OB Measurement: GS-3 Calipers

4. Measurements are numbered besides the calipers.

NOTE: Only 5 measurements are allowed at the same time.

Head Circumference (HC)

To calculate head circumference, make an ellipse measurement.

1. Press **Freeze**.
2. Select **Measure**, select the **Obstetrics** tab, select **HC**.
3. Select using the stylus to place the first caliper.
4. Select with the stylus to place the second and third caliper, the result of HC and Occipitofrontal Diameter (OFD) measurement displays in the measurement result window.

NOTE: The OFD measurement result is only available on HC (Hadlock) measurement.

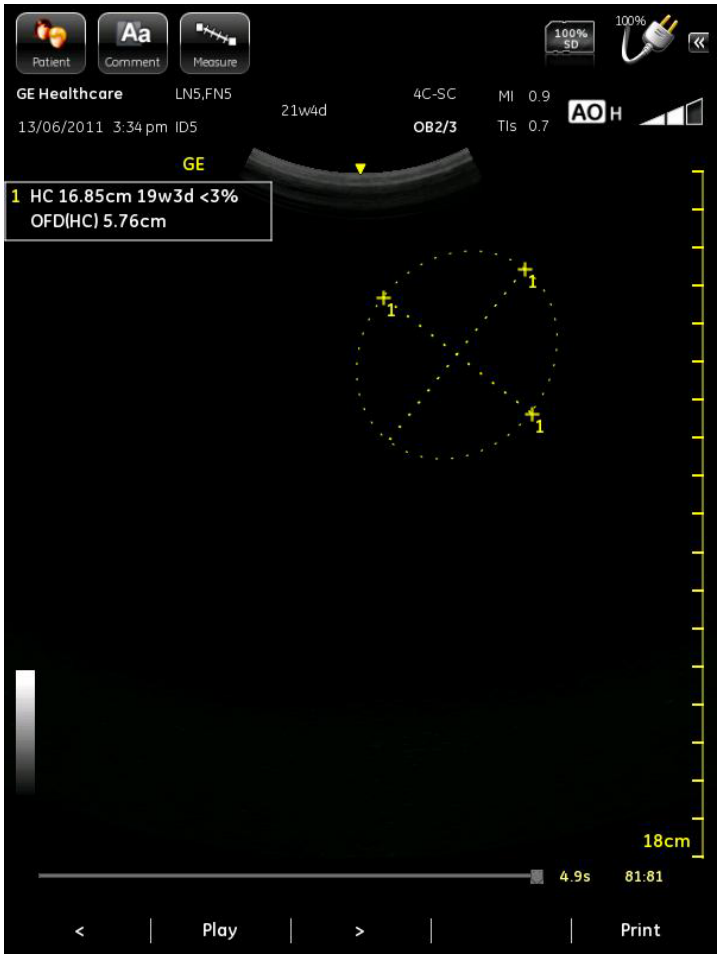


Figure 3-28. OB Measurement: HC

5. Measurements are numbered besides the calipers.

NOTE: Only 5 measurements are allowed at the same time.

Amniotic Fluid Index (AFI)

To calculate the amniotic fluid index, make one or four distance measurements.

AFI(1 Caliper)

To make a AFI (1 Caliper) measurement:

1. Press **Freeze**.
2. Select **Measure**, select the **Obstetrics** tab, select **AFI(1 Caliper)**.
3. Select using the stylus to place the first caliper.
4. Select with the stylus to place the second caliper, the result displays in the Measurement result window.

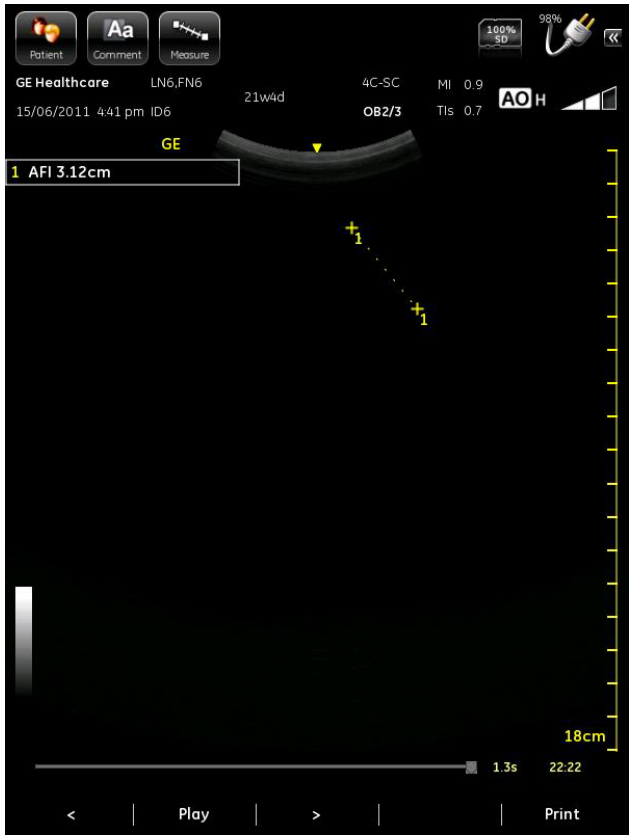


Figure 3-29. OB Measurement: AFI -1 Caliper

5. Measurements are numbered besides the calipers.

NOTE: Only 5 measurements are allowed at the same time.

AFI(4 Calipers)

To make a AFI(4 Calipers) measurement:

1. Press **Freeze**.
2. Select **Measure**, select the **Obstetrics** tab, select **AFI(4 Calipers)**.
   a. Select using the stylus to place the first caliper.
   b. Select with the stylus to place the second caliper, the result displays in the Measurement result window.
3. To make the other three distance measurements, repeat steps a-b three times.

   After you complete the fourth distance measurement, the system displays the AFI measurement in the result Window.

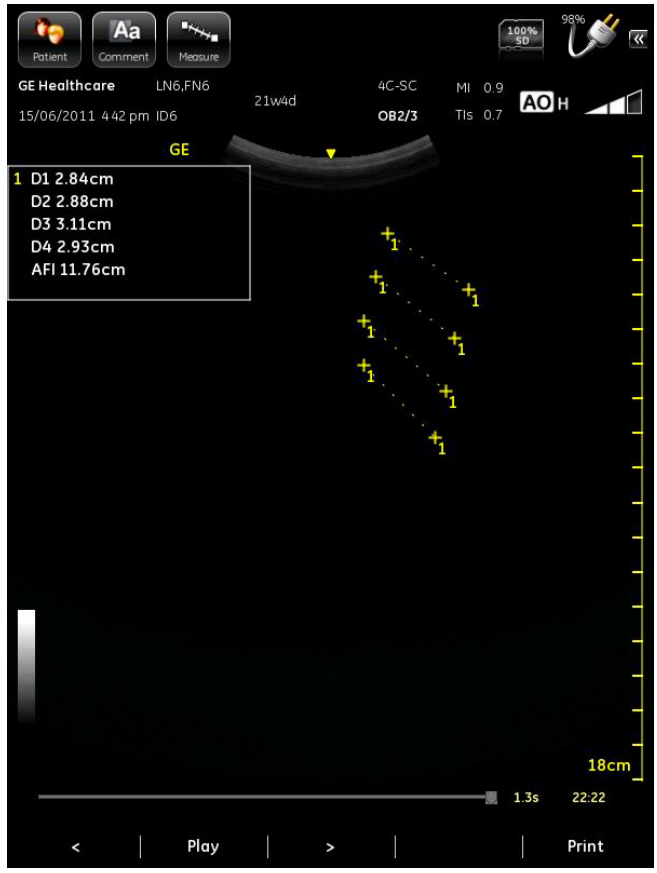


Figure 3-30. OB Measurement: AFI-4 Calipers

4. Measurements are numbered besides the calipers.

NOTE: Only 5 measurements are allowed at the same time.

Fetal Trunk Cross-Sectional Area (FTA)

USA ○ Europe ○ Tokyo ○ Osaka ● ASUM ○

To measure fetal trunk cross-sectional area, make an ellipse measurement.

1. Press **Freeze**.
2. Select **Measure**, select the **Obstetrics** tab, select **FTA**.
3. Select using the stylus to place the first caliper.
4. Select with the stylus to place the second and third caliper, the result displays in the Measurement result window.

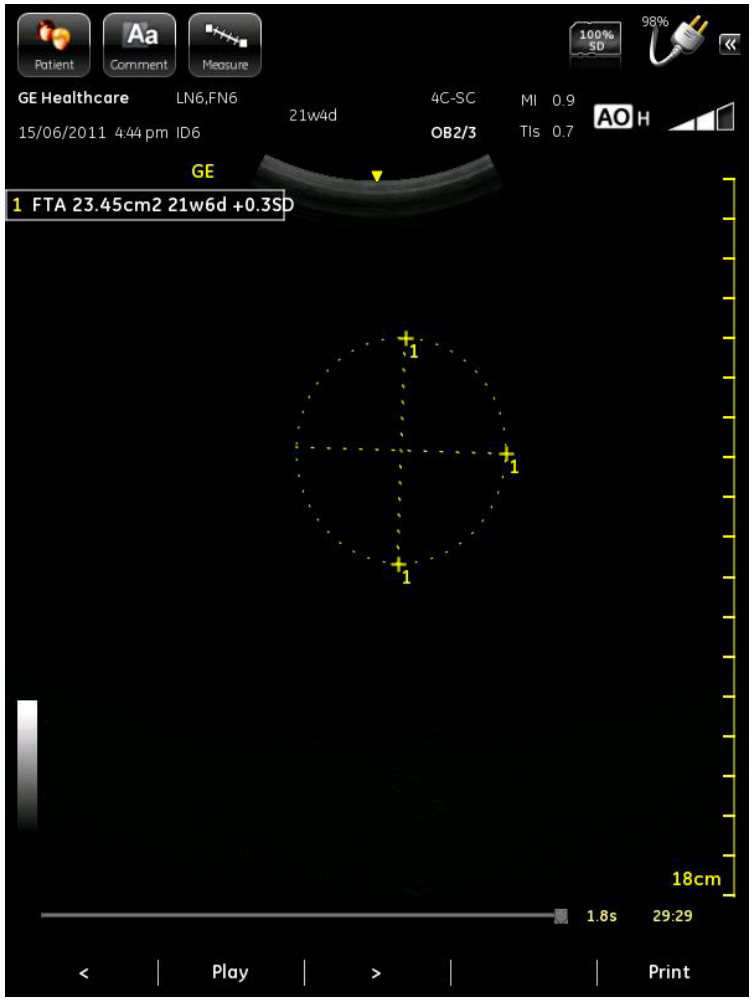


Figure 3-31. OB Measurement: FTA

5. Measurements are numbered besides the calipers.

NOTE: Only 5 measurements are allowed at the same time.

Spine Length (SL)

USA ○ Europe ○ Tokyo ● Osaka ○ ASUM ○

To measure spine length, make one distance measurement:

1. Press **Freeze**.
2. Select **Measure**, select the **Obstetrics** tab, select **SL**.
3. Select using the stylus to place the first caliper.
4. Select with the stylus to place the second caliper, the result displays in the Measurement result window.

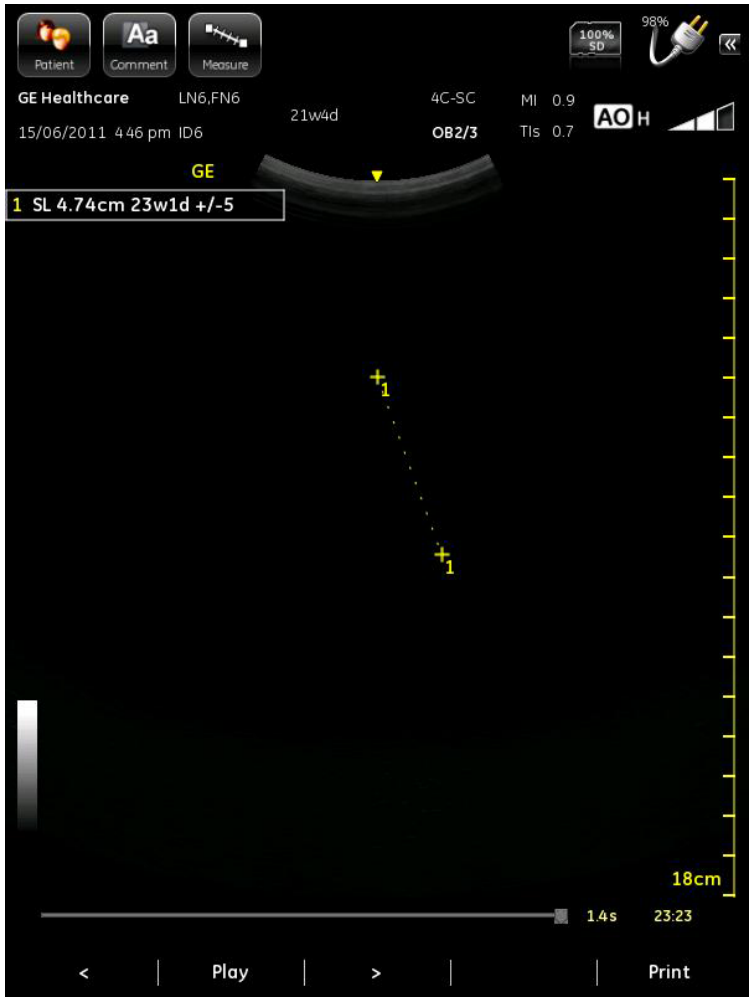


Figure 3-32. OB Measurement: SL

5. Measurements are numbered besides the calipers.

NOTE: Only 5 measurements are allowed at the same time.

Antero-Postero Trunk Diameter by Transverse Trunk Diameter (AxT)

USA ○ Europe ○ Tokyo ● Osaka ○ ASUM ○

Make two distance measurements, one of the antero-postero trunk diameter (APTD) and one of the transverse trunk diameter (TTD).

1. Press **Freeze**.
2. Select **Measure**, select the **Obstetrics** tab, select **AxT**.
3. Make a distance measurement for the antero-postero trunk diameter (APTD).
4. Make a distance measurement for the transverse trunk diameter (TTD).
5. The result displays in the Measurement result window.

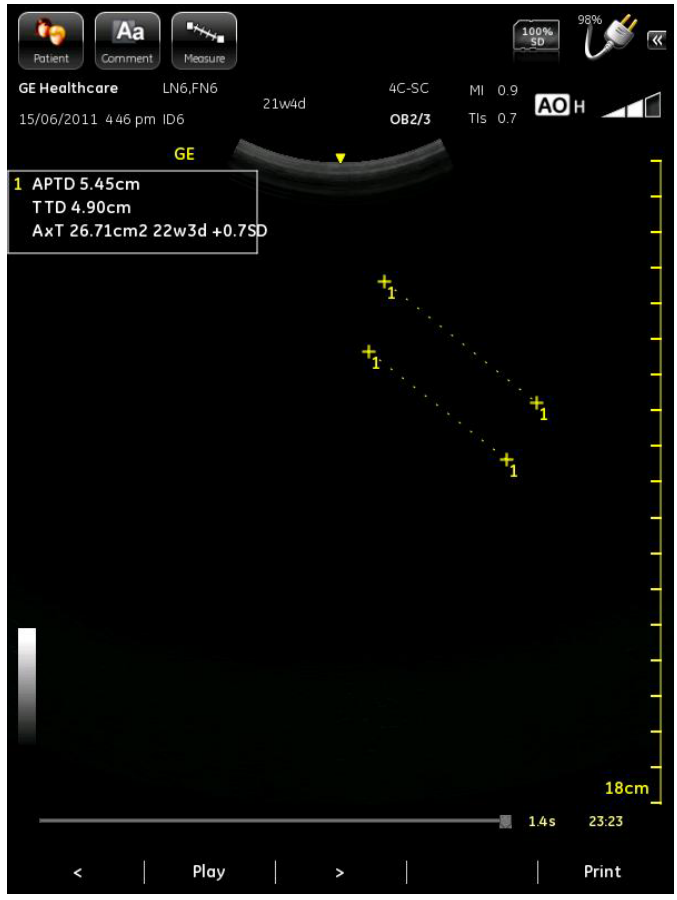


Figure 3-33. OB Measurement: AxT

6. Measurements are numbered besides the calipers.

NOTE: Only 5 measurements are allowed at the same time.

Cardio-Thoracic Area Ratio (CTAR)

USA ○ Europe ○ Tokyo ● Osaka ○ ASUM ○

To calculate cardio-thoracic area ratio, you make two ellipse measurements.

1. Press **Freeze**.
2. Select **Measure**, select the **Obstetrics** tab, select **CTAR**.
3. Make an ellipse measurement of the cardiac area.
4. Make an ellipse measurement of the thoracic area.
5. The result displays in the Measurement result window.

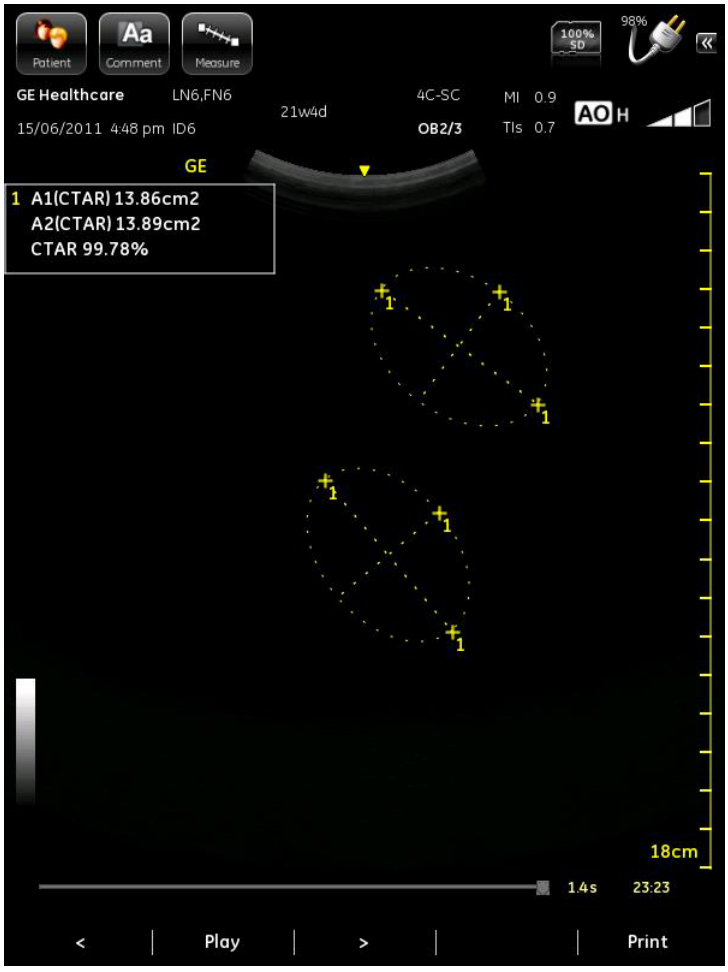


Figure 3-34. OB Measurement: CTAR

6. Measurements are numbered besides the calipers.

NOTE: Only 5 measurements are allowed at the same time.

Estimated Fetal Weight (EFW)

To measure estimated fetal weight, you make several OB measurements. These measurements can vary, based on how your system is set up. Measurements can include biparietal diameter, fetal trunk area, femur length, antero-postero trunk diameter and transverse trunk diameter, abdominal circumference, head circumference and spinal length.

The system displays each measurement and the estimated fetal weight in the OB Worksheet.

NOTE: For a description of any of the required measurements, refer to that measurement.

NOTE: The EFW could be configured in Utility->Measure->Obstetrics.

Annotations

Introduction

Select **Comment** to initiate comment mode.

The comment function provides the capability to type the comments of free text and/or insert the comments from the comment library. It also provides the user with arrow markers to point to parts of the image.

NOTE: Annotation are only available in frozen mode.

Adding comments to an image

Arrow Pointers

1. Press **Arrow**, a green arrow appears.
2. Select using the stylus to place the arrow at the target position on the screen, the arrow becomes yellow.
3. To move the arrow, select it and drag to the desired position.

Annotating an image using the library

Annotating an image using the system preset library

1. Select **Comment**, a comment text field appears.
2. Select the **Annotation** tab, select the comment from the system preset library. Select to fix, select to clear the text field.

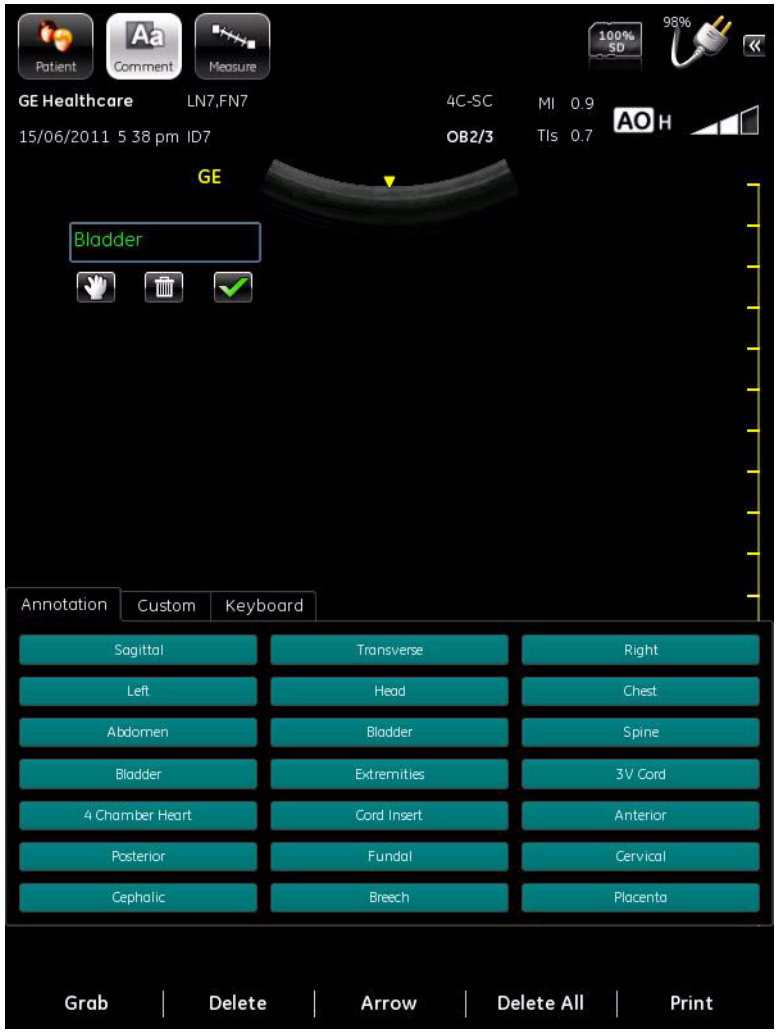


Figure 3-35. Annotating using library

3. Select to drag the annotation to the desired position.

Annotating an image using the customer defined library (R3.x.x only)

Annotating an image using the customer defined library (R3.x.x only)

1. Select **Comment**, a comment text field appears.
2. Select the **Custom** tab, select the comment from the customer defined library. Select to fix, select to clear the text field.

Figure 3-36. Annotating using customer defined library

3. Select to drag the annotation to the desired position.

Creating/Editing comments for customer defined library (R3.x.x only)

To create or edit comments for customer defined library:

1. Select  to create or edit comments for customer defined library.

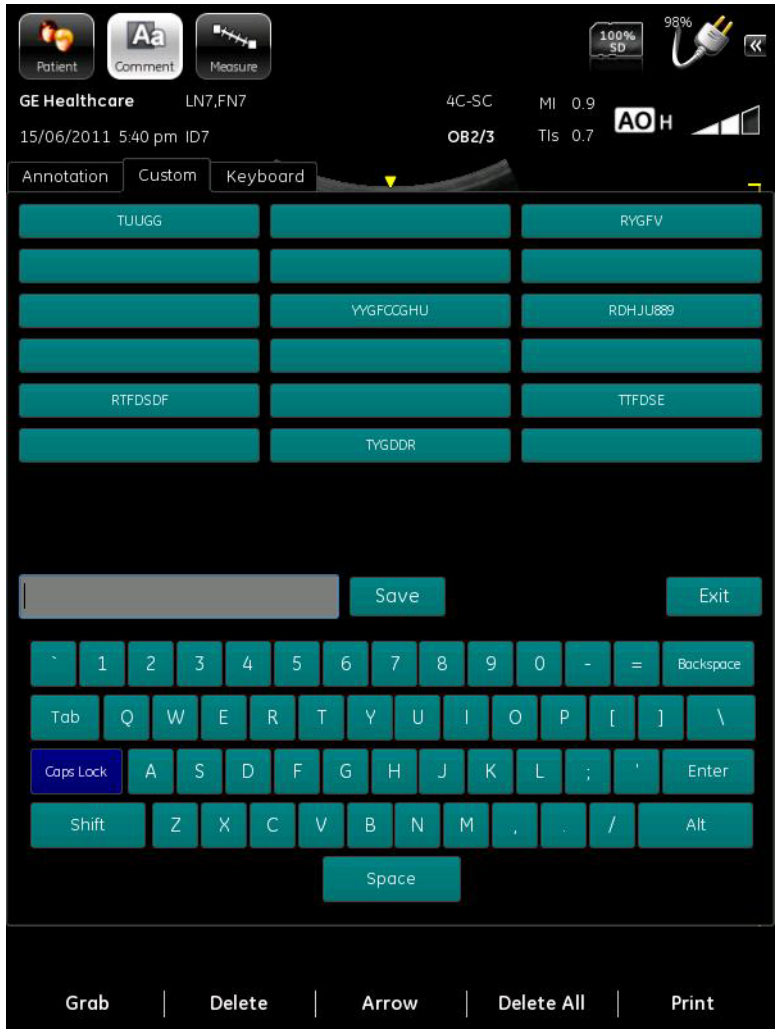


Figure 3-37. Annotating using customer defined library

Creating/Editing comments for customer defined library (R3.x.x only) (continued)

2. Select a blank tab to create a new comment or select a defined tab to edit the comment.

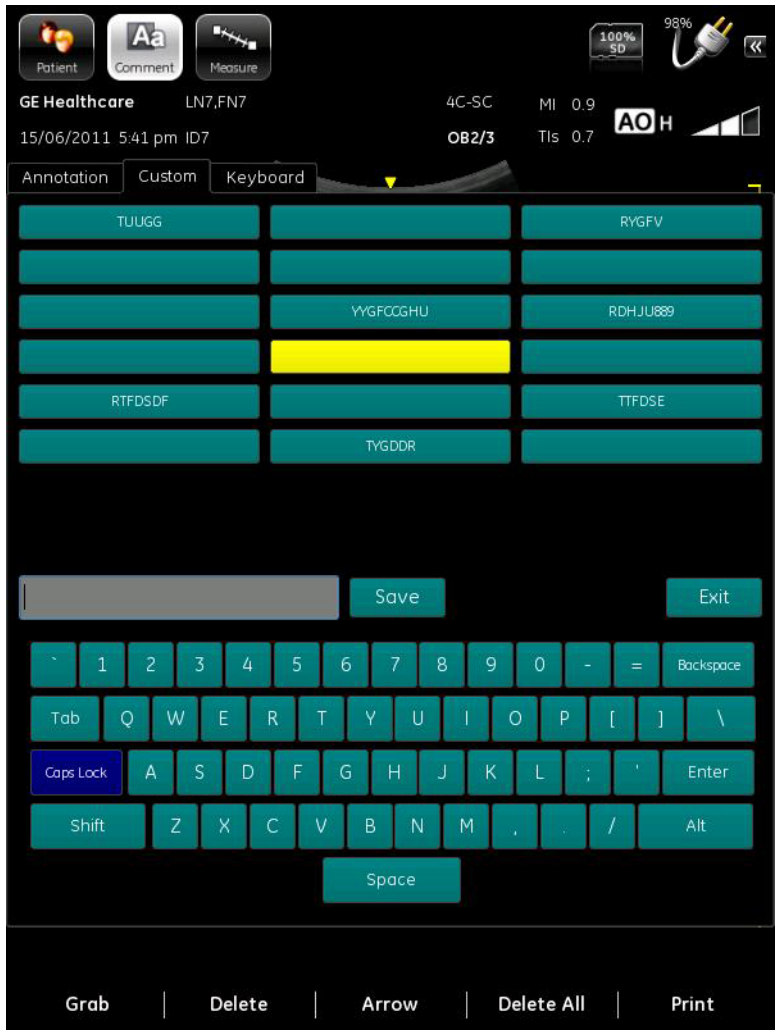


Figure 3-38. Annotating using customer defined library

Creating/Editing comments for customer defined library (R3.x.x only) (continued)

3. Select the letter(s) on the soft keyboard with the stylus to type comments.

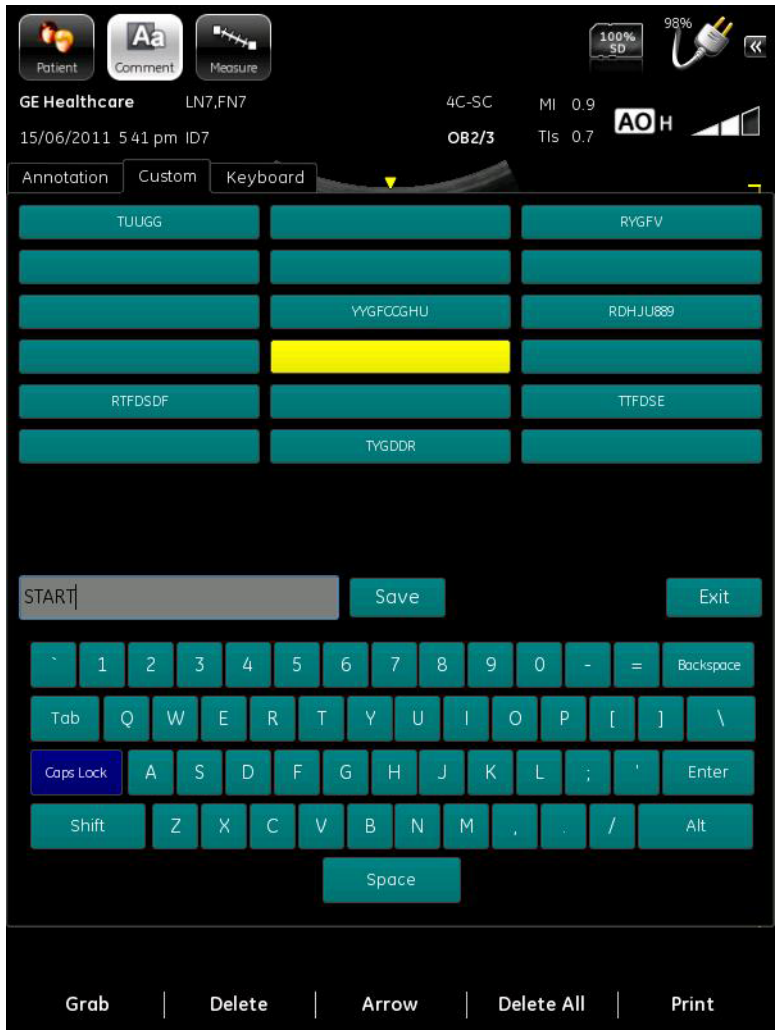


Figure 3-39. Annotating using customer defined library

Creating/Editing comments for customer defined library (R3.x.x only) (continued)

4. Select **Save** to save the new or edited comment.

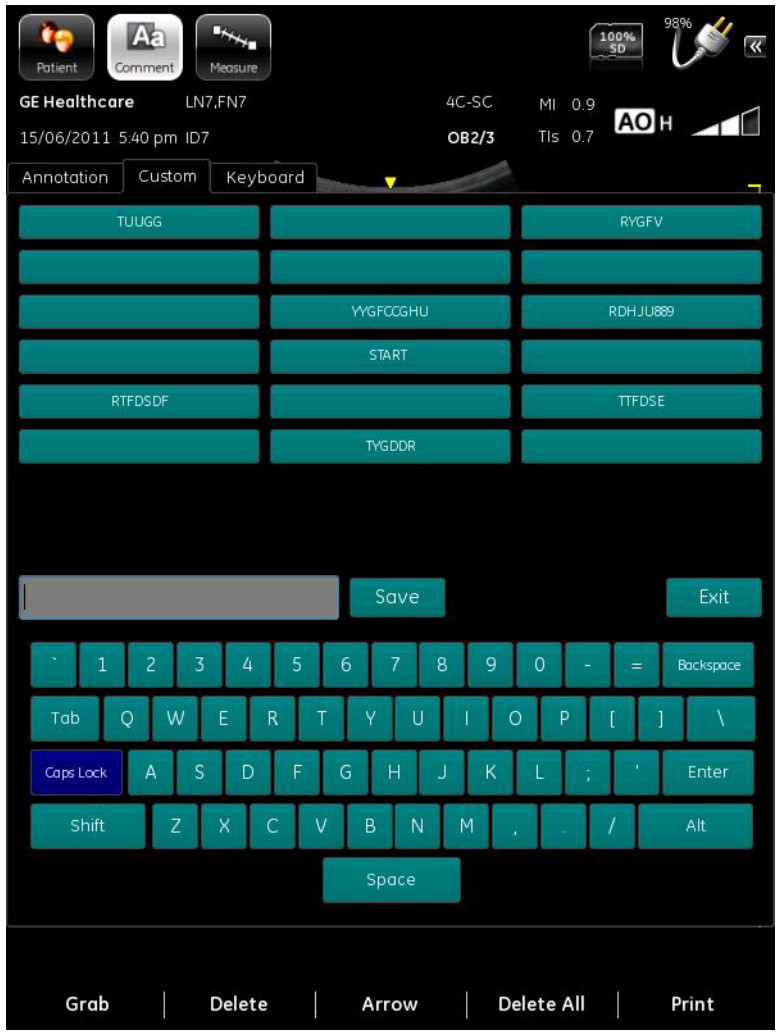


Figure 3-40. Annotating using customer defined library

5. Select **Exit** to exit comments defined screen.

Annotating an image with typed words

1. Select **Comment**, a comment text field appears.
2. Select the **keyboard** tab, select the letter(s) on the soft keyboard with the stylus to type comments. Select to fix, select to clear the text field.

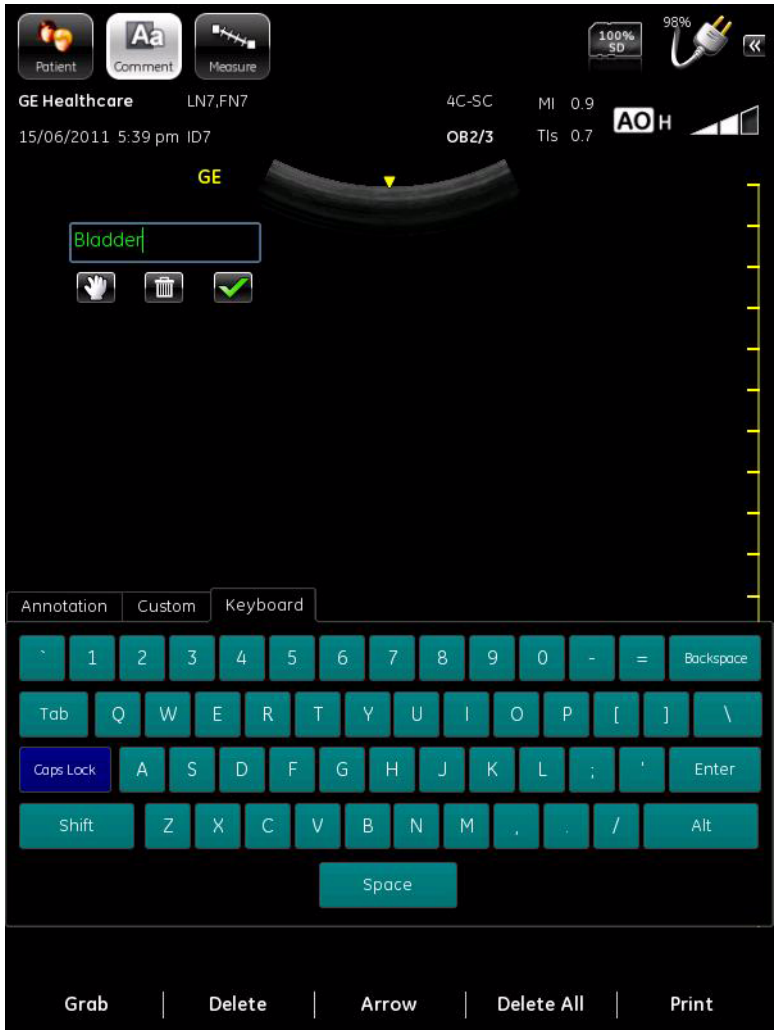


Figure 3-41. Annotating using keyboard

3. Select to drag the annotation to the desired position.

Edit while annotating

There are two states of comments available: Active and Confirm. The comments are green while active and yellow when set.

NOTE: Comments can only be edited in the active state.

To delete the annotation

Backspace over any error made. Blank spaces take the place of the letter(s) that were there. Continue typing the comment after backspacing over all incorrect letters.

Or

Select the letter(s) to delete with the stylus and type comment to replace those highlighted characters.

To move the annotation

Grab the comment, select  to drag it within the image area.

Annotation Controls

Figure 3-42. Annotation mode controls

Table 3-7: Annotation controls

Controls	Affects on image
Grab	Press to toggle among annotations.
Delete	Delete the selected annotation.
Arrow	Select for arrow placement
Del All	Delete all annotations
Print	Print the image with annotations

OB Worksheet (R3.x.x only)

OB Worksheet summarize the data obtained in the examination. They can contain data, images, and cine loops.

Once generated, the worksheet can be viewed, images can be added, and the patient's personal data can be modified. the examination data itself CANNOT be changed.

NOTE: OB Worksheet function is only available on OB1 and OB2/3 application on software version R3.x.x.

Activating the Worksheet

Select **Worksheet** on the patient screen.

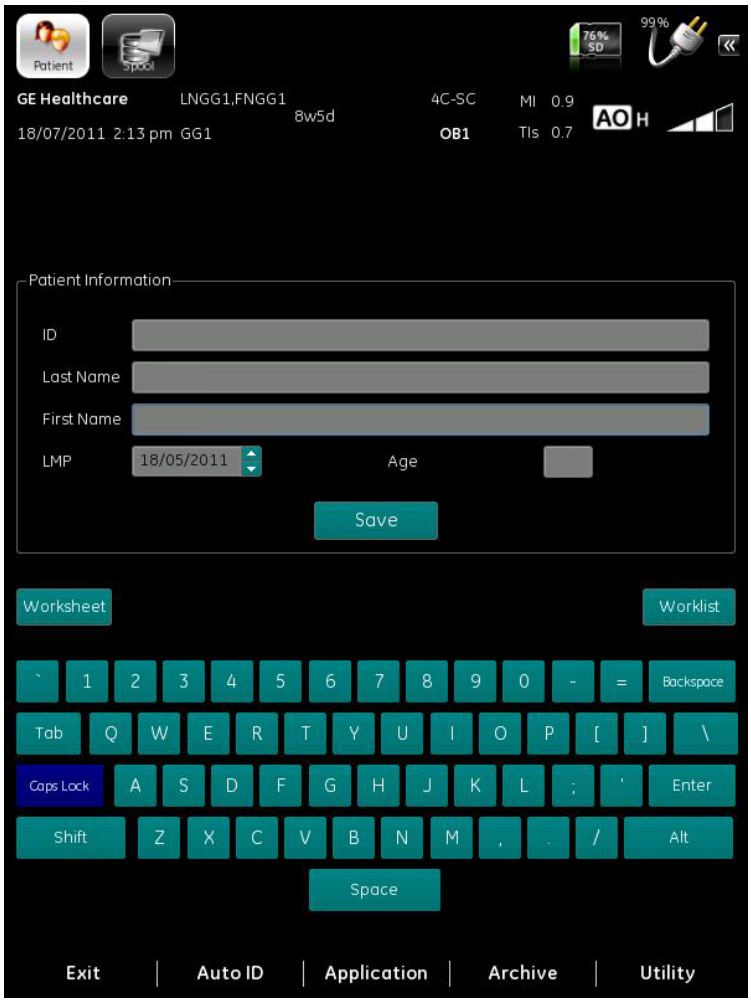


Figure 3-43. Patient Screen

OB Worksheet Controls

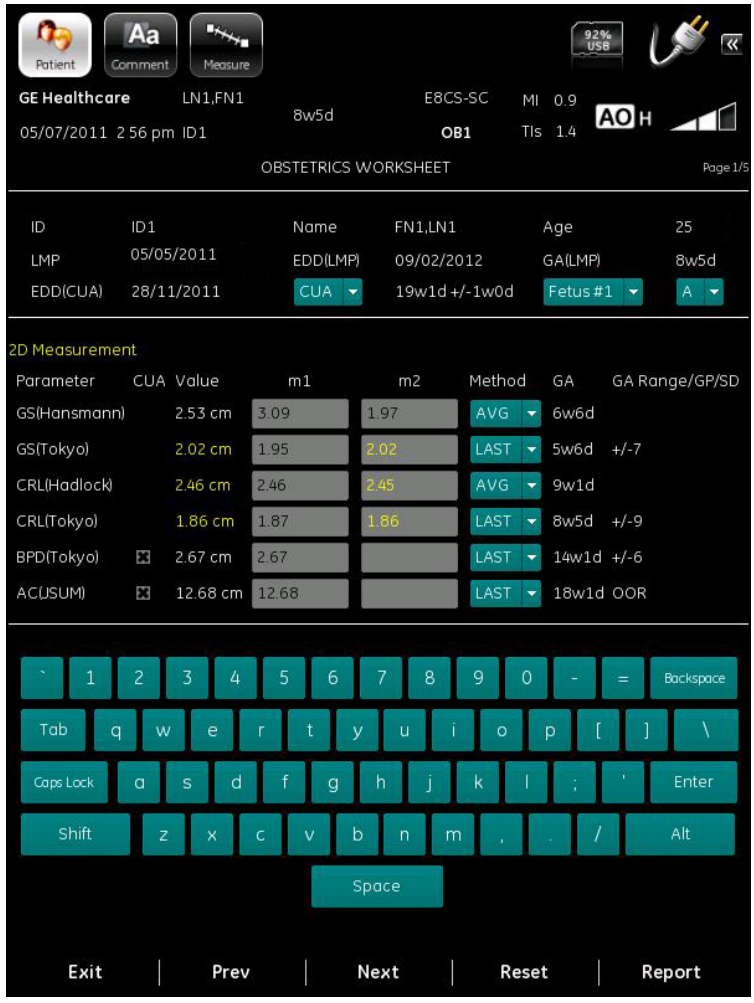


Figure 3-44. OB Worksheet Page

Table 3-8: OB Worksheet Controls

Controls	Function Description
Exit	Press to exit the worksheet
Prev	Press to view the previous worksheet page
Next	Press to view the next worksheet page
Clear/Reset	Press to remove all the worksheet information/reset the value to initial measure value after changed
Report	Press to enter into OB report page

OB Worksheet information

OB Worksheet information:

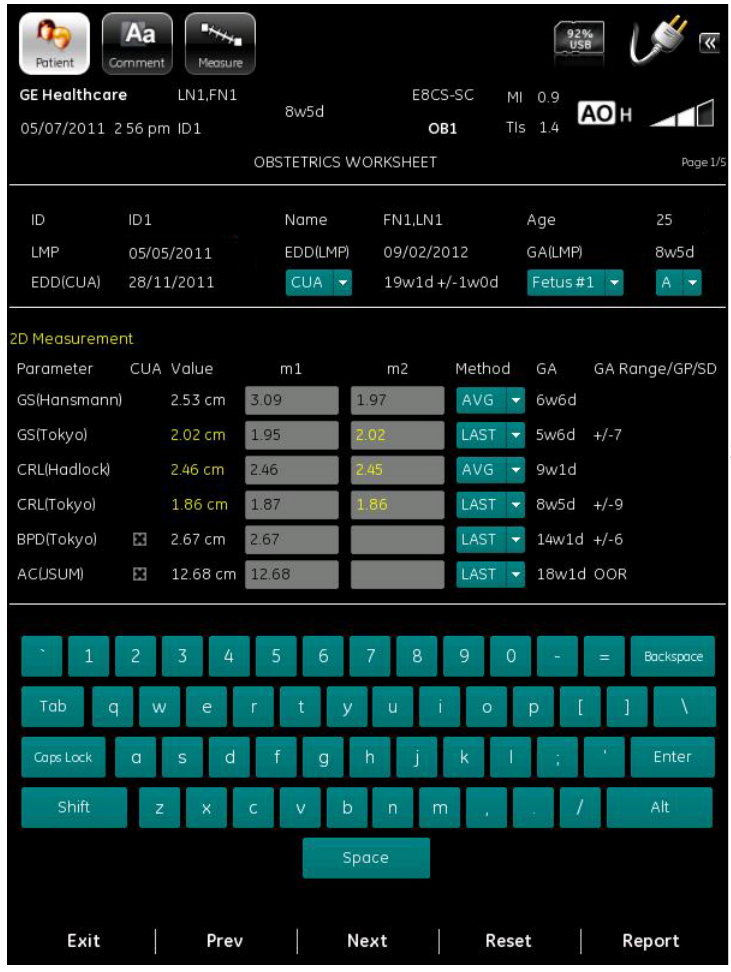


Figure 3-45. OB Worksheet page - page1

1. Patient information

Table 3-9: Patient information

Field	Description
ID, Name, Age	Patient ID, Patient name and patient age.
LMP	Last Menstrual Period; the LMP can be entered and edited in the patient Screen.
EDD(LMP)	Estimated Delivery Date by LMP; the system fills in the date after you enter the LMP.
GA(LMP)	Gestational Age by LMP; the system fills in the age after you enter the LMP.

Table 3-9: Patient information

Field	Description
EDD(CUA)/ EDD(AUA)	Estimated Delivery Date by CUA/AUA.
CUA/AUA	Select the ultrasound age calculation method in this field. CUA: Composite Ultrasound Age, regression calculation; AUA: Average Ultrasound Age, an arithmetic average.
Fetus#	Number of fetuses; default is 1. Can be 1, 2 or 3.
A/B/C	The first/second/third fetus.

2. 2D Measurements information

Table 3-10: 2D Measurements information

Field	Description
Parameter	Measurement name
CUA/AUA	If this field is checked, the system uses the measurement to calculate the ultrasound age.
Value	The measured value. If more than one measurement was made for an item, the system uses the specified method (average, last) to determine this value. Average for USA and Europe; Last for Osaka, Tokyo and ASUM.
m1, m2	Up to two measurement values for each item. If you make more than two measurements, the system uses the last two.
Method	When there is more than one measurement for an item, this specifies the method used to calculate the measurement value listed in the Value column. Average for USA and Europe; Last for Osaka, Tokyo and ASUM.
GA	Gestational Age.
GA Range/GP/SD	The typical range of gestational age/growth percentile/standard deviation for this measurement.

OB Worksheet information (continued)

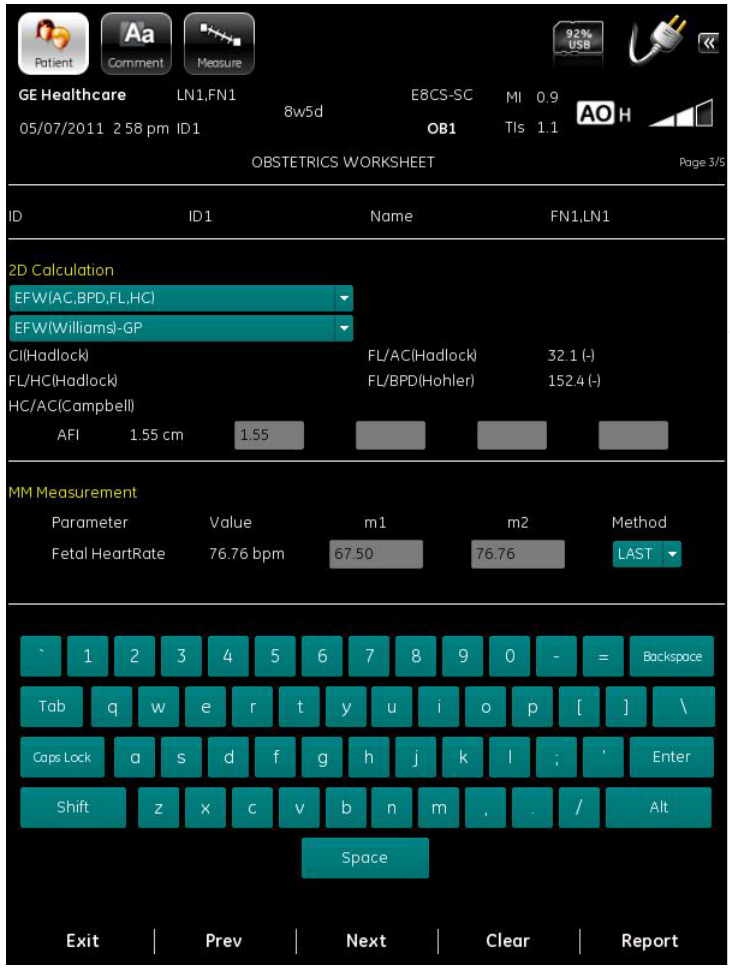


Figure 3-46. OB Worksheet page - page2

3. 2D Calculation

Table 3-11: 2D Calculation information

Field	Description
EFW	Estimated fetal weight; lists the parameters used to calculate EFW. This is followed by the calculation result. NOTE: EFW can be configured in Utility->Measure->Obstetrics.
EFW-GP	Lists the source used to calculate EFW-GP (growth percentile). This is followed by the growth percentile.
CI	Cephalic Index.

Table 3-11: 2D Calculation information

Field	Description
FL/AC, FL/HC, FL/BPD, HC/AC	Ratios for the measurements
AFI	Amniotic Fluid Index.

4. MM Measurement

Table 3-12: MM Measurements information

Field	Description
Parameter	Measurement name
Value	The measured value. If more than one measurement was made for an item, the system uses the specified method (average, last) to determine this value. AVG for USA and Europe; LAST for Osaka, Tokyo and ASUM.
m1, m2	Up to two measurement values for each item. If you make more than two measurements, the system uses the last two.
Method	When there is more than one measurement for an item, this specifies the method used to calculate the measurement value listed in the Value column. Choices are AVG, MAX, MIN or LAST.

OB Worksheet information (continued)

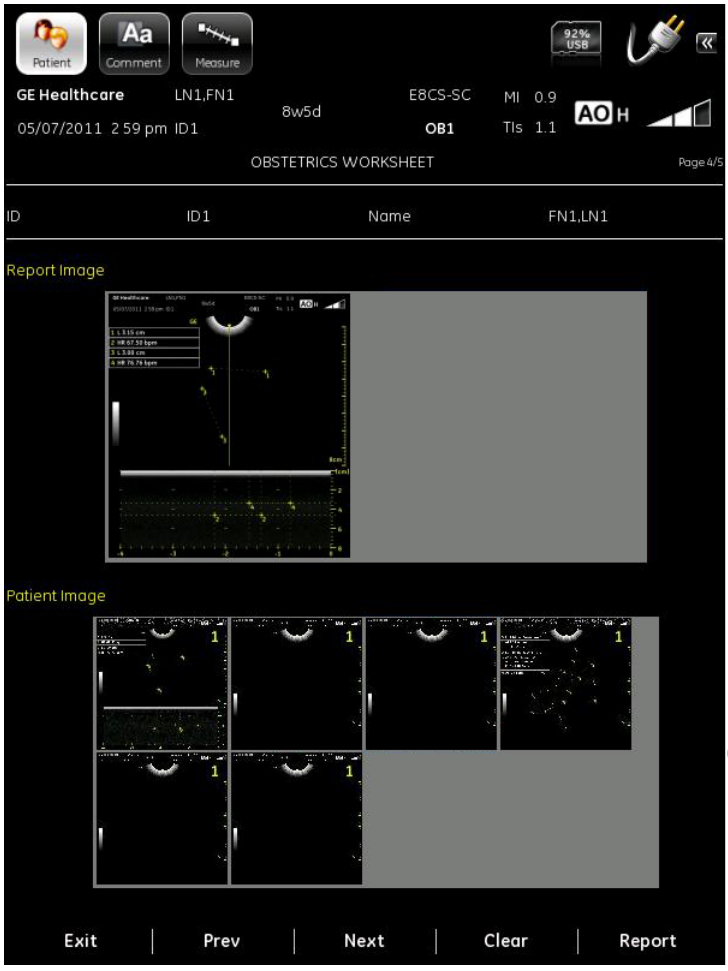


Figure 3-47. OB Worksheet page - page3

5. Report Image
6. Patient Image

NOTE: The Patient Image here do not include worksheet images.

OB Worksheet information (continued)

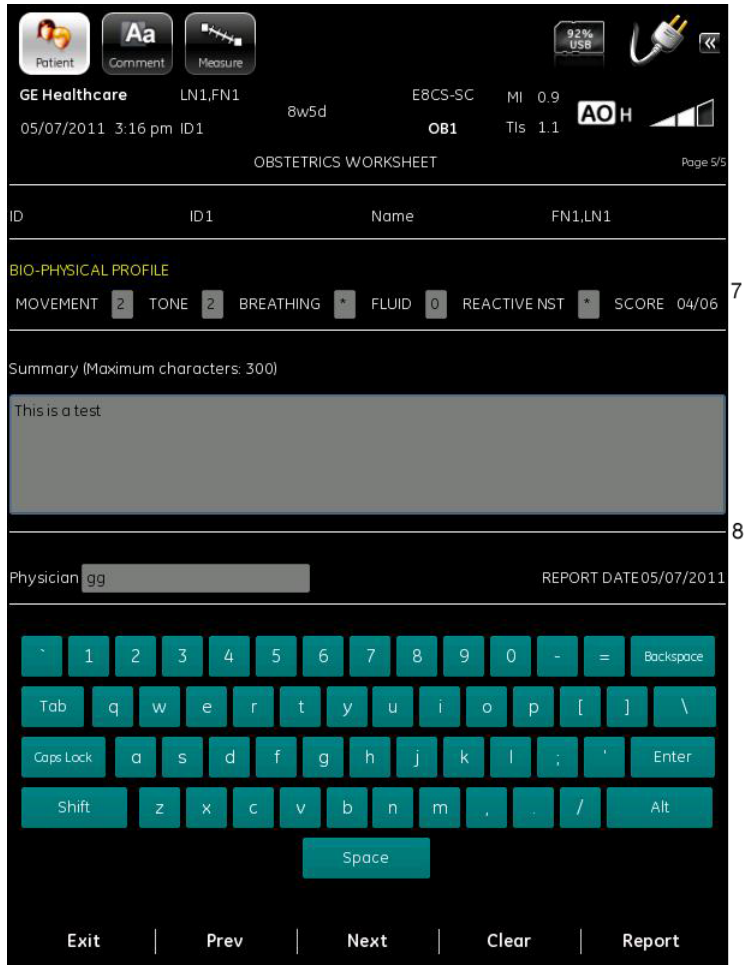


Figure 3-48. OB Worksheet page - page4

7. BIO-PHYSICAL PROFILE

Table 3-13: Measurements information

Field	Description
BIO-PHYSICAL PROFILE	The score is _ of 10 possible total points, depending upon the number of parameters entered. Enter the following information to assess the fetus's biophysical well-being.
Movement	Type 0, 2 or *
Tone	Type 0, 2 or *
Breathing	Type 0, 2 or *
Fluid	Type 0, 2 or *

Table 3-13: Measurements information

Field	Description
Reactive NST	Type 0, 2 or *

8. Summary and Physician

Table 3-14: Summary and physician information

Field	Description
Summary	Free text, the characters should be less than 300.
Physician	Physician

Editing OB Worksheet

Editing the patient information

The CUA/AUA and fetus # can be edited.

NOTE: The patient age and LMP only can be edited on patient screen.

Editing measurements

The CUA/AUA, m1, m2 and method and can be edited.

Editing calculation

The AFI can be edited.

Editing the report Image

Double click with the stylus the desired image in the patient image area to copy the image to the report image area.

Double click with the stylus the image again to delete the image from the report image area.

Editing the Bio-physical profile

The Movement, Tone, Breathing, Fluid and Reactive NST can be edited.

Editing summary and Physician by

The summary and physician can be edited.

OB Report

Select **Report** on the OB worksheet page.

Figure 3-49. OB Report page

OB Report controls

Save Text

Press to save the OB report in text format in the patient folder.

Print

Press to print the OB report. Only the information above the images will be printed.

Exit

Press to exit the OB report page and return to the OB worksheet page.

Multi gestational

Venue 40 allows you to measure and report multiple fetus development. The system can report a maximum of three fetuses.

To enter the number of fetuses

If more than one fetus is imaged during the exam, enter the number of fetuses in the OB worksheet page.

When you start OB exam, the system automatically fills in Fetus #1, it can be changed to Fetus #2 or Fetus #3.

To identify each fetus

For measurements, calculations, and worksheet displays, the system labels each fetus A, B or C.

To select a fetus

During measurements, to change between fetuses:

Select the desired fetus in OB worksheet page.

NOTE: After you change to the next fetus, any measurements you make are recorded and reported to that fetus. If you have any active measurement that is not completed when you change the fetus, the system cancels the measurement.

To view multiple fetuses

Multiple gestation data is displayed on the OB report and graph.

Storing an OB Report

The OB Report can be stored in JPEG format or Text format.

To Store an OB Report:

1. Select **Report** on the OB worksheet page to enter into OB report page.
2. Press **Save Text** to save the OB report in text format in the patient folder

   Press **Save** to save the OB report in JPEG format in the patient folder

Image Management

Using CINE

Introduction

CINE is useful for focusing on images during a specific part of the cycle or to view short segments of a scan session.

You can view CINE as a continuous loop via CINE Loop or manually review CINE images frame by frame.

Data in CINE is available until new data is acquired. CINE can be archived in the storage device.

Activating CINE

To activate CINE,

1. Press **Freeze**

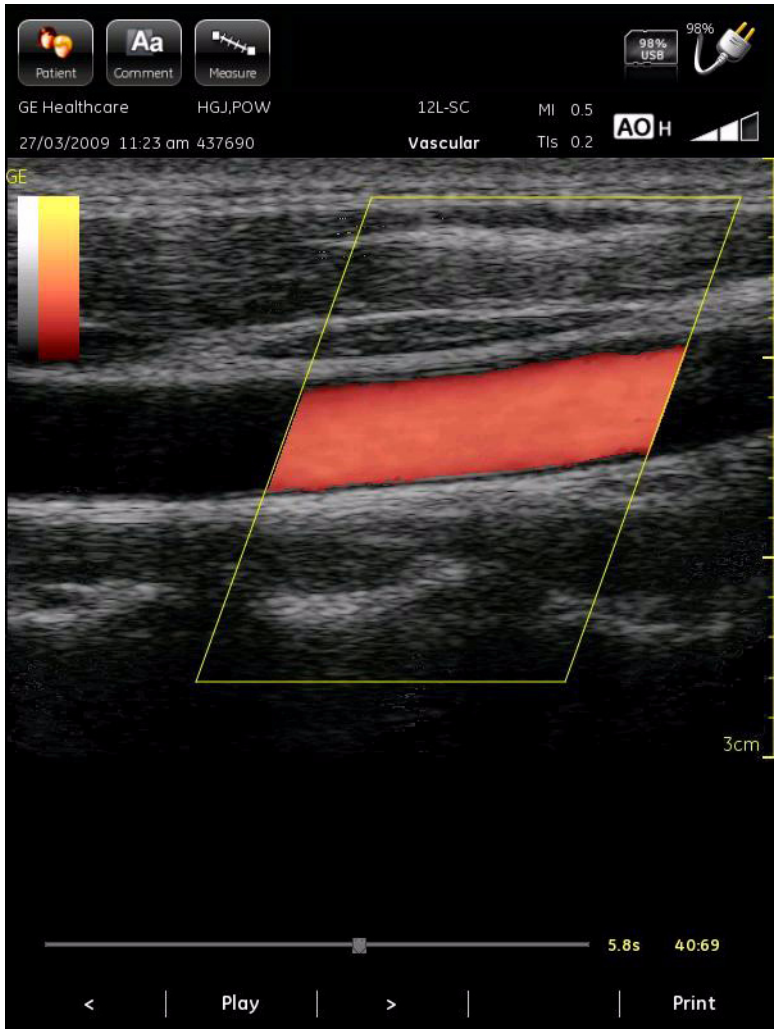


Figure 3-50. CINE screen

CINE controls

Figure 3-51. CINE controls

Table 3-15:

Controls	Affects on images
<	View previous frame
>	View next frame
Play/||	Playback/Pause the CINE loop
Print	Print the current image

NOTE: Use the stylus to select the processing bar to view frames.

Review archived information

Searching for an existing patient

1. Select **Patient**, select **Archive**, the patient gallery under the storage device displays on the screen.

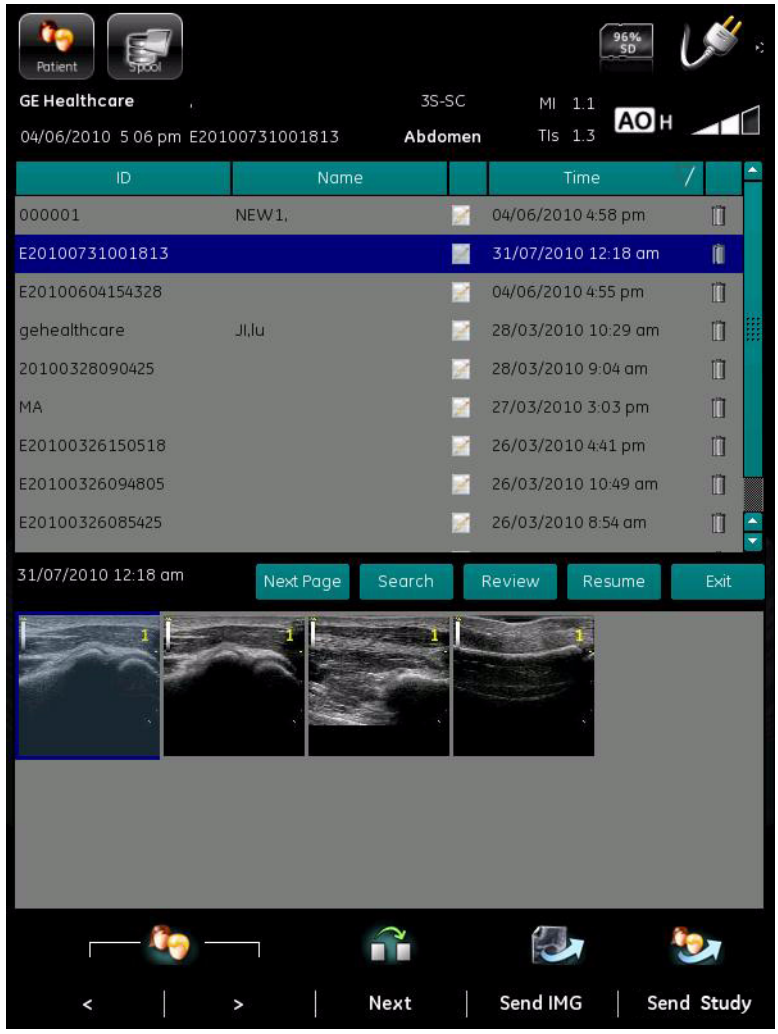


Figure 3-52. Gallery Screen

Searching for an existing patient (continued)

2. Select the Search key to display patient search screen. Enter Patient ID, Last Name or First Name, select Search to search the patient.

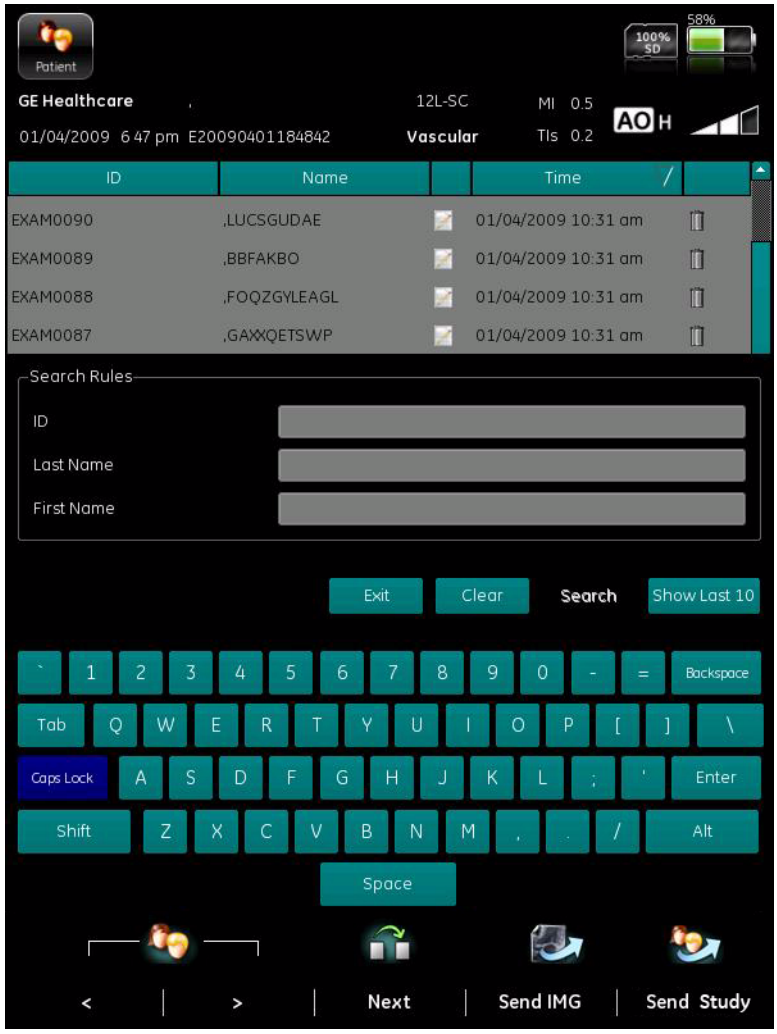


Figure 3-53. Patient Search screen

NOTE: Select Show last 10 to display the latest 10 patients.

3. An appropriate patient displays on the screen.

Editing patient information

To edit patient information,

1. Go to patient gallery, select the appropriate patient.
2. Select  to edit the patient.

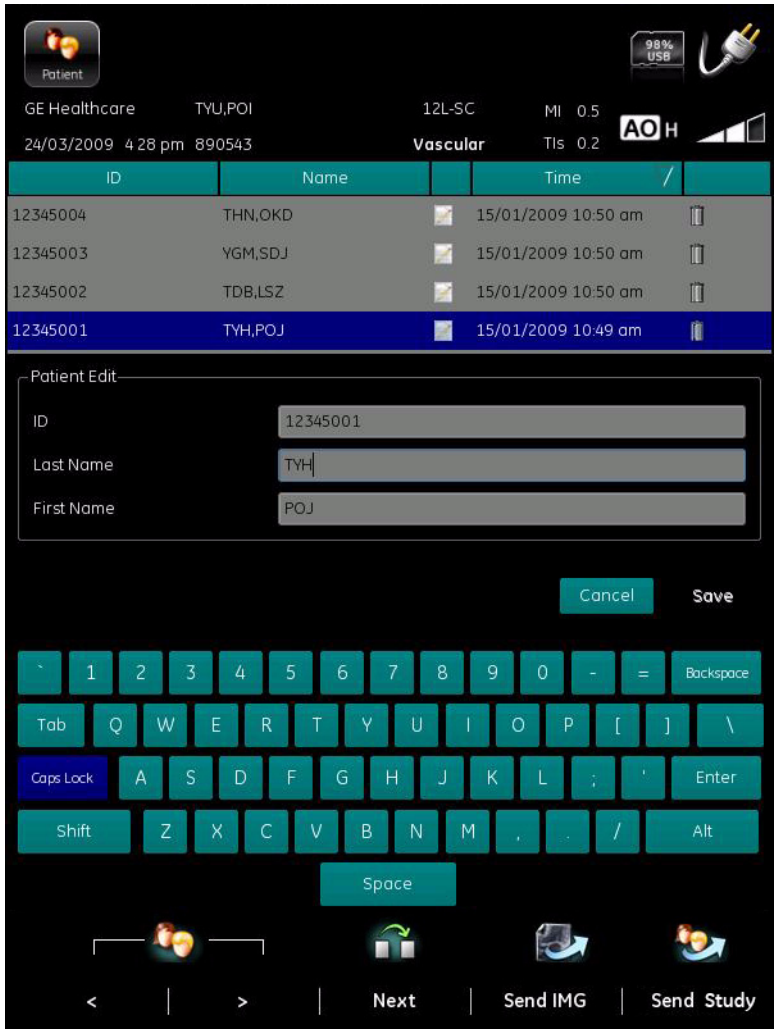


Figure 3-54. Patient Edit page

NOTE: Patient ID cannot be edited.

Reviewing the patient exam

To review the patient exam,

1. Search the patient or select the patient from the list, select the patient using the stylus.

NOTE: Select "<" or ">" to go to the next or previous patient.

2. The Image of the selected patient is displayed at the bottom of the screen.

NOTE: Select "next" to go to the next image.

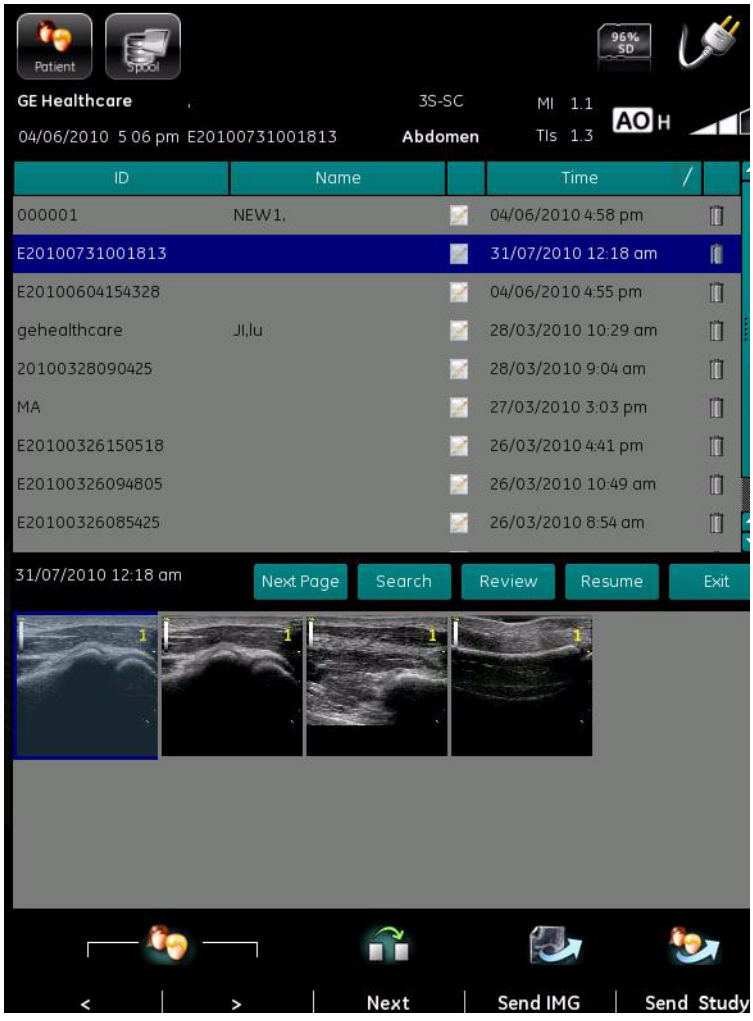


Figure 3-55. Review patient exam

Reviewing the patient exam (continued)

3. Select the image or CINE you want to review, press **Review**, the image is displayed. Press **Next** to go to the next image of the patient. Press **Resume** to exit to live scan.
4. In the review screen, press **Prev File** or **Next File** to go to the previous or next image of the patient. Press **Close** to exit to the patient gallery. Press **Delete** to delete the image. Press **Print** to print the image.

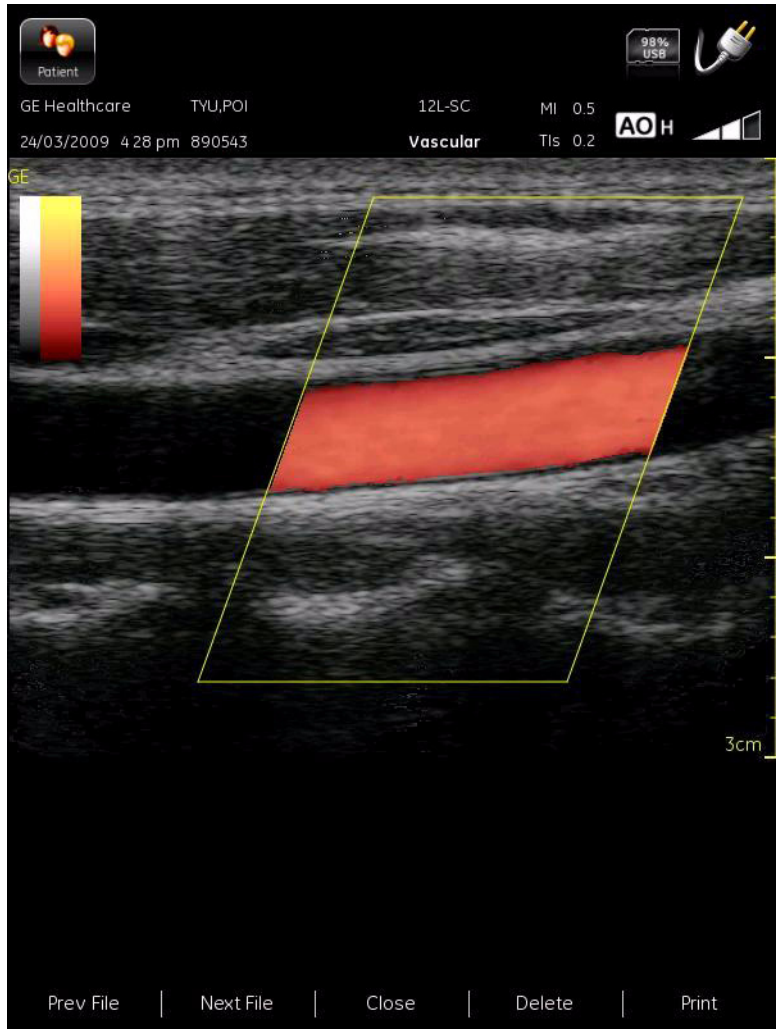


Figure 3-56. Review archived images

Deleting the existing patient/images

CAUTION

Before deleting a patient or image from the Patient Screen, make sure you have already saved the patient data. GE is not responsible for any patient information loss.

Deleting the existing patient

1. Search and select the patient in the patient list.
2. Select  . The confirmation dialog box displays.
3. Select OK to delete or cancel.

Delete the existing image

1. Select the patient in the patient list.
2. Select the image. Press **Review** to display the image.
3. Press **Delete**. A dialog box displays. Select Yes to delete, cancel to cancel.

Image Storage

Storing an image

Images can be stored in JPEG format.

To store an image

For software version R1.x.x and R2.0.x:

1. While scanning, press **Freeze**.
2. Scroll through the CINE loop and select the desired image.
3. Press **Save**. A message “Image saved successfully“ displays on top of the screen if the image is saved.

For software version R3.x.x:

1. Select **Image** for live scan save in Utility ->Settings -> General.
2. Select **Save** and exit to scan screen.
3. While scanning press **Save**. A message “Image saved successfully“ displays on top of the screen if the image is saved.

Storing a Video clip

Video clips can be stored in MPEG format.

A CINE Loop is a sequence of images recorded over a certain timeframe.

For software version R1.x.x and R2.0.x:

1. While scanning or playing back a cineloop, press **Save**.
2. A processing box showing storing progress displays.
3. A message “Video saved successfully“ displays on top of the screen if the video is saved.

For software version R3.x.x:

1. Select **Video** for live scan save in Utility ->Settings -> General.
2. Select **Save** and exit to scan screen.
3. While scanning or playing back a cineloop, press **Save**.
4. A processing box showing storing progress displays.
5. A message “Video saved successfully“ displays on top of the screen if the video is saved.

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

Do not cut off system power supply during image/video storing process.

Storage device status

View storage device status

After the selected storage device is detected by the system, there is an icon in the upper right corner of the screen. It's current capacity in percent appears "current capacity (unit: percent) USB/SD"

Figure 3-57. Storage device status icon

When the storage device is full

When the storage device is almost full, the following icon displays:

Figure 3-58. Storage device is almost full

When storing images, videos or saving patient, a warning message:" Storage space is almost full, saving image/video/ patient failed" displays.

NOTE: Please change the storage device at once and save image/ videos again.

When the storage device is not detected

If the selected storage device is not detected by the system, the following icon displays:

Figure 3-59. Storage device is not detected by system

NOTE: Make sure the selected storage device is functioning properly, or please check it in Utility. Please refer to Chapter 4 for detailed information.

NOTE: Make sure the selected storage device is connected properly.

View images/videos on PC

To view archived images/videos on a PC,

NOTE: It is recommended to view videos by QuickTime. If you do not have QuickTime on your PC, you can download it free from www.apple.com.

1. Select the storage device status icon using the stylus, select again to eject the SD Card or USB Memory Stick.

Do NOT disconnect the SD Card or USB Memory from Venue 40 without properly ejecting the device; this may result in data loss.

2. Connect the storage device to the PC.
   - For USB Memory, connect to the USB port of a PC
   - For High Capacity SD Card, insert it to SD Card Reader and connect to the USB port of a PC.
3. Find the patient images and videos in the patient folder.
   - For those who had patient information registered, the folder name is PatientID_LastName_FirstName_UserName (R1.x.x).

     Or

     PatientID@_@_LastName@_FirstName@_UserName @_StudyDate (R2.0.x, R3.x.x).
   - For those registering with Patient ID and 2nd ID, the folder name is PatientID_2ndID_LastName_FirstName_UserName (R1.x.x).

     Or

     PatientID@_2ndID@_LastName@_FirstName@_User Name@_StudyDate (R2.0.x, R3.x.x).

View images/videos on PC (continued)

- For those registering with auto Patient ID, the folder name is AutoID___UserName (R1.x.x).

  Or

  AutoID@_@_@_@_UserName@_StudyDate (R2.0.x, R3.x.x).
- For those scanning without patient registration, the folder name is EAutoID___UserName (R1.x.x).

  Or

  EAutoID@_@_@_@_UserName@_StudyDate (R2.0.x, R3.x.x).

NOTE: In case of emergency, you can scan without entering patient information. In these cases, the system automatically generates the ID.

4. View patient images and videos on a PC.

Connectivity (R2.0.x, R3.x.x only)

Overview

You can set up the connection and communication protocols for the ultrasound system. This page gives an overview of each of the connectivity functions.

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

1. **DICOM Worklist**: Search and Retrieve Patient Information
2. **DICOM Image Store**: Transfer DICOM images to DICOM image server.
3. **Network QuickSave**: Transfer images and CINE loops to network shared folder.

Network Status

View network status

Select  in the upper right corner of the screen. There are two icons indicating wired and wireless network status. The following icons indicate that the wired and wireless network is connected:

Figure 3-60. Wired network status icon - connected

Figure 3-61. Wireless network status icon - connected

When connecting to the network

The following icons indicate that the wired and wireless network is being connected to:

Figure 3-62. Wired network status icon - connecting

Figure 3-63. Wireless network status icon - connecting

When the network is disconnected

The following icons indicate that the wired and wireless network is disconnected:

Figure 3-64. Wired network status icon - disconnected

Figure 3-65. Wireless network status icon - disconnected

When the wireless network is limited

The following icons indicate that the wireless network is limited or no connection available:

Figure 3-66. Wireless network status icon - limited or no connection available

DICOM Worklist

1. Select **Patient**, select **Worklist**, the Patient list used last time displays.

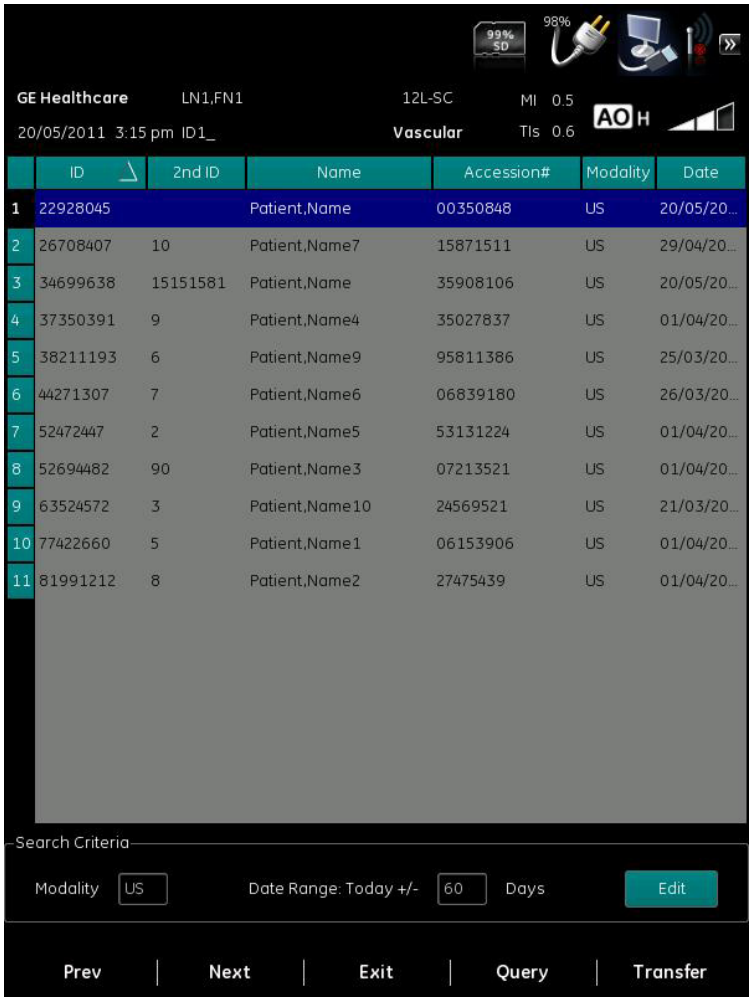


Figure 3-67. Patient list in worklist server

NOTE: The worklist server can be configured in Utility, refer to Chapter 4.

DICOM Worklist (continued)

2. Select **Edit**.

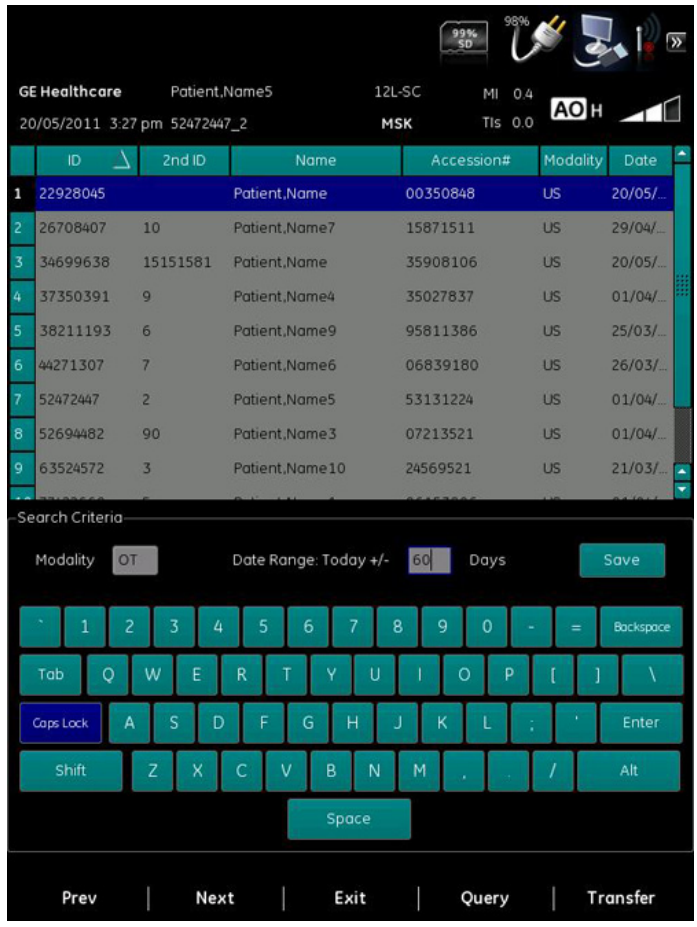


Figure 3-68. Search patient list in worklist server

DICOM Worklist (continued)

3. Input **Modality** and **Date Range** as search criteria, select **Save**.

NOTE: Only one or two bytes can be input in the modality cell.

NOTE: The default value of date range is 0, and the maximum value is 60. Set date range to 0, the Scheduled Procedure Step Start Date will include today only. Set the date range to X (an integer number between 0 and 60), the Scheduled Procedure Step Start Date will include X days prior and from today.

4. Press **Query**, the Patient list which meets the search criteria in the worklist server displays.
5. Select the desired patient, press **Transfer**, the patient information is automatically filled in.

DICOM Image Store

DICOM Image Store allows the system to send ultrasound images in a format that can be interpreted by PACS.

NOTE: Only still images can be sent via DICOM Image Store.

NOTE: The DICOM image server can be configured in Utility, refer to Chapter 4.

NOTE: Please check “Set DICOM Default“ in Utility -> Connectivity -> DICOM.

1. Select **Patient**, press **Archive**. The patient gallery displays on the screen.
2. Select the desired image, press **Send Image**. The image will be sent to the DICOM image server.

   Or

   Select the desired patient, press **Send Study**. The images of the patient will be sent to the DICOM image server.

NOTE: The transfer status can be viewed in Spooler, refer to ‘Spooler’ on page 3-91.

Network QuickSave

Network QuickSave allows the system to send ultrasound images in JPEG format and CINE loops in MPEG format.

NOTE: The network shared folders can be configured in Utility, refer to Chapter 4.

NOTE: Please check “Set QuickSave Default“ in Utility -> Connectivity -> QuickSave.

1. Select **Patient**, press **Archive**. The patient gallery displays on the screen.
2. Select the desired image or CINE loop, press **Send Image**. The image or CINE loop will be sent to the network shared folder.

   Or

   Select the desired patient, press **Send Study**. The images and CINE loops of the patient will be sent to the network shared folder.

Spooler

To monitor/control DICOM jobs, select **Spool** in patient screen. You can view and delete images from DICOM spooler by selecting a job, then specifying the action to be performed on this job.

NOTE: If you find a failed job(s) in the Spooler, please remove the failed job(s) from the Spooler.

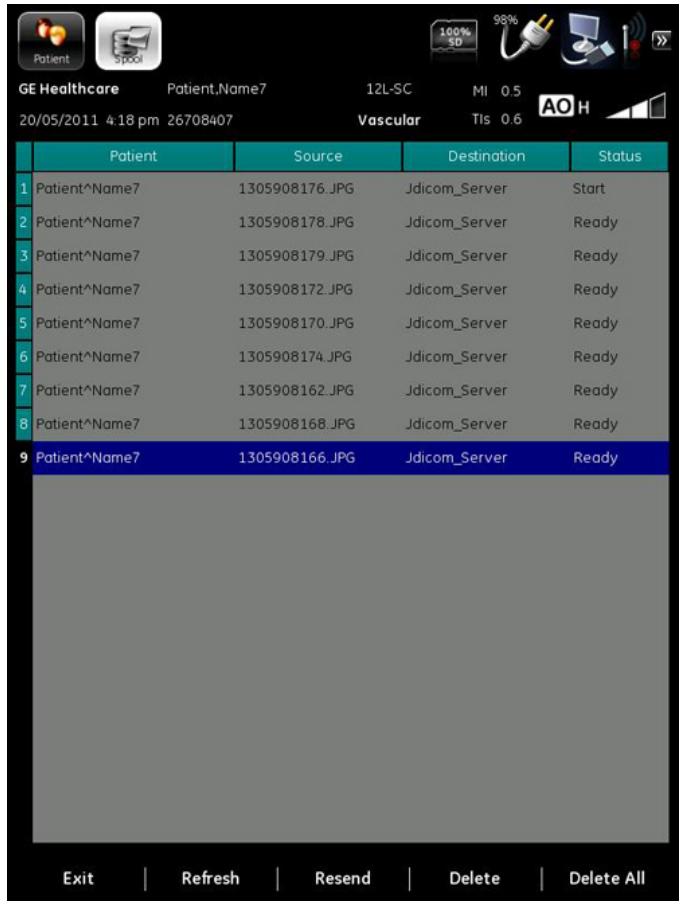


Figure 3-69. Example screen of Spooler

Table 3-16: Job status

Status	Description
Ready	The image transfer is ready
Start	The image transfer has started
Finished	The image transfer is successfully finished.
Failed	The image transfer failed.

Chapter 4

Customizing Your System

Describes how to view system information and configure system settings.

Utility

Overview

Preset Menus provides the following functionality:

- **General -** Configure general system settings
- **Setting** - Configure system settings
- **Image** - View MI and TI parameters
- ***Measure** - Configure measurement settings

NOTE: Measure configuration is not available on R1.x.x and R2.0.x.

- **System** - Product information and Software Option
- ***Connectivity** - Configure system connectivity settings

NOTE: Connectivity configuration is not available on R1.x.x.

- **About** - Software and Hardware Version

General

The General screen allows you to specify Facility Name, System Language, Date Format, System Date, Time Format and System Time.

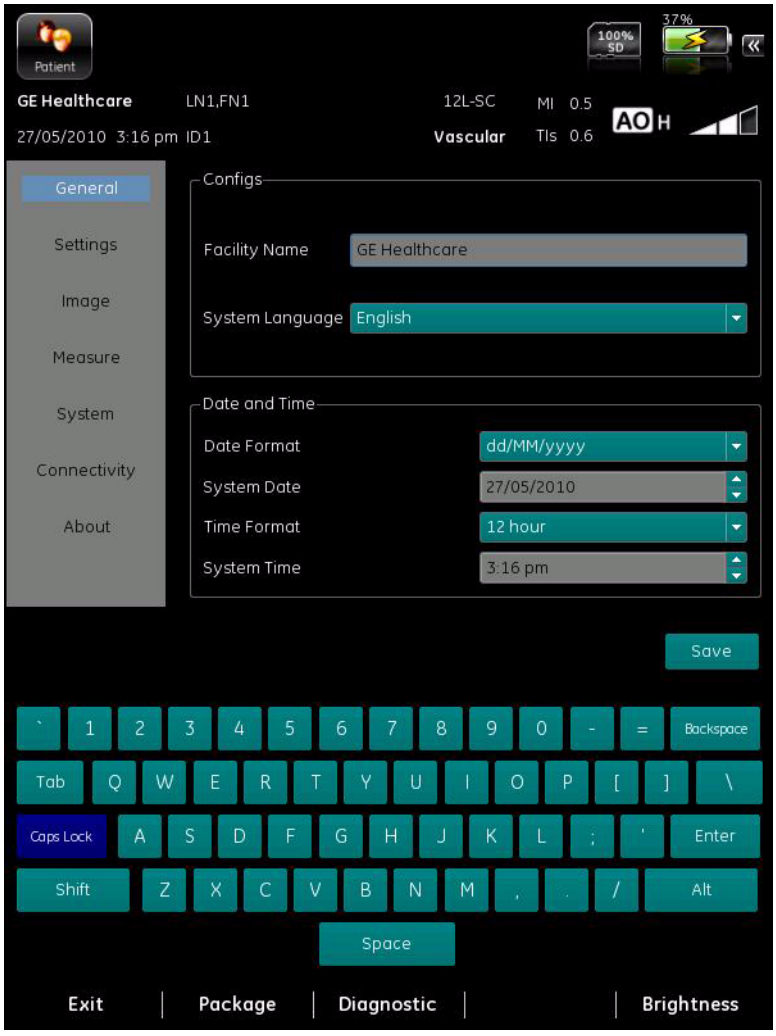


Figure 4-1. Utility General page

General (continued)

Table 4-1: General setting parameters

Preset Parameter	Description
Facility Name	Type the Hospital/Healthcare center/Institute Name
System Language	Select the appropriate language from the drop-down list.
Date Format	Select the appropriate date format from the drop-down list.
System Date	Set the appropriate date.
Time Format	Select the appropriate time format from the drop-down list.
System Time	Set the appropriate time.

Setting

General tab of the Setting screen allows you to specify parameters for the following:

- Storage Location
- Video Length in seconds
- Patients on screen
- 2nd ID
- Printer Enable
- Image Store Area

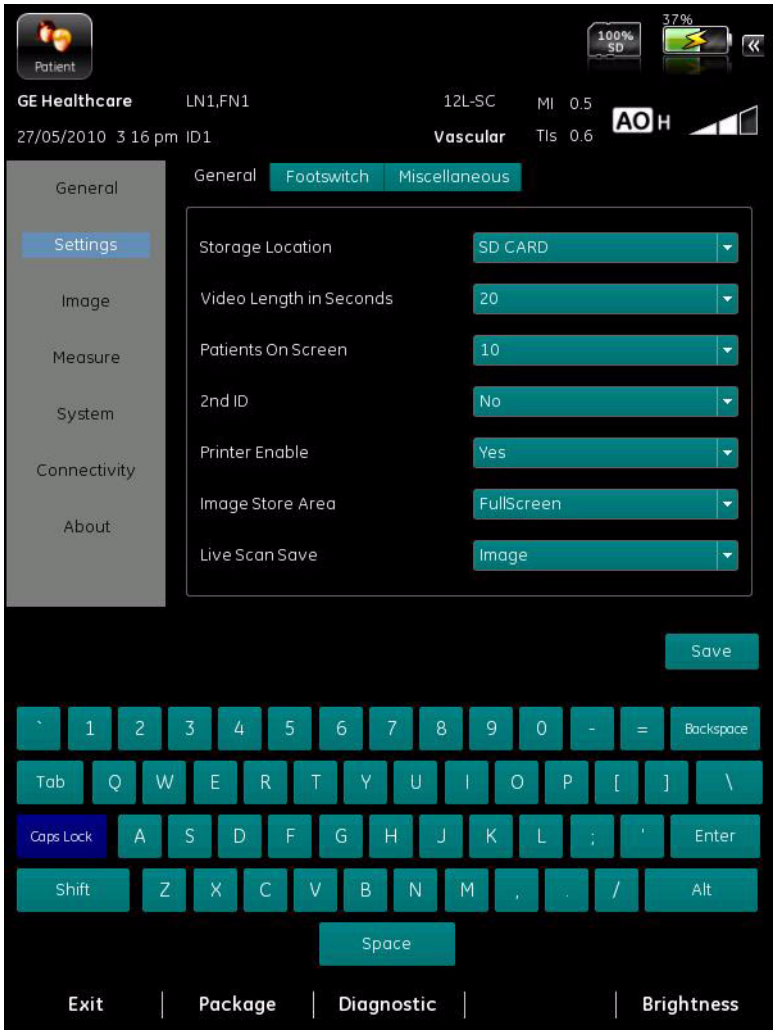


Figure 4-2. Utility Setting-General page

Setting (continued)

Miscellaneous tab of the Setting screen allows you to specify parameters for the following:

Volume portion:

- Venue 40 speaker
- Docking speaker

Following item can be viewed in Storage portion:

- Current Storage

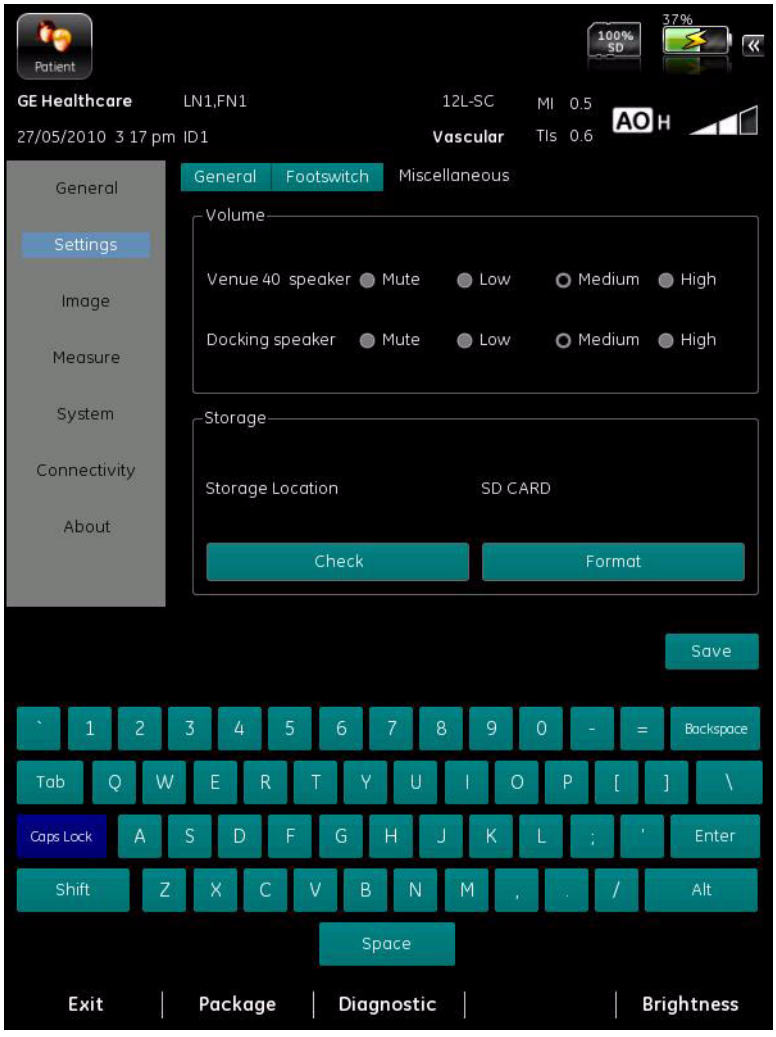


Figure 4-3. Utility Setting-Miscellaneous page

Setting (continued)

Footswith tab of the Setting screen allows you to specify parameters for the following:

Footswitch:

- Left key
- Middle key
- Right key

NOTE: Footswitch is not available on software version R1.x.x and R2.0.x.

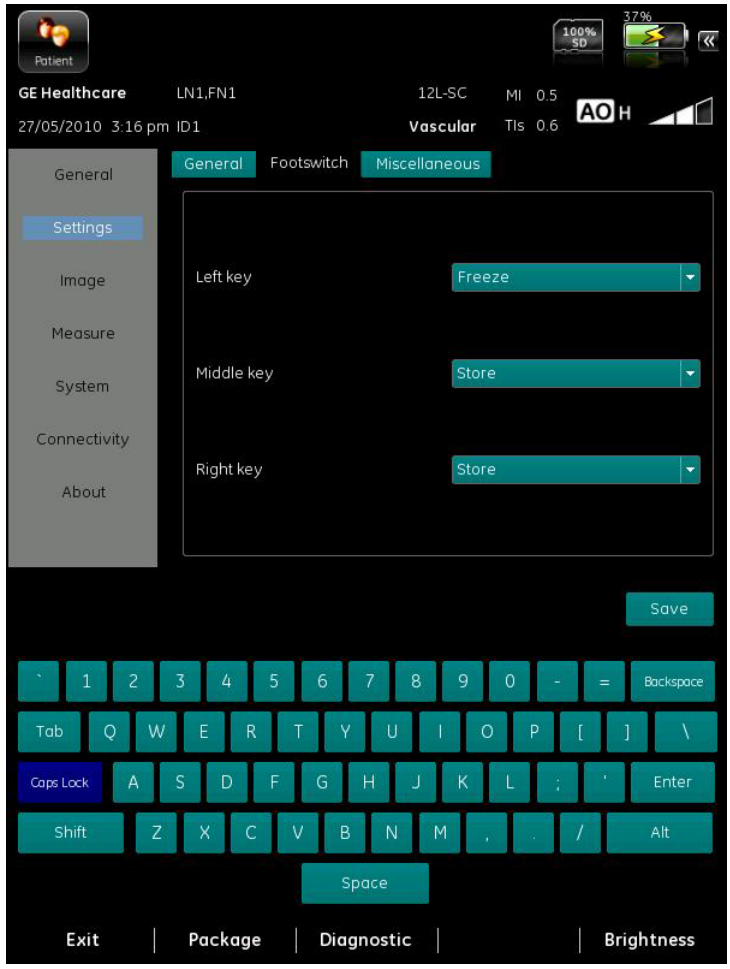


Figure 4-4. Utility Setting-footswitch page

Setting (continued)

Table 4-2: Setting-General Parameters

Preset Parameter	Description
Storage Location	Select media type to use for image storage. (SD card or USB memory stick)
Video length in seconds	Select the length of video storage.
Patients on screen	Select the numbers of patients shown on screen in the patient gallery from drop-down menu.
2nd ID	Select Yes to enable 2nd ID field in patient screen
Printer Enable	Select Yes to enable and No to disable the printer function
Image Store Area	Select Image Area or Full Screen for the image store area in the drop-down menu
Live Scan Save*	Select Image to store single frame image after pressing save during live scanning; select Video to store cine loop after pressing save during live scanning.
*NOTE: R3.x.x only	

Table 4-3: Setting-Miscellaneous Parameters

Preset Parameter	Description
Venue 40 Speaker	Select Mute, Low, Medium or High for Venue 40 speaker volume.
Docking Speaker	Select Mute, Low, Medium or High for Docking Station/Cart speaker volume.
Storage	View Storage Location.
Check	Select to check and restore current storage device.
Format	Select to format current storage device.

Setting (continued)

Table 4-4: Setting-Footswitch Parameters (R3.x.x only)

Preset Parameter	Description
Left key	Configure the left footswitch pedal for the selected application. Select the functionality from the list.
Middle key	Configure the middle footswitch pedal for the selected application. Select the functionality from the list.
Right key	Configure the right footswitch pedal for the selected application. Select the functionality from the list.

Image

The Preset portion of the Image screen allows you to select the type of TI parameter including:

- TIC
- TIS
- TIB

The Image portion of the Image screen allows you to specify parameters for the following:

- Reverse

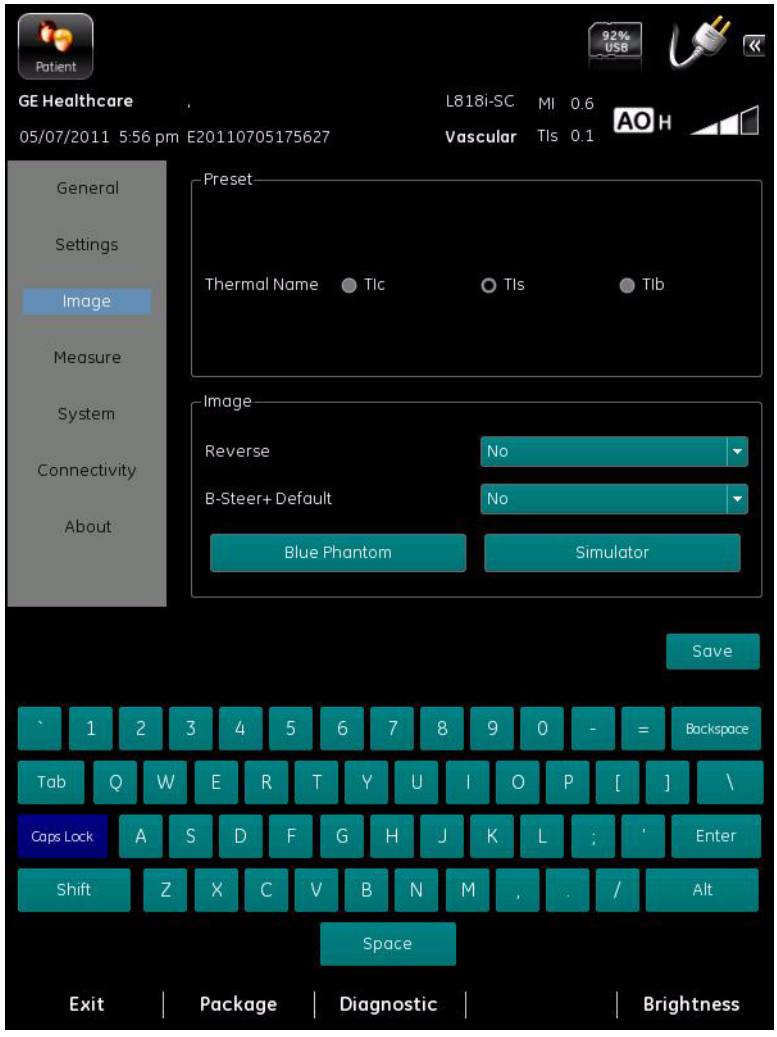


Figure 4-5. Utility Image page

Image (continued)

Table 4-5: Image Parameters

Preset Parameter	Description
Reverse	Select Yes to flip the image 180 degrees.
Load Phantom Preset	Select to load Phantom preset. If selected, the system should not be used to perform scan on human subjects. Only for Linear probes. Note: R2.0.x only
B-Steer+ Default*	Select Yes to set B-steer+ screen as default when entering in B Mode for Linear probes. Only for Linear probes. Note: R3.x.x only
Blue Phantom*	Select to load Blue Phantom preset. If selected, the system should not be used to perform scan on human subjects. Only for Linear probes. Note: R3.x.x only.
Simulator*	Select to load Simulator preset. If selected, the system should not be used to perform scan on human subjects. Only for Linear probes. Note: R3.x.x only.

NOTE: If select Blue Phantom or Simulator, the system should not be used to perform scan on human subjects.

Measure (R3.x.x only)

The Measure screen lists measurement configurations.

The Obstetrics tab shows the OB measurement settings of the Venue 40:

- OB Type
- EFW Format
- OB table

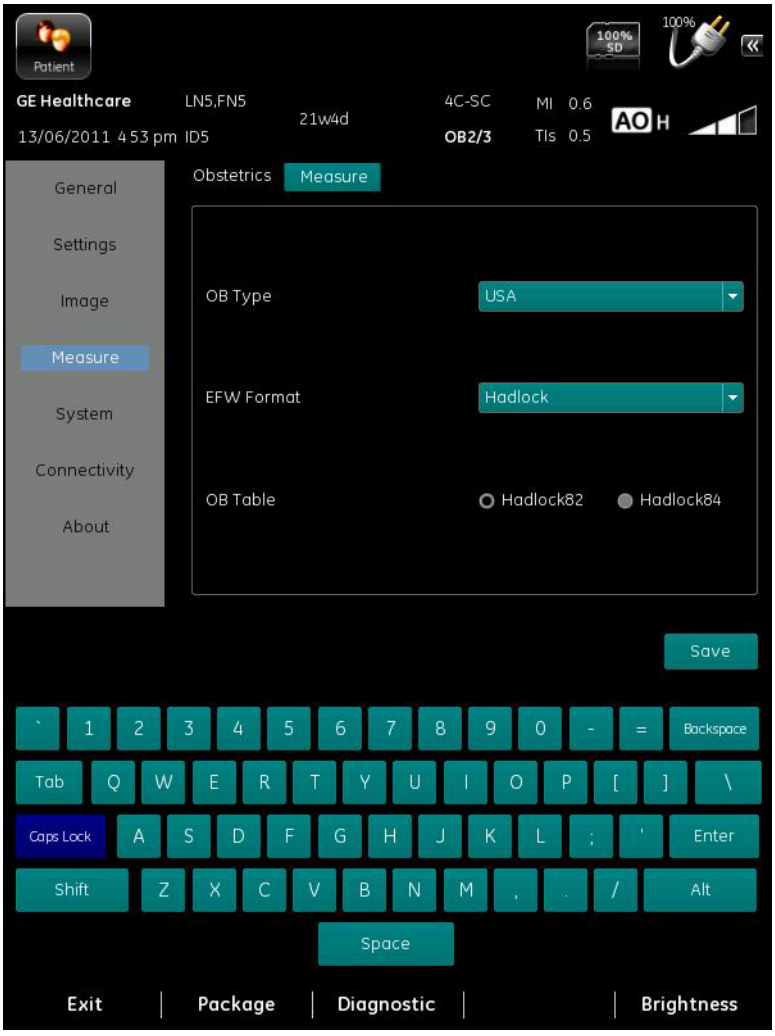


Figure 4-6. Utility Measure-Obstetrics page

Measure (R3.x.x only) (continued)

The Measure tab shows the configuration of measure:

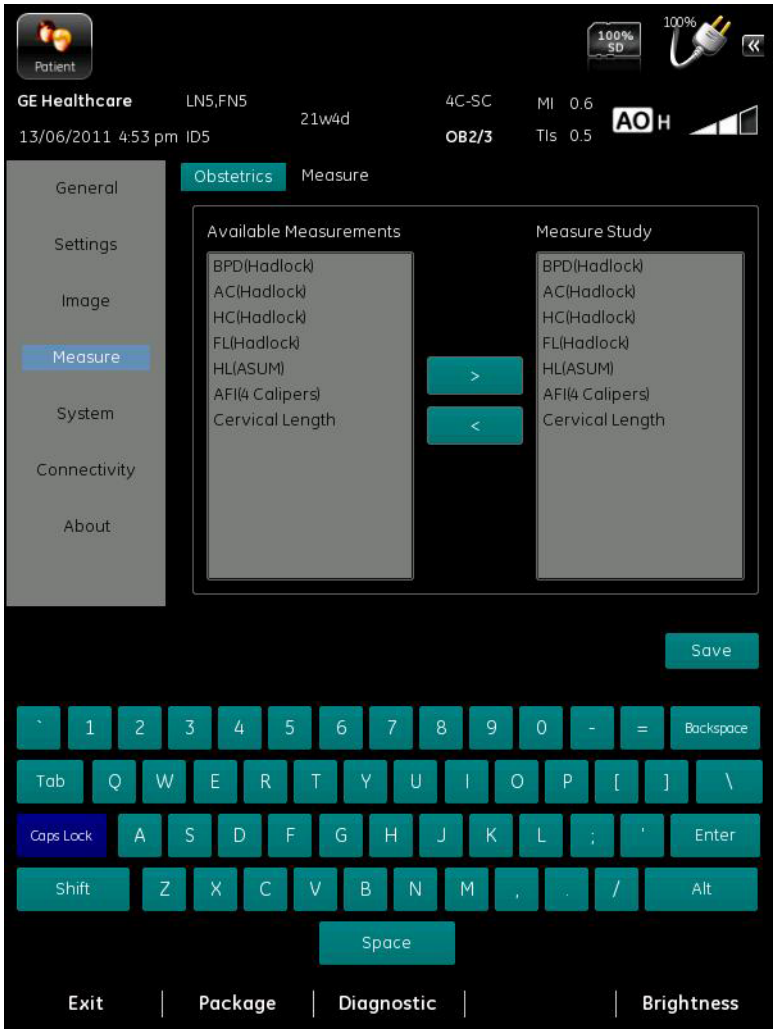


Figure 4-7. Utility Measure-measure page

Measure (R3.x.x only) (continued)

Table 4-6: Obstetrics settings

Preset Parameter	Description
OB Type	Select which OB measurements and calculations studies to use: USA, Europe, Tokyo, Osaka, or ASUM.
EFW Format	Select the source used to calculate EFW (Estimated Fetal Weight): Hadlock, Tokyo or Osaka.
OB Table	Select Hadlock82 or Hadlock 84.

Table 4-7: Measure settings

Available measurements	The available obstetrics measurements for current OB Type.
Measure Study	The selected obstetrics measurements (maximum of 10 measurements).

System

The System screen lists system information.

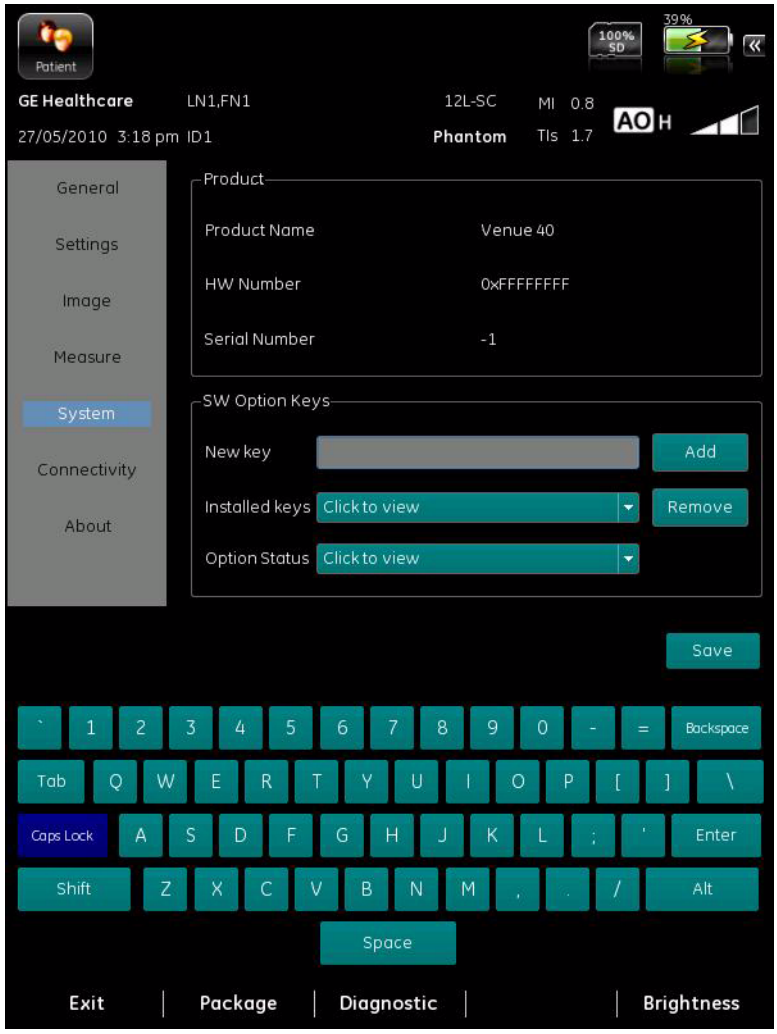


Figure 4-8. Utility System page

System (continued)

Table 4-8: Product Parameters

Preset Parameter	Description
Product Name	Display the system name
HW Number	Display converted hardware ID of the serial number
Serial Number	Display system serial number.

Table 4-9: SW Option Parameters

Preset Parameter	Description
New key	Add new software option keys when installing software options.
Installed keys	Click to view the installed keys in the system.
Option status	Click to view installed software option status.

Connectivity (R2.0.x, R3.x.x only)

The Connectivity screen lists connectivity configurations.

The TCP/IP screen shows the IP status of the Venue 40:

- IP Address
- Subnet Mask
- Default Gateway

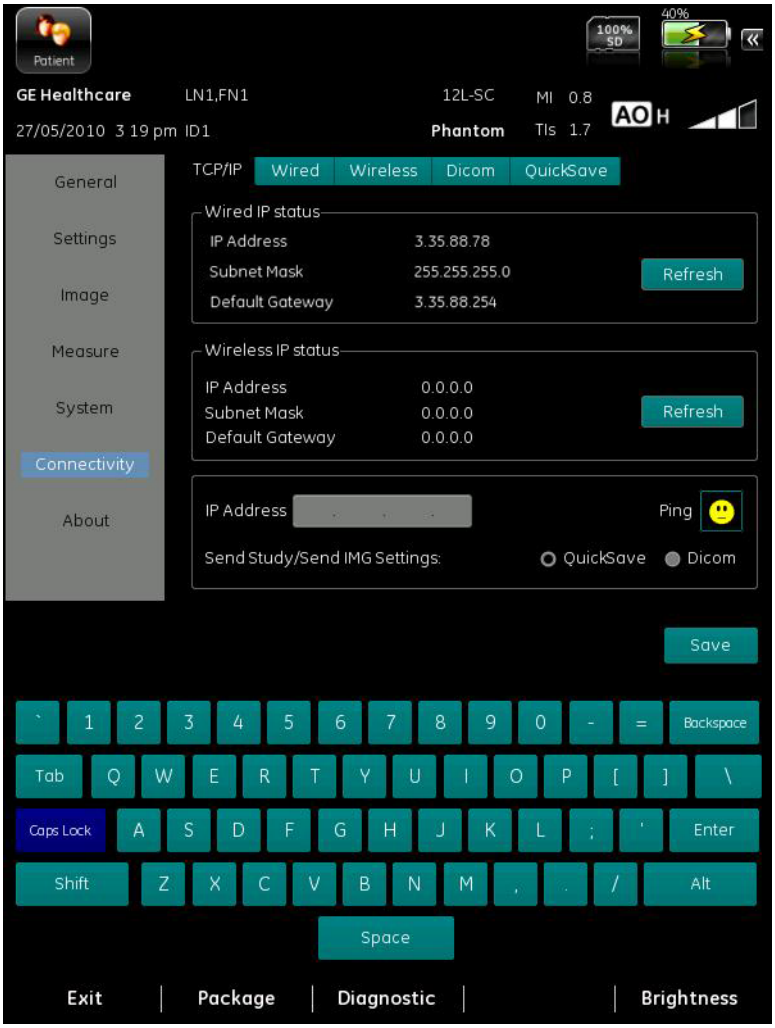


Figure 4-9. Utility Connectivity-TCP/IP page

Connectivity (R2.0.x, R3.x.x only) (continued)

The Wired screen shows the configuration of wired network:

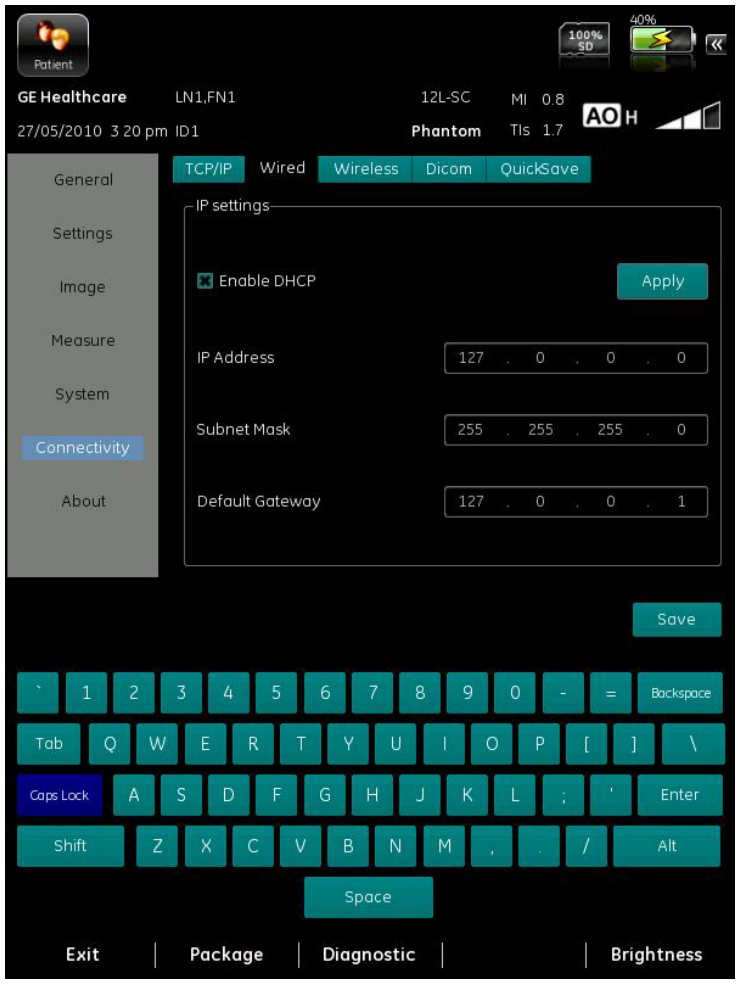


Figure 4-10. Utility Connectivity-Wired page

Table 4-10: IP settings

Preset Parameter	Description
Enable DHCP	Select to enable dynamic IP Address selection.
IP Address	Type the IP Address of the Venue 40.
Subnet Mask	Type the subnet mask address.
Default Gateway	Type the default gateway address.

Connectivity (R2.0.x, R3.x.x only) (continued)

The Wireless screen shows the configuration of wireless network:

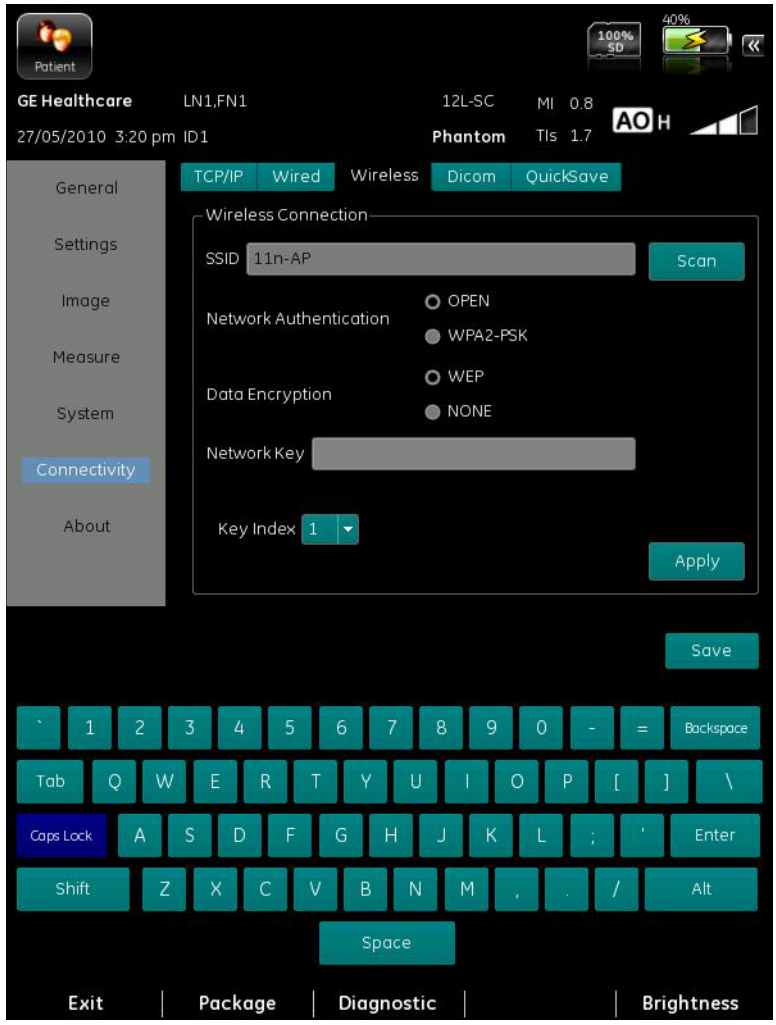


Figure 4-11. Utility Connectivity-Wireless page

Connectivity (R2.0.x, R3.x.x only) (continued)

Table 4-11: Wireless Connection

Preset Parameter	Description
SSID	Select Scan, the list of the available wireless netwok displays. Select the wireless network that needs to be connected to.
Network Authentication	Select OPEN or WPA2-PSK for Network Authentication
Data Encryption	Select WEP or NONE for Data Encryption type if the Network Authentication is OPEN. Select AES or TKIP if the Network Authentication is WPA2-PSK.
Network Key	Type the Network Key.
The key is provided for me automatically	Check it so that the Key Index is automatically set to 1.
Key Index	Select 1 to 4 from the drop-down menu for Key Index. NOTE: only available when the Network Authentication is OPEN and the Data Encryption is WEP.

Connectivity (R2.0.x, R3.x.x only) (continued)

The DICOM screen shows the configuration of DICOM:

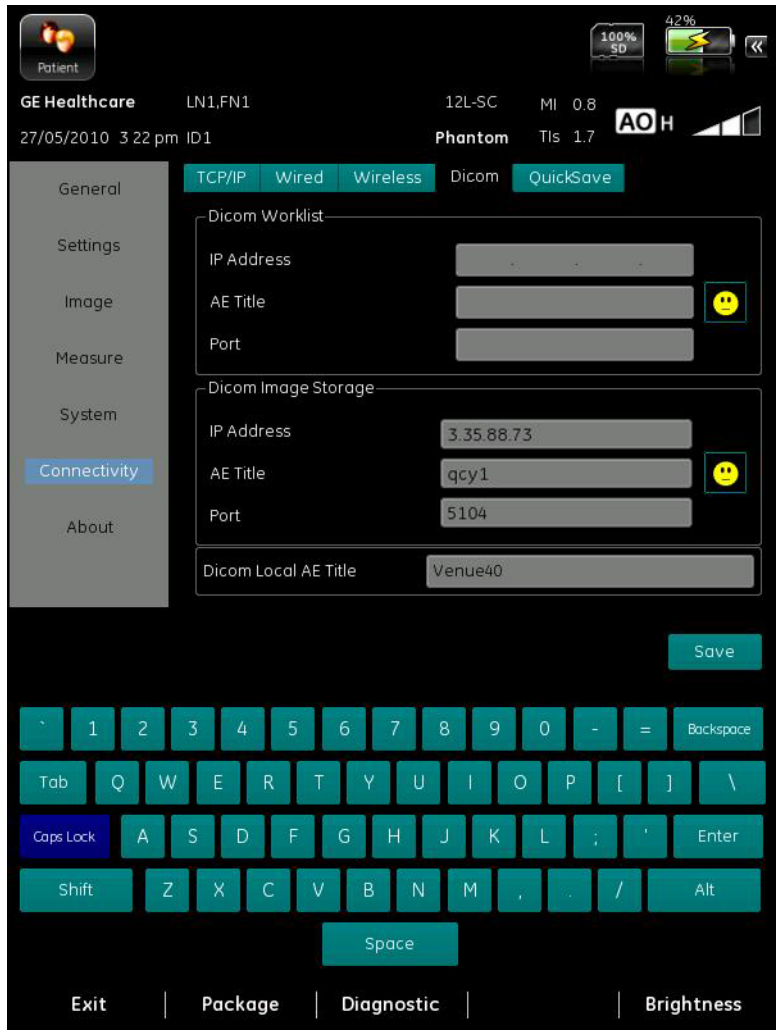


Figure 4-12. Utility Connectivity-DICOM page

Table 4-12: DICOM Worklist settings

Preset Parameter	Description
IP Address	Type the IP Address of the worklist server
AE Title	Type the calling AE Title of the worklist server
Port	Type the port of the worklist server

Connectivity (R2.0.x, R3.x.x only) (continued)

Table 4-13: DICOM Image Storage settings

Preset Parameter	Description
IP Address	Type the IP Address of the DICOM image server
AE Title	Type the calling AE Title of the DICOM image server
Port	Type the port of the DICOM image server

Table 4-14: DICOM settings

Preset Parameter	Description
DICOM local AE Title	Type the local DICOM called AE Title
Set Dicom Default	Select to set DICOM as default when sending images or patients.

Connectivity (R2.0.x, R3.x.x only) (continued)

The QuickSave screen shows the configuration of QuickSave:

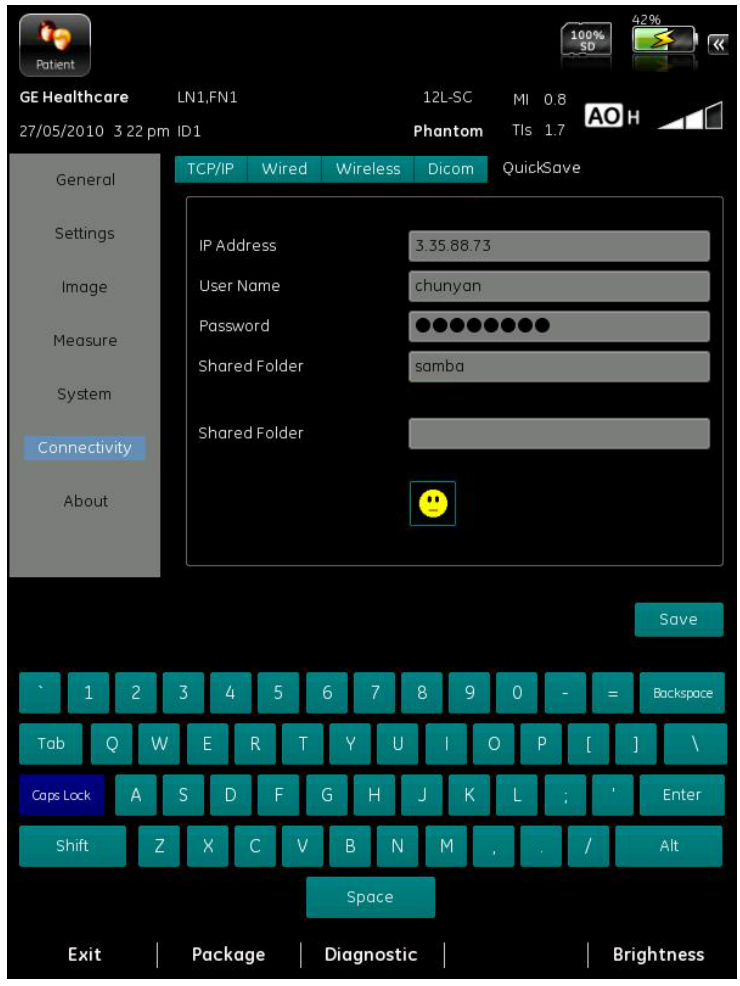


Figure 4-13. Utility Connectivity-QuickSave page

Table 4-15: QuickSave settings

Preset Parameter	Description
IP Address	Type the IP Address of the shared folder.
User Name	Type the User Name.
Password	Type the password.
Shared folder	Type the Shared folder name.

About

The About screen allows you to view software and hardware versions:

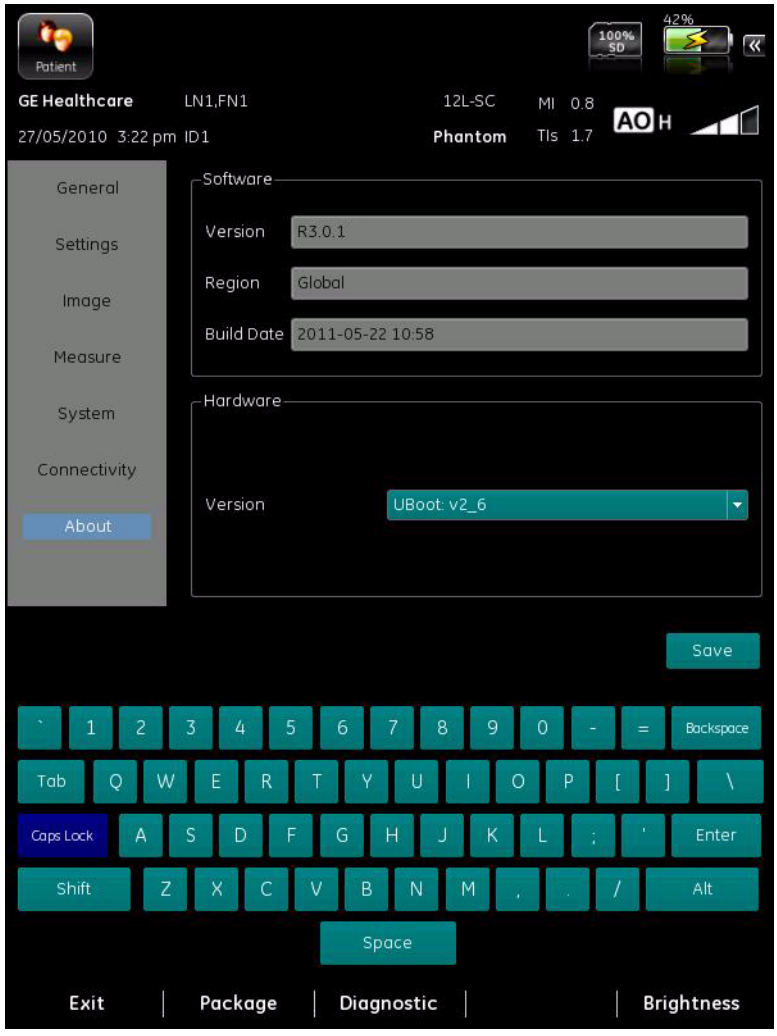


Figure 4-14. Utility About page

About (continued)

Table 4-16: Software version Parameters

Preset Parameter	Description
Version	View software version.
Region*	Region of the preset.
Build Date	View software build date.
*R2.0.x and R3.x.x only.	

Table 4-17: Hardware version Parameters

Preset Parameter	Description
Version	View hardware version of main boards.

Chapter 5

Probes and Biopsy

This chapter consists of the information of each probe and describes some special concerns, biopsy kits and accessories as well as basic procedures for attaching a bispsy guide to the different types of probes.

Probe Overview

Ergonomics

Probes have been ergonomically designed to:

- Handle and manipulate with ease
- Connect to the system with one hand
- Be lightweight and balanced
- Have rounded edges and smooth surfaces.
- Stand up to typical wear by cleaning and disinfectant agents, contact with approved gel, etc.

Cables have been designed to:

- Connect to system with appropriate cable length

Cable handling

Take the following precautions with probe cables:

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

Probe orientation

Each probe is provided with an orientation marking (refer to Figure 5-1). This mark is used to identify the end of the probe corresponding to the side of the image having the orientation mark on the display.

Figure 5-1. Orientation Marking on Probe (Example)

1. Orientation Mark

Labeling

Each probe is labeled with the following information:

- Seller's name and manufacturer
- Operating frequency (not shown on all probes)
- GE part number
- Probe serial number
- Month and year of manufacture
- Probe designation-provided on the probe grip and the top of the connector housing, so it is easily read when mounted on the system and is also automatically displayed on the screen when the probe is selected.

Probe Applications

Table 5-1: Probe Indications for Use

Probe Application	3S-SC	12L-SC	4C-SC*	L8-18i-SC*	E8CS-SC*
Peripheral Vascular		x		x	
Fetal/OB	x		x		x
Abdominal	x	x	x	x	
GYN			x		x
Urology			x		x
Pediatric	x	x	x	x	
Small Organ		x		x	
Neonatal Cephalic	x	x		x	
Adult Cephalic	x				
Cardiac	x				
Conventional Musculoskeletal		x	x	x	
Superficial Musculoskeletal		x		x	
Thoracic (fluid, Pleural and motion detection)	x	x	x	x	
Interventional Guidance		x	x	x	
Intraoperative	x	x	x	x	
Vascular Access		x		x	
Tissue Biopsy	x	x	x	x	
Non Vascular (including Nerve Block)		x	x	x	
Transvaginal					x

*Note: 4C-SC probe is not available on software version R1.0.x
*Note: L8-18i-SC probe is not available on software version R1.x.x
*Note: E8CS-SC probe is not available on software version R1.x.x and R2.0.x

Probe Specifications

Table 5-2: System Probe Definitions

Probe Designation	Center Image Frequency [MHz)	Doppler Frequency (MHz)	
		Normal	Penetration
3S-SC	2.0 ± 20%	2.2	1.8
12L-SC	7.5 ± 20%	4.4	4.0
4C-SC*	3.1 ± 10%	3.08	2.5
L8-18i-SC*	9.5 ± 20%	8.7	5.71
E8CS-SC*	6.5 ± 20%	5.0	4.0
*Note: 4C-SC probe is not available on software version R1.0.x *Note: L8-18i-SC probe is not available on software version R1.x.x *Note: E8CS-SC probe is not available on software version R1.x.x and R2.0.x			

Probe Slice Thickness Specifications

Table 5-3: System Probe Definitions

Probe	Slice Thickness
3S-SC	<=10mm
12L-SC	<=8mm
4C-SC*	<=8mm
L8-18i-SC*	<=8mm
E8CS-SC*	<=13mm
*Note: 4C-SC probe is not available on software version R1.0.x *Note: L8-18i-SC probe is not available on software version R1.x.x *Note: E8CS-SC probe is not available on software version R1.x.x and R2.0.x	

Probe Usage

For details on connecting, activating, deactivating, disconnecting, transporting and storing the probes, See ‘Probes’ on *page 2-35 for more information.*

Care and Maintenance

Inspecting probes

Perform After Each Use

Inspect the probe's lens, cable, casing, and connector. Look for any damage that would allow liquid to enter the probe. If any damage is found, do not use the probe until it has been inspected and repaired/replaced by a GE Service Representative.

NOTE: Keep a log of all probe maintenance, along with a picture of any probe malfunction.

Environmental Requirements

Probes should be operated, stored, or transported within the parameters outlined below.

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

Table 5-4: Probe Environmental Requirements

	Operational	Storage	Transport
Temperature	10° - 40° C 50° - 104° F	-5° - 50° C 14° - 140° F	-5° - 50° C -40° - 140° F
Humidity	30 - 75% non-condensing	10 - 90% non-condensing	10 - 90% non-condensing
Pressure	700 - 1060hPa	700 - 1060hPa	700 - 1060hPa

Probe Safety

Handling precautions

Ultrasound probes are highly sensitive medical instruments that can easily be damaged by improper handling. Use care when handling and protect from damage when not in use. DO NOT use a damaged or defective probe. Failure to follow these precautions can result in serious injury and equipment damage.

Electrical shock hazard

The probe is driven with electrical energy that can injure the patient or user if live internal parts are contacted by conductive solution:

- **DO NOT** immerse the probe into any liquid beyond the level indicated by the immersion level diagram. Refer to the immersion illustration in the Probe Cleaning Process section. Never immerse the probe connector or probe adaptors into any liquid.
- **DO NOT** drop the probes or subject them to other types of mechanical shock or impact. Degraded performance or damage such as cracks or chips in the housing may result.
- Prior to each use, visually inspect the probe lens and case area for cracks, cuts, tears, and other signs of physical damage. DO NOT use a probe which appears to be damaged until you verify functional and safe performance. You must perform a more thorough inspection, including the cable, strain relief, and connector, each time you clean the probe.
- Before inserting the connector into the probe port, inspect the probe connector pins. If a pin is bent, do not use the probe until it has been inspected and repaired/replaced by a GE Service Representative.
- **DO NOT** kink, tightly coil, or apply excessive force on the probe cable. Insulation failure may result.
- Electrical leakage checks should be performed on a routine basis by GE Service or qualified hospital personnel. Refer to the service manual for leakage check procedures.

Mechanical hazards

A defective probe or excessive force can cause patient injury or probe damage:

- Observe depth markings and do not apply excessive force when inserting or manipulating intercavitary probes.
- Inspect probes for sharp edges or rough surfaces that could injure sensitive tissue.
- DO NOT apply excessive force to the probe connector when inserting into the probe port. The pin of a probe connector may bend.

Special handling instructions

Using protective sheaths

Protective barriers may be required to minimize disease transmission. Probe sheaths are available for use with all clinical situations where infection is a concern. Use of legally marketed, sterile probe sheaths is strongly recommended for intra-cavitary and intra-operative procedures. Use of legally marketed, sterile, pyrogen free probe sheaths is REQUIRED for neurological intra-operative procedures.

Instructions. Custom made sheaths are available for each probe. Each probe sheath kit consists of a flexible sheath used to cover the probe and cable and elastic bands used to secure the sheath.

Sterile probe sheaths are supplied as part of biopsy kits for those probes intended for use in biopsy procedures. In addition to the sheath and elastic bands, there are associated accessories for performing a biopsy procedure which are included in the kit. Refer to the biopsy instructions for the specific probes in the Discussion section of this chapter for further information.

Reordering. To reorder sheaths, please contact your local distributor or the appropriate support resource.

Devices containing latex may cause severe allergic reaction in latex sensitive individuals. Refer to FDA's March 29, 1991 Medical Alert on latex products.

Do not use pre-lubricated condoms as a sheath. In some cases, they may damage the probe. Lubricants in these condoms may not be compatible with probe construction.

DO NOT use an expired probe sheath. Before using probe sheaths, verify whether the term of validity has expired.

Probe handling and infection control

This information is intended to increase user awareness of the risks of disease transmission associated with using this equipment and provide guidance in making decisions directly affecting the safety of the patient as well as the equipment user.

Diagnostic ultrasound systems utilize ultrasound energy that must be coupled to the patient by direct physical contact. Depending on the type of examination, this contact occurs with a variety of tissues ranging from intact skin in a routine exam to recirculating blood in a surgical procedure. The level of risk of infection varies greatly with the type of contact.

One of the most effective ways to prevent transmission between patients is with single use or disposable devices. However, ultrasound transducers are complex and expensive devices that must be reused between patients. It is very important, therefore, to minimize the risk of disease transmission by using barriers and through proper processing between patients.

CAUTION

Risk of Infection. ALWAYS clean and disinfect the probe between patients to the level appropriate for the type of examination and use FDA-cleared probe sheaths where appropriate.

CAUTION

Adequate cleaning and disinfection are necessary to prevent disease transmission. It is the responsibility of the equipment user to verify and maintain the effectiveness of the infection control procedures in use. Always use sterile, legally marketed probe sheaths for intra-cavitary and intra-operative procedures.

For neurological intra-operative procedures, use of a legally marketed, sterile, pyrogen free probe sheath is REQUIRED. Probes for neuro surgical use must not be sterilized with liquid chemical sterilants because of the possibility of neuro toxic residues remaining on the probe.

Probe Cleaning Process

You MUST disconnect the probe from the Venue 40 prior to cleaning/disinfecting the probe. Failure to do so could damage the system.

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.

To minimize the risk of infection from blood-borne pathogens, you must handle the probe and all disposables which have contacted blood, other potentially infectious materials, mucous membranes, and non-intact skin in accordance with infection control procedures. You must wear protective gloves when handling potentially infectious material. Use a face shield and gown if there is a risk of splashing or splatter.

Cleaning probes (continued)

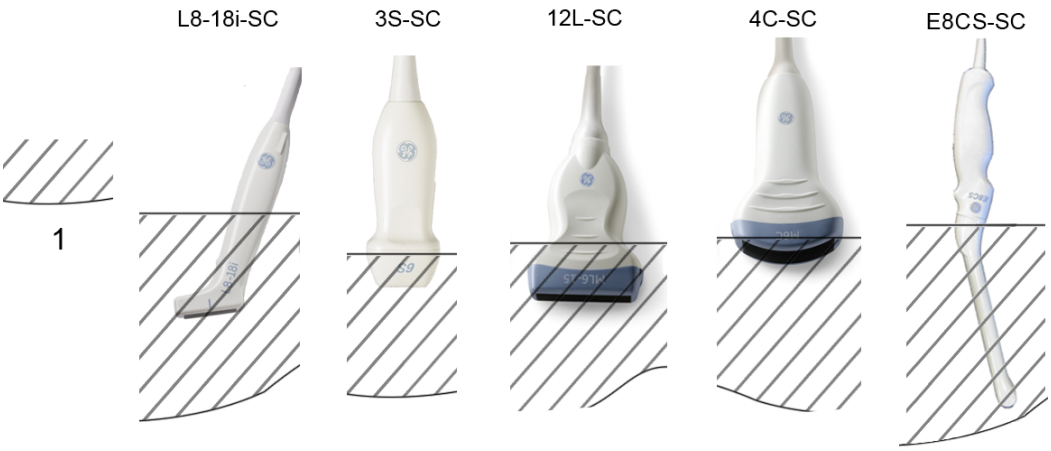


Figure 5-2. Probe Immersion Levels

1. Fluid Level

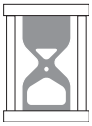
The immersed part of the probe is IPX7.

Disinfecting probes

Perform After Each Use

Ultrasound probes can be disinfected using liquid chemical germicides. The level of disinfection is directly related to the duration of contact with the germicide. Increased contact time produces a higher level of disinfection.

Table 5-5: 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)

Review the probe care card that is packed with each probe. The following website contains the most current and up-to-date recommendations:

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

Cidex Plus has been approved for all probes available on the Venue 40.

Pera Safe high level disinfectant has been approved for the 12L-SC probes.

T-spray low-level disinfectant has been approved for the 12L-SC, L8-18i-SC and 3S-SC probes. T-Spray II has been approved for all the probes available on the Venue 40.

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 Venue 40 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)

WARNING

CREUTZFIELD-JAKOB DISEASE

Failure of the probe sheath or direct contact of the probe with dura or any intra-cranial tissue of patients with Creutzfield-Jakob disease requires that the probe be destroyed. There is no effective means for decontamination of the probe. For more information, see the Center of Disease Control and Prevention http://www.cdc.gov/ncidod/hip/sterile/cjd.htm.

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.

Coupling gels

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

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.

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

Planned Maintenance

The following maintenance schedule is suggested for the system and probes to ensure optimum operation and safety..

Table 5-6: Planned Maintenance Program

Do the Following	Daily	After Each Use	As Necessary
Inspect the Probes	X		X
Clean the Probes		X	X
Disinfect Probes		X	X

Returning/Shipping Probes and Repair Parts

US Department of Transportation and GE Medical Systems policy requires that equipment returned for service MUST be clean and free of blood and other infectious substances.

When you return a probe or part for service (Field Engineer or customer), you need to clean and disinfect the probe or part prior to packing and shipping the equipment.

Ensure that you follow probe cleaning and disinfection instructions provided in the Basic User Manual.

This ensures that employees in the transportation industry as well as the people who receive the package are protected from any risk.

Probe Discussion

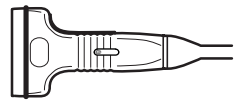
Introduction

The Venue 40 supports the following types of probes:

- **Curved Array (Convex).** Curved Array (Convex) probes, including `micro' convex, are usually designated by the prefix/suffix "C"; the endocavitary probe is designated by the prefix/suffix "E".
- **Linear Array.** Linear Array probes are designated by the prefix/suffix "L"; the linear intra-operative probes are designated by the prefix/suffix "I" or "T".
- **Phased Array Sector.** Phased Array Sector probes are designated by the prefix/suffix "S"; the biplane TEE probe is designated by the prefix/suffix "B"; the multi-plane TEE probe is designated by the prefix/suffix "T".

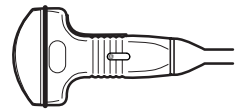
Linear Probes

Table 5-7: Linear Array Probes

Probe	Intended Uses	Capabilities and Features	Illustration
12L-SC	• Peripheral Vascular • Pediatric • Small Organ • Conventional Musculoskeletal • Superficial Musculoskeletal • Nonvascular (including Nerve Block) • Interventional • Thoracic (Fluid, Pleural and motion detection) • Abdominal • Neonatal Cephalic • Intraoperative • Vascular Access • Tissue Biopsy	• Wide field of view • Slant scan • Wide field of view for B-Mode resolution & homogeneity • CFM Doppler sensitivity	
L8-18i-SC	• Peripheral Vascular • Pediatric • Small Organ • Conventional Musculoskeletal • Superficial Musculoskeletal • Nonvascular (including Nerve Block) • Thoracic (Fluid, Pleural and motion detection) • Interventional • Abdominal • Neonatal Cephalic • Intraoperative • Vascular Access • Tissue Biopsy	• Wide field of view (Trapezoid) • Small and Lightweight	
*Note: L8-18i-SC probe is not available on software version R1.x.x.			

Convex Probes

Table 5-8: Curved Array (Convex) Probes

Probe	Intended Uses	Capabilities and Features	Illustration
4C-SC*	• Fetal/OB • Abdominal • GYN • Urology • Pediatric • Conventional Musculoskeletal • Interventional • Nonvascular (including Nerve Block) • Thoracic (Fluid, Pleural and motion detection) • Intraoperative • Tissue Biopsy	• Wide field of view • Penetration • Good image uniformity • CFM/Doppler detectability • Biopsy capability	
E8CSC-SC*	• Fetal/OB • GYN • Urology • Transvaginal	• Wide field of view • Good image uniformity • CFM/Doppler detectability	
*Note: 4C-SC probe is not available on software version R1.0.X. *Note: E8CS-SC probe is not available on software version R1.x.x and R2.0.x.			

Sector Probes

Table 5-9: Sector Probes

Probe	Intended Uses	Capabilities and Features	Illustration
3S-SC	• Abdominal • Fetal/OB • Pediatric • Neonatal Cephalic • Adult Cephalic (transcranial) • Cardiac (Adult and Pediatric • Thoracic (Fluid, Pleural and motion detection) • Tissue Biopsy • Intraoperative	• Small footprint • Wide field of view for B-Mode resolution and homogeneity • CFM Doppler sensitivity	

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.

Precautions Concerning the Use of Biopsy Procedures (continued)

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.

Improper cleaning methods and the use of certain cleaning and disinfecting agents can cause damage to the plastic components that will degrade imaging performance or increase the risk of electric shock.

See ‘Probe Safety’ on *page 5-7 for more information.*

Preparing for a Biopsy

Displaying the Guidezone

Activate the Biopsy Kit by selecting Guide from the B-Mode Top Menu.

The available biopsy options appear when Biopsy Kit is selected. There are fixed and adjustable angle biopsy kits available with the Venue 40 depending on the probe. Select the desired biopsy kit.

Displaying the Guidezone (continued)

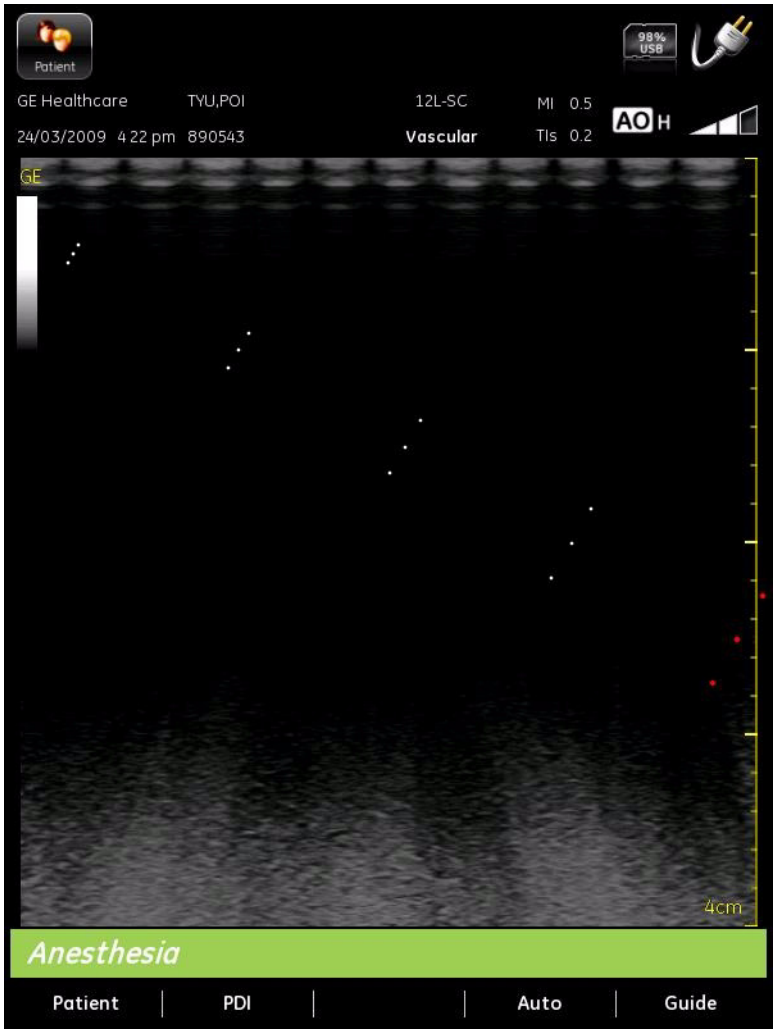


Figure 5-3. Biopsy Guidezones

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.

Displaying the Guidezone (continued)

The needle may vary from the center line or guidezone for various reasons:

- Needle barrel to needle clearance or strength.
- Bracket manufacturing tolerance.
- Needle deflection due to tissue resistance.
- Needle size chosen. Thinner needles may deflect more.

Table 5-10: Biopsy Guide Availability

Probe	Fixed Angle	Multi-Angle		
		MBX1	MBX2	MBX3
3S-SC		4.0	5.5	8.0
12L-SC		1.5	2.5	3.5
4C-SC*		4.1	6.07	10.05
*Note: 4C-SC probe is not available on software version R1.0.x				

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.

NOTE: Although the multi-angle guides are compatible with the Civco Ultrapro and Ultrapro II, it is recommended the multi-angle guides only be used with the Ultrapro II.

Preparing the Biopsy Guide Attachment

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.

Fixed Needle Biopsy Guide Assembly

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).

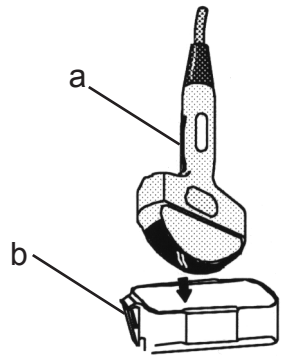


Figure 5-4. Probe/Bracket Alignment

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

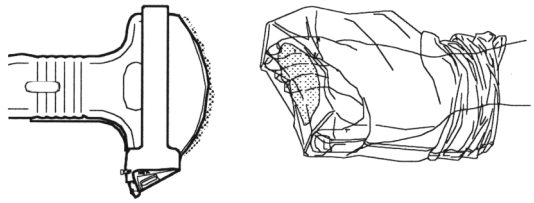


Figure 5-5. Applying Sanitary Sheath

Fixed Needle Biopsy Guide Assembly (continued)

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

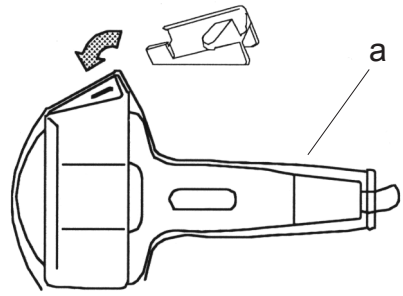


Figure 5-6. Fixed Needle Clip Attachment

a. Sheath

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

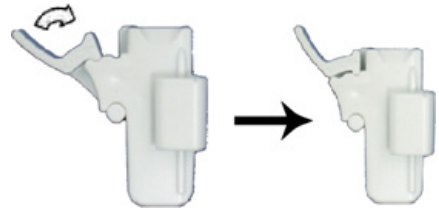


Figure 5-7. Locking the Needle Clip

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

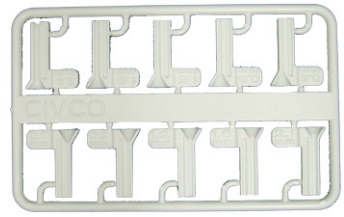


Figure 5-8. Needle Barrel Selection

Fixed Needle Biopsy Guide Assembly (continued)

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

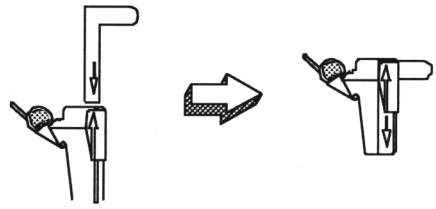


Figure 5-9. Needle Barrel Installation

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 A1 to A3 to decide the best angle setting for needle path.
2. Identify the appropriate biopsy guide bracket by matching the label on the bracket with the probe to be used.

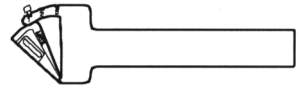


Figure 5-10. Multi-Angle Biopsy Guide Bracket

3. Orient the bracket so that the needle clip attachment will be on the same side as the probe orientation mark (ridge).

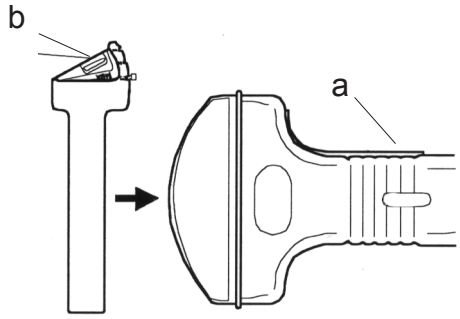


Figure 5-11. Probe/Bracket Alignment

a. Probe Orientation Mark
b. Bracket

4. Attach the biopsy bracket to the probe by sliding the bracket over the end of the probe until it clicks or locks in place.

Multi Angle Biopsy Guide Assembly (continued)

5. Pull up on the knob to freely move the needle guide attachment. Align the knob with the selected position of the needle guide attachment from MBX1, MBX2 and MBX3, to match the guidezone display on the ultrasound system.

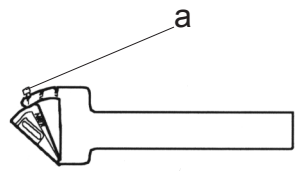


Figure 5-12. Select the angle position

a. Pull up

6. Push the knob down into the desired slot to secure the angle position of the needle guide attachment.

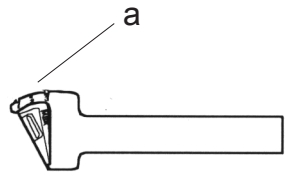


Figure 5-13. Fix the angle position

a. Push

CAUTION

Hold the bracket in place on the probe when pushing the knob to secure the angle position of the needle guide attachment. Excessive force may cause the bracket to release from the probe.

Multi Angle Biopsy Guide Assembly (continued)

7. Place an adequate amount of coupling gel on the face of the probe.
8. Place the proper sanitary sheath tightly over the probe and biopsy bracket. Use the rubber bands supplied to hold the sheath in place.

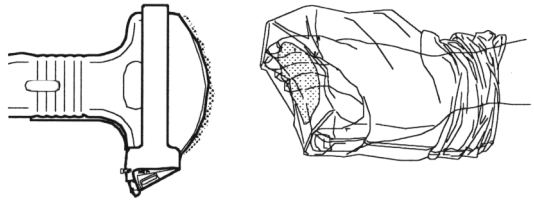


Figure 5-14. Applying Sanitary Sheath

9. Snap the needle clip onto the biopsy guide bracket.

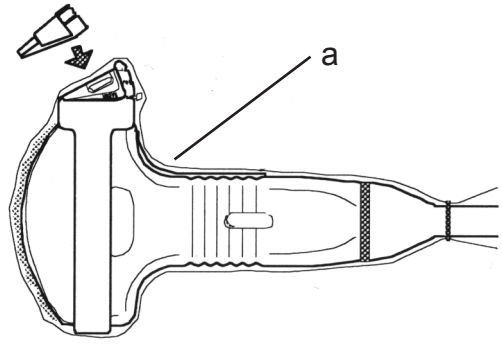


Figure 5-15. Fixing the Needle Clip Attachment

a. Sheath

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

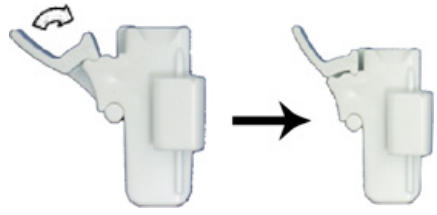


Figure 5-16. Locking the Needle Clip

Multi Angle Biopsy Guide Assembly (continued)

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

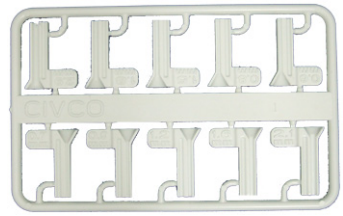


Figure 5-17. Needle Barrel Selection

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

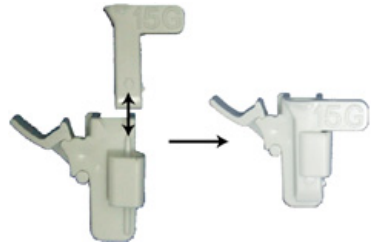


Figure 5-18. Needle Barrel Installation

CAUTION

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

Releasing the needle

According to the following procedure, you remove the needle from a probe and an assembly without moving the needle.

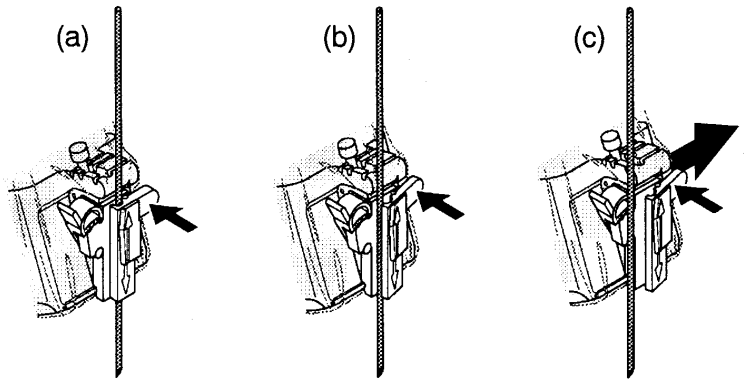


Figure 5-19. Release the needle from assembly

a. Push the knob portion of a sleeve in the direction of the arrow.
b. The needle is released from the assembly.
c. Push the probe and the assembly in the direction of the larger arrow to remove the needle.

Biopsy Needle Path Verification

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

- Properly install the bracket and biopsy guide.
- Scan in a container filled with water (47° C).
- Display the biopsy guidezone on the monitor.
- Ensure that the needle echo falls within the guidezone markers.

The Biopsy Procedure

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 by pressing **Guide**. When using multi-angle guides, ensure that the proper guidezone angle is displayed.
3. Scan to locate the target. Center the target in the electronic guidezone path.

NOTE: Enabling color flow would allow for visualization of the vascular structure around the area to be biopsied.

4. Place the needle in the guide between the needle barrel and needle clip. Direct it into the area of interest for specimen retrieval.

Post Biopsy

When the biopsy is complete, remove the needle barrel, needle clip and probe sheath. Properly dispose of these items in accordance with current facility guidelines.

Clean and disinfect the probe. See ‘Probe Cleaning Process’ on *page 5-11 for more information.*

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

CAUTION

When the biopsy needle guide kit (UP, UP2 or UP2+) is opened, all parts must be discarded after the procedure whether they have been used or not.

Interventional Use

Preparing for Interventional Procedures

Preparing the transducer for interventional use follows the same sterile procedure as for biopsy use except that no biopsy attachments are used. See ‘Preparing the Biopsy Guide Attachment’ on *page 5-28 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.

For interventional procedures, a sterile environment is required. Therefore, both the operator and probe needs to be sterile.

Preparing for Interventional Procedures (continued)

To ensure a sterile environment during the procedure, it is recommended that this be a two-person job.

1. Perform a high level disinfection of the probe.
2. The scanner (surgeon, sonographer, etc.) should be sterile and gloved.
3. Place an adequate amount of sterile coupling gel on the face of the probe.
4. Place the proper sterile sheath over the probe and cord.

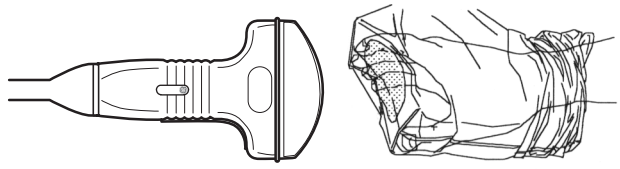


Figure 5-20. Applying Sterile Sheath

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 interventional procedures for probe cleaning and disinfection.

Chapter 6

User Maintenance

This chapter supplies system data, assistance information, and system care and maintenance instructions.

System Data

Features/Specifications

NOTE: Some feature(s)/probe(s) may not be available in some country(ies)/region(s), please contact your sales representative for detailed information.

Table 6-1: Physical Attributes

Dimensions and Weight • Height: 282 mm (console only) • Width: 274 mm • Depth: 56 mm (console only) • Weight: 3.4 Kg (with battery) Electrical Power • Voltage:100-240 Vac • Frequency: 50/60 Hz • Power Consumption: 180VA max.	Console Design • Tablet Style • Lithium-ion Battery Pack (Standard) • 1 Probe port with SC-connector • Speaker • Stylus • Docking Station/Cart (Option)

Table 6-2: User Interface

Touch Screen • Simplified layout • Mode specific controls • Alphanumeric Keyboard • Measurement • Annotation • Utility settings • Patient information entry • Touch and stylus user interface	Display Screen • 10.4 inch High-Resolution Color 800*600 LCD • Touch screen user interface Hard Keys • 9/10* Ergonomic Hard Key Operation (backlit) • On/Off button *NOTE: 9 hard keys on R1.x.x; 10 hard keys on R2.0.x, R3.x.x. LED • Battery remaining capacity

Table 6-3: System Overview

Packages • Vascular Access • Musculoskeletal • Anesthesia • Point of Care • Interventional Standard Features • Standard CINE Memory • Auto Tissue Optimization • Loops storage from memory • Distance/Area* Measurement *NOTE: Area measurement on R2.0.x, R3.x.x only. Transducer Types • Electronic Phased Array • Electronic Convex Array • Electronic Linear Array Operating Modes • B-Mode • M-Mode • Power Doppler Imaging (PDI) • Color Flow (CFM) • B-Steer+ (R3.x.x only)	Display Modes • B-Mode • M-Mode • Power Doppler Imaging (PDI) • Color Flow (CFM) Software Options • Applications • Color/PDI • M-Mode • DICOM • B-Steer+ (R3.x.x only) Accessory Options • Battery • Docking Station • Docking Cart • Probes Media Options • USB Memory Stick Peripheral Option • USB thermal B/W Printer: SONY UP-D897 (option) • Footswitch: MKF 2 1S/1S-MED HID GP26 (option) (R3.x.x only)

Table 6-4: System Parameters

Pre-Processing • Acoustic Power Output • Color Flow (CFM Gain; Steer; PRF) Post-Processing • B-Mode (Auto Tissue Optimization) • B-Steer+ with Needle Recognition (R3.x.x only)	System Setup • Diagnostic Categories: Customer focused • Factory Default Application Data • Operation Error: Error message display • Patient Name Format: Last, First • System Boot Up: <17 sec • Probe Loading: <5 sec

Table 6-5: Imaging Processing and Presentation

Software Intensive Ultrasound Imaging Platform • Image Reverse: Right/ Left • Imaging Depth: 0.5-27cm, Probe dependent • Digital Beamformer • Continuous Dynamic Receive Focus/Aperture • Multi-Frequency/Wideband Technology CINE Memory/Image Memory • Standard CINE Memory (120MB) • CINE Review: Frame-by-frame, Loop replay • Live Scan Save: Configure save button to save an image during live scanning (R3.x.x only)	Image Archive • Image Browser: Archived images from past patient appear as well as images stored for the current patient - Previewing an image • Image Management (removable media): Delete Selected Image, Review in Full Image Area • 1 Print UI Key to approved printer • Live Scan Save: Configure save button to save an image during live scanning (R3.x.x only) • Archiving Format: JPEG, MPEG • Capture Area: Image Area, Full Screen • Archiving Image Frames: Single - stores single frame while in Freeze mode, Multiple - stores image loops while in Live scan mode. • Patient Information Window, Search/Create Patient Window: Column header sorting in Image Review Screen by Name, Date and ID; Automatic generation of patient ID; Search by ID, First Name and Last Name • DICOM*: DICOM store, Worklist query • Network Quicksave* *Note: R2.0.x and R3.x.x only

Table 6-6: Scanning Parameters

B-Mode • B Acoustic Output: preset in 3 step toggle for Low, Med, High • Thermal Index: TI • Gain: preset in 3 step toggle for Low, Med and High • Depth: 0.5-27cm, probe dependent • Frequency: defined by the application • Grey Map: defined by the application • B-Steer+: depth specific steer angles (R3.x.x only) CF-Mode • Invert: On/Off • CF Acoustic Output: preset in 3 step toggle for Low, Med, High • PRF: preset 3 step toggle, probe dependent • Gain: preset 3 step toggle • Steer: preset 3 step toggle for Right, Center, Left • CF Vertical Size (mm): default preset • CF Center Depth (mm): default preset • CF Frequency: defined by the application • Color Map: defined by the application	M-Mode • B Acoustic Output: preset in 3 step toggle for Low, Med, High • Thermal Index: TI • Gain: preset in 3 step toggle for Low, Med, High • Depth: 0.5-27cm, probe dependent • Speed: 7 steps • Frequency: defined by the application PDI-Mode • PDI Acoustic Output: preset in 3 step toggle for Low, Med, High • PRF: preset 3 step toggle, probe dependent • Gain: preset 3 step toggle • Steer: preset 3 step toggle for Right, Center, Left • PDI Vertical Size (mm): default preset • PDI Center Depth (mm): default preset • PDI Frequency: defined by the application • Color Map: defined by the application

Table 6-7: Measurements

General Measurements • Distance • Area* • Depth* • Heart Rate/Time* *NOTE: R2.0.x, R3.x.x only OB Worksheet (R3.x.x only) • Patient Information: Fetus Number, CUA/AUA Selection • Measurement Information: AFI, AC, HC, BPD, FL • Calculation Information: EFW, EFW GP (Growth Percentile), FL/BPD, FL/AC, HC/AC, FL/HC, CI (Cephalic Index) • OB Graphs: Fetal Growth Curve Graphs - Quad views, Fetal Growth Bar Graph - Ultrasound age and gestational age	Obstetrics Measurements/Calculations (R3.x.x only) • Abdominal Circumference (AC) • Amniotic Fluid Index (AFI) [Moore] • Area • Antero-Postero Trunk Diameter and Transverse Trunk Diameter (APTD-TTD) • Biparietal Diameter (BPD) • Crown Rump Length (CRL) • Estimated Fetal Weight (EFW) • Femur Length (FL) • Gestational Sac (GS) • Head Circumference (HC) • Humerus Length (HL) • Occipitofrontal Diameter (OFD) • Cardio-Thoracic Area Ratio (CTAR) • Fetal Trunk Cross-Sectional Area (FTA) • Spine Length (SL) • Multi-Gestational Calculations up to 3 fetuses • Comparison of multiple fetus data on a graph and a worksheet

Table 6-8: Probes

• 12L-SC Wide Band Linear Probe (Applications: Peripheral Vascular, Pediatric, Small Organ, Conventional Musculoskeletal, Superficial Musculoskeletal, Thoracic (fluid, Pleural and motion detection), Non vascular (including Nerve Block), Interventional, Abdominal, Neonatal Cephalic, Intraoperative, Vascular Access and Tissue Biopsy) • L8-18i-SC*: Wide Band Linear Probe (Applications: Peripheral Vascular, Pediatric, Small Organ, Conventional Musculoskeletal, Superficial Musculoskeletal, Non vascular (including Nerve Block), Thoracic (fluid, Pleural and motion detection), Interventional, Abdominal, Neonatal Cephalic, Intraoperative, Vascular Access and Tissue Biopsy)	• 3S-SC: Wide Band Phased Array Sector Probe (Application: Abdominal, Fetal/OB, Pediatric, Neonatal Cephalic, Adult Cephalic (transcranial), Cardiac (Adult and Pediatric), Thoracic (fluid, Pleural and motion detection), Tissue Biopsy and Intraoperative) • 4C-SC*: Wide Band Phased Array Convex Probe (Application: Fetal/OB, GYN, Urology, Abdominal, Pediatric, Thoracic (fluid, Pleural and motion detection), Conventional Musculoskeletal, Non vascular (including Nerve Block), Interventional, Introperative and Tissue Biopsy) • E8CS-SC*: Wide Band Phased Array Convex Probe (Application: Fetal/OB, GYN, Urology and Transvaginal)
*Note: 4C-SC probe is not available on software version R1.0.x. *Note: L8-18i-SC probe is not available on software version R1.x.x. *Note: E8CS-SC probe is not available on software version R1.x.x and R2.0.x.	

Table 6-9: Inputs and Outputs Signal

Inputs • DVI interface on Docking Station/Cart	Outputs • USB interface on Docking Station/Cart • Docking Connector • Removable SD Card • Wireless LAN* • Wired LAN *NOTE: R2.0.x, R3.x.x only

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 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 6-10: System Measurements and Accuracies

Measurement	Units	Useful Range	Accuracy	Limitations or Conditions
Distance:				
Axial	mm	Full Screen	±5%	
Lateral	mm	Full Screen	±5%	Linear Probes
Lateral	mm	Full Screen	±5%	Sector Probes
Lateral	mm	Full Screen	±5%	Convex probes
Circumference:				
Ellipse	mm^2	Full Screen	±5%	
Area:				
Ellipse	mm^2	Full Screen	±10%	
Heart Rate	BPM	Full Screen	±5%	

Doppler Sensitivity

Measurements were obtained with each transducer over a range of fluid velocities as indicated in the following table. The maximum detectable depth of motion was measured and converted to round-trip sensitivity in dB corresponding to the depth and transmit frequency. The chart below summarizes the sensitivities for all transducers in penetration-on mode.

Table 6-11: Doppler sensitivity data summary

Probe	Velocity Range (cm/s)		Max Depth (cm)	Frequency (MHz)	Sensitivity (dB)
12L-SC	L	15	5.75	4.00	23
	M	63	5.75	4.00	23
	H	110	5.75	4.00	23
3S-SC	L	15	8.00	2.50	20
	M	63	14.31	2.50	35.775
	H	110	14.59	2.50	36.475
4C-SC*	L	15	13.82	2.50	34.55
	M	63	14.86	2.50	37.15
	H	110	14.73	2.50	36.825
L8-18i-SC	L	15	4.00	5.00	20
	M	63	4.00	5.00	20
	H	110	4.00	5.00	20
E8CS-SC*	L	15	3.72	4.00	14.88
	M	63	3.72	4.00	14.88
	H	110	3.72	4.00	14.88

*Note: 4C-SC probe is not available on software version R1.0.x.
*Note: L8-18i-SC probe is not available on software version R1.x.x.
*Note: E8CS-SC probe is not available on software version R1.x.x and R2.0.x.

System Care and Maintenance

Overview

Refer to Chapter 10 of the Venue 40 Service Manual for any additional maintenance guidance.

Contact the local Service Representative for parts or periodic maintenance inspections.

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 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.

Biological 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 Monitor/Operator Controls
- Stylus
- Docking Station/Docking Cart
- Printer
- Footswitch

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

Cleaning the system

Prior to cleaning any part of the system:

1. Turn off the system power.

LCD Monitor/Operator Controls cleaning and sterilization

To clean the monitor face:

Use the protective bag to wipe monitor face gently.

Or

Wipe the LCD monitor and Operator controls with the following cleaners:

- PDI Sani-Cloth Plus Germicidal Disposable Cloth (low Alcohol)
- PDI Super Sani-Cloth Germicidal Disposable Cloth (high Alcohol)
- PDI Sani-Cloth HB (Germicidal, Alcohol free)
- Sporicidin (Phenol)
- DisCide - recommended for clarity (63% isopropyl)
- Meliseptol Foam Pure

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

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

Footswitch

To clean the footswitch:

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

Stylus

To clean the stylus:

Use the protective bag to wipe gently.

Or

Use a soft, folded cloth with lukewarm water. Gently wipe the stylus. Dry with a cloth or dry in air.

Docking Station/Cart

To clean the Docking Station/Docking Cart:

Use a soft, folded cloth with lukewarm water. Gently wipe the monitor face. Dry with a cloth or dry in air.

Or

Wipe the Docking Station/Cart with the following cleaners:

- PDI Sani-Cloth Plus Germicidal Disposable Cloth (low Alcohol)
- PDI Super Sani-Cloth Germicidal Disposable Cloth (high Alcohol)
- PDI Sani-Cloth HB (Germicidal, Alcohol free)
- Sporicidin (Phenol)
- DisCide - recommended for clarity (63% isopropyl)
- Meliseptol Foam Pure

Printer

To clean the printer:

1. Turn off the power. If possible, disconnect the power cord.
2. Wipe the external surfaces of the unit with a soft, clean, dry cloth.
3. Remove stubborn stains with a cloth lightly dampened with a mild detergent solution.

NOTE: Never use strong solvents, such as thinner or benzine, or abrasive cleansers because they will damage the cabinet.

No further maintenance, such as lubrication, is required.

To clean the surface of the print head:

1. Run the cleaning sheet (provided with the printer) through the printer.

For more information, see the Printer's Operator Manual.

Other Maintenance

Battery Replacement and Disposition

Battery replacement every three years is recommended.

Contact a local Service Representative for the replacement of the battery. Used batteries will be discarded appropriately by GE.

NOTE: Disposing of the battery should meet local law and regulatory requirements.

Stylus tip replacement

After long use of the stylus, when it's getting blunt, replacement of tip is recommended.

To replace the tip:

1. Use the grooved stylus tip tool, grasp and pull out the stylus tip.
2. To insert a new stylus tip, insert the flat end into the stylus securely using the grooved stylus tip tool.

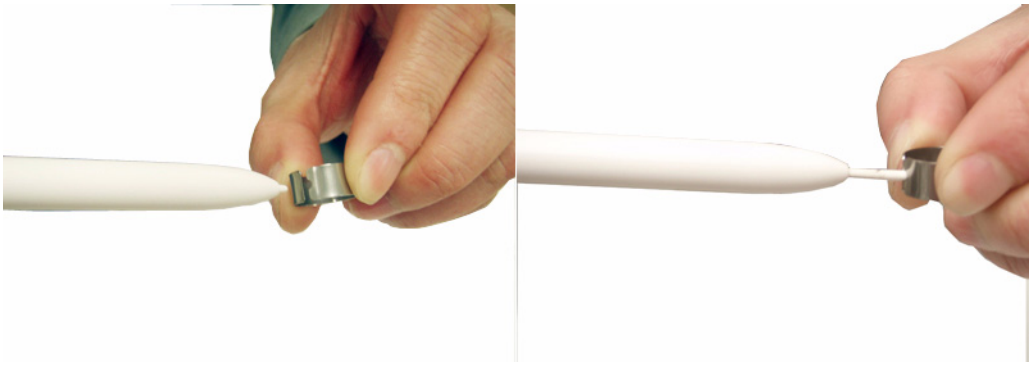


Figure 6-1. Stylus refill replacement

Quality Assurance

Introduction

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

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

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

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

For details on system and peripheral routine preventive maintenance instructions, See ‘System Care and Maintenance’ on *page 6-9 for more information.*

Typical Tests to Perform

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

- Axial Measurement Accuracy
- Lateral Measurement Accuracy
- Axial and Lateral Resolution
- Penetration
- Functional & Contrast Resolution

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

Frequency of tests

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

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

A mobile system may require more frequent tests.

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

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

Phantoms

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

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

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

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

Phantoms (continued)

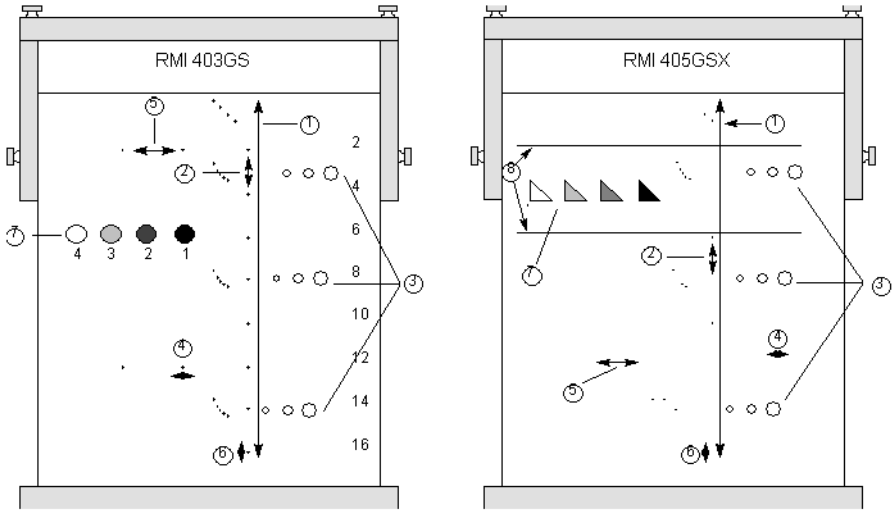


Figure 6-2. Phantoms

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

Baselines

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

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

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

Periodic Checks

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

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

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

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

Results

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

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

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

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

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

System Setup

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

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

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

Test Procedures

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

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

Axial distance measurements

Description

Axial measurements are the distance measurements obtained along the sound beam. See Figure 6-2 for more information.

Benefit

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

Method

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

Procedure

To measure axial distance:

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

Contact a Service Engineer if vertical measurements differ by more than 5% of the actual distance.

Lateral distance measurements

Description

Lateral measurements are distance measurements obtained perpendicular to the axis of the sound beam. See Figure 6-2 for more information.

Benefit

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

Method

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

Procedure

To measure lateral distance:

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

Contact a Service Engineer if horizontal measurements differ by more than 3mm or 5% of that depth, whichever is greater.

Axial resolution

Description

Axial resolution is the minimum reflector separation between two closely-spaced objects to produce discrete reflections along the axis of the sound beam. It can also be monitored by checking the vertical size of known pin targets. See Figure 6-2 for more information.

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

Benefit

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

Procedure

To measure Axial resolution:

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

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

Lateral resolution

Description

Lateral resolution is the minimum reflector separation between two closely spaced objects to produce discrete reflections perpendicular to the axis of the sound beam. It can also be monitored by checking the horizontal size of known pin targets. See Figure 6-2 for more information.

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

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

Benefit

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

Procedure

To measure lateral resolution:

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

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

Penetration

Description

Penetration is the ability of an imaging system to detect and display weak echoes from small objects at large depths. See Figure 6-2 for more information.

Penetration can be affected by the system's:

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

Benefit

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

Method

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

Procedure

To measure penetration:

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

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

Functional resolution

Description

Functional resolution is an imaging system's ability to detect and display the size, shape, and depth of an anechoic structure, as opposed to a pin target. See Figure 6-2 for more information.

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

Benefit

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

Procedure

To measure functional resolution:

1. Gain and acoustic output can be adjusted as necessary, since these values are displayed on the monitor.
2. Scan a test phantom with a vertical row of anechoic cyst targets to typical depths for the probe being used.
3. Evaluate the cysts at various depths for a good (round) shape, well-defined borders and no fill in.
4. Document all results for future reference and comparison.

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

Contrast resolution

Description

Contrast resolution is the ability of an imaging system to detect and display the shape and echogenic characteristics of a structure. See Figure 6-2 for more information.

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

Benefit

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

Method

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

Procedure

To measure contrast resolution:

1. Gain and acoustic output can be adjusted, as necessary, since these values are displayed on the monitor.
2. Scan a test phantom with echogenic targets at the depths available.
3. Evaluate the echogenic targets for contrast between each other and between the surrounding phantom material.
4. Document all results for future reference and comparison.

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

Setting up a Record Keeping System

Preparation

The following is needed:

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

Record Keeping

Complete the following:

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

Ultrasound Quality Assurance Checklist

Table 6-12: Ultrasound Quality Assurance Checklist (Part 1)

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

Table 6-13: (Part 2)

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

NOTE: This is an example checklist, not all the items are available for Venue 40.

Supplies/Accessories

CAUTION

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.

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

Peripherals

Table 6-14: Peripherals and Accessories

Accessory	Unit
Sony B/W Printer (UP-D897)	Each
Kingston High-Capacity SD Card 4GB/8GB	Each
Transcend SD Card Reader P5	Each
SanDisk USB Memory Stick 4GB	Each
Edimax Wireless Network Card	Each

Console

Table 6-15: Console Accessories

Accessory	Units
Battery Pack model (NZBP42)	Each
Footswitch (MKF 2 1S/1S-MED HID GP26)*	Each
*Note: Footswitch is not available on software version R1.x.x and R2.0.x	

Probes

Table 6-16: Probes and Accessories

Accessory	Units
3S-SC	Each
12L-SC	Each
4C-SC*	Each
L8-18i-SC*	Each
E8CS-SC*	Each
*Note: 4C-SC is not available on software version R1.0.x *Note: L8-18i-SC is not available on software version R1.x.x *Note: E8CS-SC is not available on software version R1.x.x and R2.0.x	

Gel

Table 6-17: Gel

Accessory	Units
Aquasonic 100 Scan Gel	5 liter jug
	250 ml plastic bottles (12/ case)

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

USA

GE Healthcare TEL: (1) 800-437-1171
Ultrasound Service Engineering FAX: (1) 414-721-3865
9900 Innovation Drive
Wauwatosa, WI 53226

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

For service for compact products in the United States, call

TEL: (1) 877-800-6776

In other locations, contact your local Service Representative.

Accessories Catalog Requests

To request the latest GE Accessories catalog or equipment brochures in the United States, call the Response Center

TEL: (1) 800-643-6439

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

Contacting GE Healthcare Ultrasound (continued)

Placing an Order

To place an order, order supplies or ask an accessory-related question in the United States, call the GE Access Center

TEL: (1) 800-472-3666

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

CANADA

GE Healthcare TEL: (1) 800-668-0732
Ultrasound Service Engineering
9900 Innovation Drive
Wauwatosa, WI 53226
Customer Answer Center TEL: (1) 262-524-5698

LATIN & SOUTH AMERICA

GE Healthcare TEL: (1) 262-524-5300
Ultrasound Service Engineering
9900 Innovation Drive
Wauwatosa, WI 53226
Customer Answer Center TEL: (1) 262-524-5698

EUROPE

GE Ultraschall TEL: 0130 81 6370 toll free
Deutschland GmbH & Co. KG TEL: (33) 130.831.300
Beethovenstrasse 239 FAX: (49) 212.28.02.431
Postfach 11 05 60
D-42655 Solingen

ASIA

GE Ultrasound Asia (Singapore) TEL: 65-291 8528
Service Department - Ultrasound FAX: 65-272-3997
298 Tiong Bahru Road #15-01/06
Central Plaza
Singapore 169730

JAPAN

GE Healthcare Japan Corporation TEL: (81) 42-648-2910
Customer Service Center FAX: (81) 42-648-2905

Contacting GE Healthcare Ultrasound (continued)

ARGENTINA GEME S.A. TEL: (1) 639-1619
Miranda 5237 FAX: (1) 567-2678
Buenos Aires - 1407

AUSTRIA GE GesmbH Medical Systems Austria TEL: 0660 8459 toll free
Prinz Eugen Strasse 8/8 FAX: +43 1 505 38 74
A-1040 WIEN TLX: 136314

BELGIUM GE Healthcare BVBA TEL: +32 0 2 719 72 04
Koutervеldstraat 20 FAX: +32 0 2 719 72 05
B-1831 Diegem

BRAZIL GE Sistemas Medicos TEL: 0800-122345
Av Nove de Julho 5229 FAX: (011) 3067-8298
01407-907 Sao Paulo SP

CHINA GE Healthcare - Asia TEL: (8610) 5806 9403
No. 1, Yongchang North Road FAX: (8610) 6787 1162
Beijing Economic & Technology Development Area
Beijing 100176, China

DENMARK GE Medical Systems TEL: +45 4348 5400
Fabriksparken 20 FAX: +45 4348 5399
DK-2600 GLOSTRUP

FRANCE GE Medical Systems TEL: 05 49 33 71 toll free
738 rue Yves Carmen FAX: +33 1 46 10 01 20
F-92658 BOULOGNE CEDEX

GERMANY GE Ultraschall TEL: 0130 81 6370 toll free
Deutschland GmbH & Co. KG TEL: (49) 212.28.02.207
Beethovenstrasse 239 FAX: (49) 212.28.02.431
Postfach 11 05 60
D-42655 Solingen

GREECE GE Medical Systems Hellas TEL: +30 1 93 24 582
41, Nikolaou Plastira Street FAX: +30 1 93 58 414
G-171 21 NEA SMYRNI

ITALY GE Medical Systems Italia TEL: 1678 744 73 toll free
Via Monte Albenza 9 FAX: +39 39 73 37 86
I-20052 MONZA TLX: 3333 28

LUXEMBOURG TEL: 0800 2603 toll free

Contacting GE Healthcare Ultrasound (continued)

MEXICO
GE Sistemas Medicos de Mexico S.A. de C.V.
Rio Lerma #302, 1° y 2° Pisos TEL: (5) 228-9600
Colonia Cuauhtemoc FAX: (5) 211-4631
06500-Mexico, D.F.

NETHERLANDS
GE Medical Systems Nederland B.V. TEL: 06 022 3797 toll free
Atoomweg 512 FAX: +31 304 11702
NL-3542 AB UTRECHT

POLAND
GE Medical Systems Polska TEL: +48 2 625 59 62
Krzywickiego 34 FAX: +48 2 615 59 66
P-02-078 WARSZAWA

PORTUGAL
GE Medical Systems Portuguesa S.A.
TEL: 05 05 33 7313 toll free
Rua Sa da Bandeira, 585 FAX: +351 2 2084494
Apartado 4094 TLX: 22804
P-4002 PORTO CODEX

RUSSIA
GE VNIIEM TEL: +7 495 739 6931
18C, Krasnopresnenskaya nab. FAX: +7 495 739 6932
MOSCOW 123317 TLX: 613020 GEMED SU

SPAIN
GE Healthcare TEL: +34 (91) 663 25 00
Edificio Gobelas I FAX: +34 (91) 663 25 01
C/ Gobelas 35-37
E- 28023-Madrid

SWEDEN
GE Medical Systems TEL: 020 795 433 toll free
PO-BOX 1243 FAX: +46 87 51 30 90
S-16428 KISTA TLX: 12228 CGRSWES

SWITZERLAND
GE Medical Systems (Schweiz) AG TEL: 155 5306 toll free
Sternmattweg 1 FAX: +41 41 421859
CH-6010 KRIENS

TURKEY
GE Healthcare Turkiye TEL: +90 212 398 07 00
FAX: +90 212 284 67 00
Esentepe Mah. Harman sok. 34394 No:8
Sisli-Istanbul Turkey

Contacting GE Healthcare Ultrasound (continued)

UNITED KINGDOM

GE Medical Systems TEL: 0800 89 7905 toll free
Coolidge House FAX: +44 753 696067
352 Buckingham Avenue
SLOUGH
Berkshire SL1 4ER

OTHER COUNTRIES

NO TOLL FREE TEL: international code + 33 1 39 20 0007

Manufacturer

GE Medical System (China) Co., Ltd.
No. 19, Changjiang Road
WuXi National Hi-Tech Development Zone
Jiangsu, P.R. China 214028
TEL: +86 510 85225888; FAX: +86 510 85226688

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