Technical Publications

Direction 5446729-100 English

Rev. 7

CE 0197

Venue 50 Basic User Manual

R4.x.x

Operating Documentation

Regulatory Requirement

Venue 50 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 50. It applies to all versions of the R4.x.x software for the Venue 50 ultrasound system.

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Revision History

Reason for Change

REV	DATE (YYYY/MM/DD)	REASON FOR CHANGE
Rev.1	2013/01/04	Initial Release
Rev.2	2013/05/21	Update UI and software functions
Rev.3	2013/09/17	Update UI and software functions
Rev.4	2013/12/12	Update UI and software functions
Rev.5	2014/01/13	Update UI
Rev.6	2014/03/13	Remove "*NOTE: 10C-SC is not available in U.S.*"
Rev.7	2014/09/05	Software updated

List of Effective Pages

SECTION NUMBER	REVISION NUMBER	SECTION NUMBER	REVISION NUMBER
Title Page	Rev. 7	Chapter 3	Rev. 7
Revision History	Rev. 7	Chapter 4	Rev. 7
Regulatory Requirements	Rev. 7	Chapter 5	Rev. 7
Table of Contents	Rev. 7	Chapter 6	Rev. 7
Chapter 1	Rev. 7	Index	Rev. 7
Chapter 2	Rev. 7		

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

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Regulatory Requirements

Conformance Standards

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

- 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 1.
  - Continuous Operation.
- According to CISPR 11,
  - Equipment is Group 1, Class A ISM Equipment.
  - Docking Station/Cart is Group 1, Class A ISM Equipment.
- According to IEC 60529,
  - The footswitch rate is IP X8 (MKF 2 1S/1S-MED HID GP 26).
  - Probe head (immersible portion) and cable are IPX7.

    Probe connector is not waterproof.

This product complies with the regulatory requirement of the following:

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

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

EC REP

Authorized EU Representative

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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 60601-1-2 Electromagnetic compatibility - Requirements and tests.
  - IEC/EN 60601-1-6 (Usability), EN 1041 (Information supplied with medical devices).
  - IEC 60601-2-37 Medical electrical equipment. Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment.
- International Organization of Standards (ISO):
  - ISO 10993-1 Biological evaluation of medical devices.
- Canadian Standards Association (CSA):
  - CSA 22.2, 601.1 Medical Electrical Equipment, Part 1 General Requirements for Safety.
- ANSI/AAMI ES60601-1.
- NEMA/AIUM Acoustic Output Display Standard (NEMA UD-3, 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

Importer Information

- Turkey

  İTHALATÇI
  PENTA ELEKTRONİK MEDİKAL
  SİSTEMLER SAN. VE TİC. A.Ş.
  HOŞDERE CAD. FUAR SOK. 5 / 3
  Y. AYRANCI / ANKARA

Table of Contents

Chapter 1

Introduction/Safety

This chapter consists of information concerning indications for use, how documents are organized (?), and 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 50 system.

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

Disregarding information on safety is considered abnormal use.

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

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

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

Documentation

Safety instructions must be reviewed before operating the unit.

Venue 50 documentation consists of various manuals:

- The Basic User Manual (TRANSLATED) and User Guide (ENGLISH ONLY) provide information needed by the operator to operate the system safely. They describe the basic functions of the system, safety features, operating modes, measurements/calculations, probes, user care and maintenance.
- 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 Obstetrics (OB) and Acoustic Output tables.
- The Service Manual (ENGLISH ONLY) supplies block diagrams, lists of spare parts, descriptions, adjustment instructions or similar information which helps qualified technical personnel in repairing those parts of the system which have been defined as repairable.
- AIUM Booklet (USA only)

The Venue 50 manuals are written for operators who are familiar with basic ultrasound principles and techniques. They do not include sonographic training or detailed clinical procedures.

NOTE: The screen graphics in this manual are only for illustrational purposes. Actual screen output may differ.

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.

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 operator 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 50 is intended for use by a qualified physician or sonographer for ultrasound evaluation.

The Venue 50 is intended for ultrasound imaging, measurement and analysis of the human body for multiple clinical applications including: Ophthalmic; Fetal/OB; Abdominal (GYN & Urology); Pediatric; Small Organ (breast, testes, thyroid); Neonatal Cephalic; Adult Cephalic; Cardiac (adult & pediatric); Peripheral Vascular; Musculoskeletal Conventional & Superficial; Transvaginal; Intraoperative (abdominal, thoracic and peripheral); Thoracic/Pleural for motion and fluid detection and imaging guidance of interventional procedures (Tissue Biopsy/ Fluid Drainage, Vascular Access, Nonvascular).

NOTE: Ophthalmic and Orbits are not available for Japan.

To avoid injury to the patient, select the Ophthalmic or Orbits preset when performing an eye exam. The system will not exceed the lower acoustic energy limits for ophthalmic use only if the Ophthalmic or Orbits preset is selected.

Be sure to use the appropriate probes for eye scanning.

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

Frequency of Use

Daily (Typically 8 hours)

Operator Profile

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

Prescription Device

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

Owner Responsibility

Owner requirements

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

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

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

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

CAUTION

For USA only:

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

Notice against user modification

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

Safety Precautions

Precaution Levels

Icon description

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

d  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

w  WARNING

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

- Severe personal injury
- Substantial property damage

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

Important Safety Considerations

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

Improper use can result in serious injury. The use of the system outside the described conditions or intended use, and disregarding safety related information is considered abnormal use. The manufacturer is not liable for damage caused by abnormal use of the device.

The operator must be thoroughly familiar with the instructions and potential hazards involving ultrasound examination before attempting to use the device. Training assistance is available from GE if needed.

Patient Safety

Related Hazards

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

Patient identification

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

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

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

Diagnostic information

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

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

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

CAUTION

Allowing the machine to transmit acoustic output with the probe not in use (or in its holder) can cause the transducer to build up heat.

CAUTION

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

CAUTION

Be certain to ensure privacy of patient information data.

Mechanical hazards

The use of damaged probes or improper use and manipulation of intracavity probes can result in injury or increased risk of infection. Inspect probes often for sharp, pointed, or rough surface damage that could cause injury or tear protective barriers. Become familiar with all instructions and precautions provided with special purpose probes.


Electrical Hazard

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


WARNING

To avoid risk of electric shock, this equipment must only be connected to a supplymains with protective earth.

Scanner and electrosurgical units

DO NOT use high-frequency surgical equipment with the Venue 50.

ALARA

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

Training

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

Equipment and Personnel Safety

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

Do not use this equipment if a safety problem is known to exist. Have the unit repaired and performance verified by qualified service personnel before returning to use.

Related Hazards


WARNING

This equipment contains dangerous voltages that are capable of serious injury or death.

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

There are no operator serviceable components inside the console. Refer all servicing to the repair center.

Ensure that unauthorized personnel do not tamper with the unit.


Electrical Hazard

To avoid injury:

- Do not remove protective covers. No operator serviceable parts are inside. Refer servicing to qualified service personnel.
- To assure adequate grounding, connect the attachment plug to a reliable (hospital grade) grounding outlet (having equalization conductor ⏚).
- Never use any adaptor or converter of a three-prong-to-two-prong type to connect with a main power plug. The protective earth connection will loosen.
- Be sure that liquid does not drip into the console.
- In North America, a 220-240V installation requires the use of a center-tapped AC power source.

Related Hazards (continued)

Smoke & Fire Hazard

The system must be supplied from an adequately rated electrical circuit. The capacity of the supply circuit must be as specified.

WARNING

Only approved and recommended peripherals and accessories should be used.

All peripherals and accessories must be securely mounted to the Venue 50 or Docking Station/Cart.

WARNING

Venue 50 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.

Explosion Hazard

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

WARNING

Connecting electrical equipment to multiple socket-outlet effectively leads to creating a mechanical system, and can result in a reduced level of safety.

Related Hazards (continued)


Explosion Hazard

Never operate the equipment in the presence of flammable or explosive liquids, vapors or gases. Malfunctions in the unit or sparks generated by fan motors, can electrically ignite these substances. Operators should be aware of the following points to prevent such explosion hazards.

- If flammable substances are detected in the environment, do not plug in or turn on the system.
- If flammable substances are detected after the system has been turned on, do not attempt to turn off the unit, or to unplug it.
- If flammable substances are detected, evacuate and ventilate the area before turning off the unit.


CAUTION

Peripheral devices that use their own AC power source CANNOT be attached to the Venue 50. DO NOT connect the peripheral device's power cord into the Venue 50 system.

Use a USB printer cable that is less than 3 meters (9.8 feet) in length.


CAUTION

Do not use this equipment if a safety problem is known to exist. Have the unit repaired and performance verified by qualified service personnel before returning to use.

Related Hazards (continued)


Biological Hazard

For patient and personnel safety, be aware of biological hazards while performing invasive procedures. To avoid the risk of disease transmission:

- Use protective barriers (gloves and probe sheaths) whenever possible. Follow sterile procedures when appropriate.
- Thoroughly clean probes and reusable accessories after each patient examination and disinfect or sterilize as needed. Refer to *Probes and Biopsy* for probe use and care instructions.
- Follow all infection control policies established by your office, department or institution as they apply to personnel and equipment.


CAUTION

Contact with natural rubber latex may cause a severe anaphylactic reaction in persons sensitive to the natural latex protein. Sensitive operators 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

To avoid injury or system damage, NEVER place any object or liquid on the operator panel.

CAUTION

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

CAUTION

DO NOT use high-frequency surgical equipment with the Venue 50.

CAUTION

Make sure to verify the media after writing of data, including Save, Backup and Restore.

Before deleting a patient or image from the patient screen, make sure you have saved the data and verify that the media transfer of data was successful.

CAUTION

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

DO NOT touch the conducting parts of the USB, ethernet, video, audio cables when connecting equipment to the unit.

General Caution

CAUTION

Standard maintenance must be performed by authorized service personnel during 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 Venue 50. Failure to do so may cause serious injury or system damage.

CAUTION

The maximum capacity load is 8kg (17.6lbs) for the Printer Shelf (1) and 2kg (4.4lbs) for the Accessories Shelf (2). Please refer to the figure below.

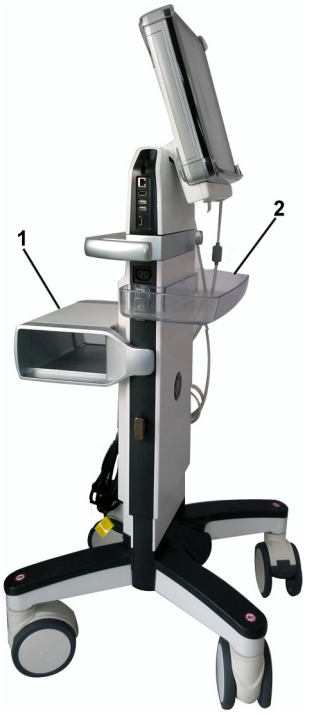


Figure 1-1. Capacity Load

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 operator (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 operators' 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.

Proper installation following the service manual is required in order to achieve the full EMC performance of the product.

The product must be installed as stipulated in “Notice upon Installation of Product” section.

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 operators’ authority to operate the equipment.

CAUTION

Do not use devices which intentionally transmit RF signals (cellular phones, transceivers, or radio controlled products), other than those supplied by GE (wireless microphone, broadband over power lines, for example) unless intended for use with this system, in the vicinity of this equipment as it may cause performance outside the published specifications.

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

The 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 requirement.

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 1-2: Portable and mobile radio communications equipment distance requirements

Frequency Range:	**150 kHz - 80 MHz**	**80 MHz - 800 MHz**	**800 MHz - 2.5 GHz**
Calculation Method:	d=[3.5/V_1] square root of P	d = [3.5/E_1] square root of P	d = [7/E_1] square root of P
Where: d= separation distance in meters, P = rated power of the transmitter, V_1=compliance value for conducted RF, E_1 = compliance value for radiated RF			
If the maximum transmitter power in watts is rated	**The separation distance in meters should be**		
5	2.6	2.6	5.2
20	5.2	5.2	10.5
100	12.0	12.0	24.0

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 operator 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 operators in EC countries with updated information concerning the connection of the Venue 50 to image recording and other devices or communication networks.

Peripheral used in the patient environment

The Venue 50 has been verified for overall safety, compatibility and compliance with the image recording devices listed in ‘Supplies/Accessories’ on *page 6-36*.

The Venue 50 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.

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

General precautions for installing an alternate off-board, remote device or a network would include:

- The added device(s) must have appropriate safety standard conformance and CE Marking.
- There must be adequate mechanical mounting of the device and stability of the combination.
- Risk and leakage current of the combination must comply with IEC/EN 60601-1.
- 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 environments. The operator must assure that the system is used according to the specified guidance and only in the electromagnetic environment listed below.

Table 1-3: Declaration of Emissions

Guidance and manufacturer's declaration - electromagnetic emissions		
The system is intended for use in the electromagnetic environment specified below. The operator 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 environments. The operator must assure that the system is used according to the specified guidance and only in the electromagnetic environment listed below.

Table 1-4: Declaration of Immunity

Immunity Type	Equipment Capability	Regulatory Acceptable Level	EMC Environment and Guidance
IEC 61000-4-2 Static discharge (ESD)	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. Mains power quality should be that of a typical commercial and/or hospital environment. If the operator 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 50: SD Card socket and 1 USB port
2. Left side of Venue 50: Lithium-ion battery port
3. Left side of Docking Station/Cart:
   - 1 LAN port
   - 3 Master USB ports
   - 1 HDMI port
4. Left side of Docking Cart: Printer AC power input socket
5. Bottom of Venue 50: Docking port
6. Right side of Venue 50: Probe port
7. Right side of Docking Station: AC power input socket

   Bottom of Docking 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.

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

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 50 must conform to one or more of the requirements listed below:

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

Accessories, Options, Supplies

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

Acoustic Output

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 operator 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** -> **Image**. This preset is application dependent so each application could specify a different TI type.

TI and MI Display Accuracy

When display MI >= 0.6, TI >= 3.6, the displayed values of MI and TI is not lower than 50% or higher than 150% of the measured values.

When display MI < 0.6, TI < 3.6, the absolute error of MI <= 0.3, the absolute error of TI <= 1.8.

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

HINTS

Raise the Acoustic Output only after attempting image optimization with controls that have no effect on Acoustic Output, such as Gain and TGC.

WARNING

Be sure to have read and understood control explanations for each mode used before attempting to adjust the Acoustic Output control or any control that can effect Acoustic Output.

Acoustic Output Hazard

Use the minimum necessary acoustic output to get the best diagnostic image or measurement during an examination. Begin the exam with the probe that provides an optimum focal depth and penetration.

Acoustic Output Default Levels

In order to assure that an exam does not start at a high output level, the Venue 50 initiates scanning at a reduced default output level. This reduced level preset depends upon the exam application and probe selected.

To modify acoustic output, go to **Utility**->**Image**->**User Define**, then adjust the acoustic output level in **AO** select box.

Device Labels

Icon Description

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

Table 1-5: Label Icons

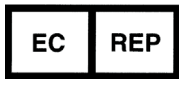
Label/Icon	Purpose/Meaning	Location
Identification and Rating Plate 	• Manufacture's name and address • Date of manufacture • Model and serial numbers • Electrical ratings (Volts, Amps, phase, and frequency)	Rating Plate Label. 'Warning label locations' on page 1-33
Type/Class Label	Used to indicate the degree of safety or protection.	Rating Plate Label
IP Code (IPX8) IPX8: MKF 2 1S/1S-MED HID GP 26	Indicates the degree of protection provided by the enclosure per IEC60529. IPX8 can be used in an operating room environment.	Footswitch
	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.	Probe connector and rating plate
	General Warning	Various

Table 1-5: Label Icons

Label/Icon	Purpose/Meaning	Location
	"Consult accompanying documents" is intended to alert the operator to refer to the operator manual or other instructions when complete information cannot be provided on the label.	Various
	"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 • Docking cart
	"Equipotentiality" indicates the terminal to be used for connecting equipotential conductors when interconnecting (grounding) with other equipment. Connection of additional protective earth conductors or potential equalization conductors is not necessary in most cases and is only recommended for situations involving multiple equipment in a high-risk patient environment to provide assurance that all equipment is at the same potential and operates within acceptable leakage current limits. An example of a high-risk patient would be a special procedure where the patient has an accessible conductive path to the heart such as exposed cardiac pacing leads. IEC60417-5021	Docking Cart
	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.	Back of Venue 50

Table 1-5: Label Icons

Label/Icon	Purpose/Meaning	Location
	This symbol indicates that waste electrical and electronic equipment must not be disposed of as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.	Rating Plate
	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
	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.	Bottom Note: Only after Russian regulatory registration is complete, this label will be located on the console rating plate.

Table 1-5: Label Icons

Label/Icon	Purpose/Meaning	Location
	INMETRO Certification: TUV Rheinland Brazil	Back of the system Note: Only after Brazilian regulatory registration is complete, this label will be located on the console rating plate.
	Do not put anything weighed over 5kg (11 lbs) on the shelf.	Printer shelf of Docking Cart
	Do not push the system	Back of Docking Cart and Rating plate
	Do not step on the system	Base chassis covers of Docking Cart

Warning label locations

Venue 50 warning labels are provided in English.

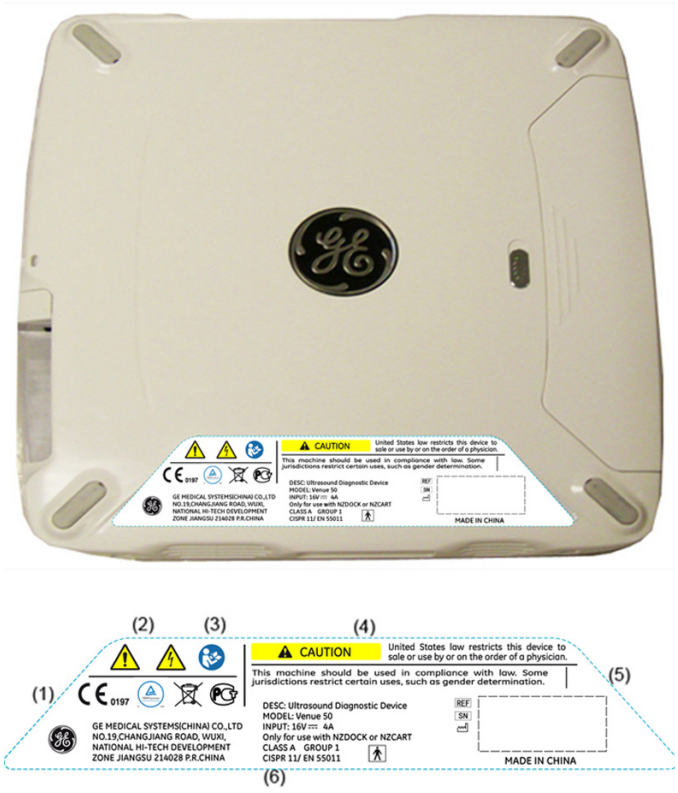


Figure 1-3. Label location explanations

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 operator serviceable parts are inside. Refer servicing to qualified service personnel.
3. “Consult accompanying documents” is intended to alert the operator 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 50 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
DESC.	**Description**
MODEL	**Model**
INPUT	**Input**
OUTPUT	**Output**
MADE IN CHINA	Made in China
MADE BY CORETRONIC	Made by Coretronic
Ultrasound Diagnostic Device	Ultrasound Diagnostic Device
Only for use with Venue 50	Only for use with Venue 50
Only for use with NZDOCK or NZCART	Only for use with Docking Cart or Docking Station

Warning label locations (continued)

Figure 1-4. Docking Station Label

Figure 1-5. Docking Station label location

Warning label locations (continued)

Figure 1-6. Docking Cart warning label

Figure 1-7. Docking Cart label location

Warning label locations (continued)

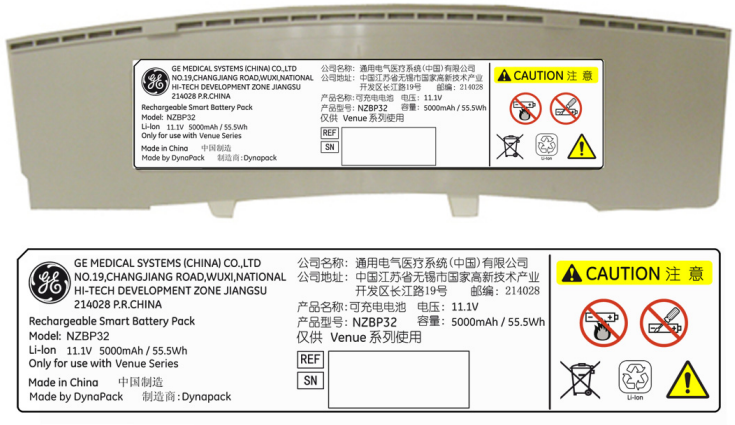


Figure 1-8. Battery Label

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 50 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 6-13 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 6-16 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/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	3 - 40°C 37 - 104°F	-5 - 50°C 23 - 122°F	-5 - 50°C 23 - 122°F
Humidity	30 - 80% non-condensing	10 - 90% non-condensing	10 - 90% non-condensing
Pressure	700 - 1060hPa	700 - 1060hPa	700 - 1060hPa

Acclimation Time

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

Table 2-2: System Acclimation Time Chart

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

°C	5	0	-5	-10	-15	-20	-25	-30	-35	-40
°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 50 system (with Docking Station)

1. Venue 50
2. Docking Station

Console graphics (continued)

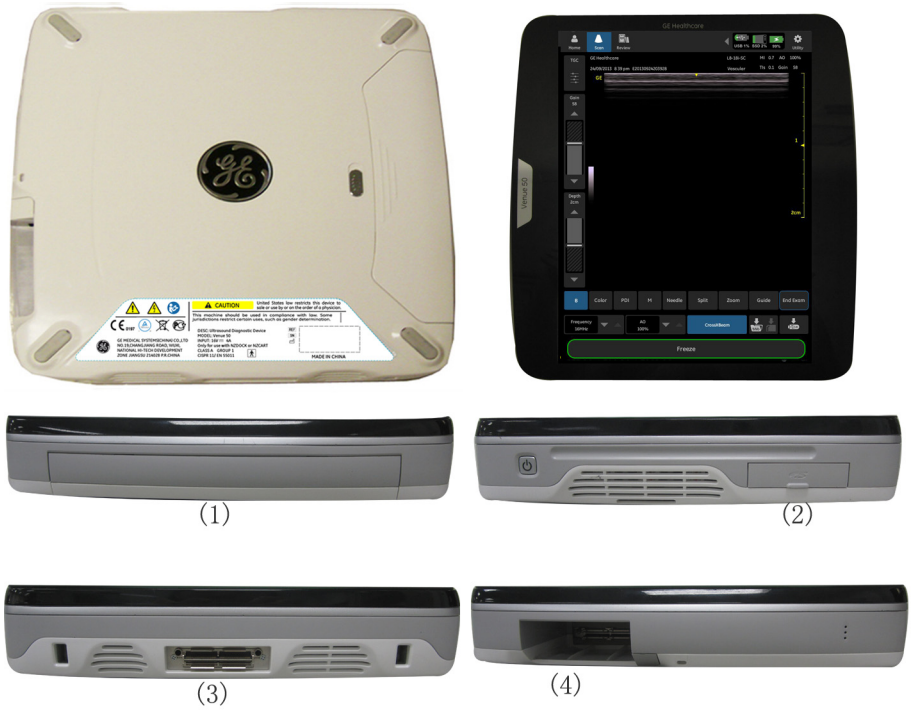


Figure 2-2. Venue 50 views

1. Battery
2. SD Card Socket and USB Port
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.

Docking Cart

Figure 2-3. Docking Cart

1. Docking
2. Plastic shelf - for accessories and disposals
3. Pedal
4. Wheels brake pedal - for Cart brakes
5. Cart Handle
6. Printer shelf (option)
7. 3-probe port box (option)
8. Multi-probe holder (option)
9. Basket - for accessories and disposals (option)

CAUTION

Be sure to lock the wheels before Venue 50 is mounted to the Docking Cart.

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 50. Lithium ion batteries last longer than conventional batteries and do not require replacement as often. You can expect 40 minutes of battery life with a single fully charged battery.

The lithium ion technology used in your Venue 50'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.

- The battery has a safety device. Do not disassemble or alter the battery.
- Charge and discharge the batteries only when the ambient temperature is between 3°C and 40°C (37°F and 104°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°C (122°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 50 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 -5°C (23°F) and 50°C (122°F).

Battery (continued)

- Long term (3 months or more) storage of battery pack:
  - Store the battery in a temperature range between -5°C (23°F) and 50°C (122°F)
  - Upon receipt of the Venue 50 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 or more, 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 50 automatically shut down.

    2. Charge the Venue 50 to 100% FCC (full current capacity).

    3. Discharge of Venue 50 for complete shut down (takes one hour for discharge).
  - When storing batteries for more than 6 months, charge the batteries at least once every 6 months to prevent leakage and deterioration in performance.
- Use only GE approved 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)".

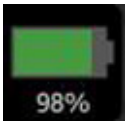


Figure 2-4. Battery icon

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: "Battery is critical, system will shut down in 1 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:

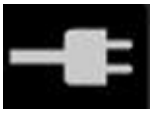


Figure 2-7. AC power only or battery charging complete

Battery (continued)

Battery Replacement

1. Lay the Venue 50 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/Cart.

View battery capacity

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

Figure 2-9. View battery capacity

Peripheral/Accessory Connection

Peripheral/Accessory Connector Panel of Docking Station/Cart

Venue 50 System peripherals and accessories can be properly connected using the side panels of the Docking Station/Cart.

Each outer (case) ground line of peripheral/accessory connectors are **earth grounded**.

Signal ground lines are not isolated.

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)

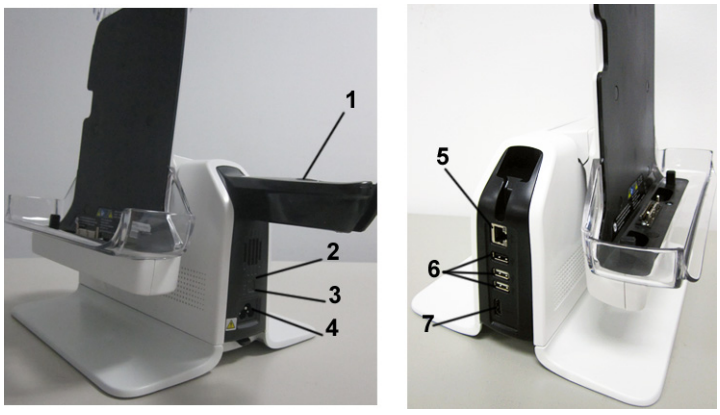


Figure 2-10. Docking Connector Panel

Docking Station provides DC power to Venue 50 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. LAN Port
6. 3 USB Ports (for peripherals connection)
7. HDMI Port (for external monitor connection)

NOTE: Without AC power, only the first USB port (from top to bottom) is available.

NOTE: Without AC power, LAN port, the second and third USB ports and HDMI port are not available.

CAUTION

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

Peripherals Connection

1. Insert the SD Card into the SD Card Socket on top of the system. Ensure the labeled side is facing the front.

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 HDMI port of the Docking Station/Cart.

Figure 2-14. HDMI Connection

Peripherals Connection (continued)

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

Figure 2-15. Wireless Network Adapter Connection

6. Connect the footswitch to the USB port of the Docking Station/Cart.

Figure 2-16. Footswitch Connection

Peripherals Connection (continued)

7. Connect the barcode reader to the USB port of the Docking Station/Cart.

Figure 2-17. Barcode Reader Connection

To set up the barcode reader, please follow the steps below:

- Connect barcode reader to the system.
- Go to **Utility** -> **Settings** -> **USB Accessories** to set Barcode Reader **on**.
- Scan the three bar code below in order, from top to bottom. First scan the **Remove Custom Defaults** bar code, then scan **Activate Defaults**. This resets the scanner to the factory default settings. Finally, scan the PAP_AT bar code. It programs a carriage return (CR) suffix. Now the Barcode Reader is ready for use.

Figure 2-18. Barcode

Mount Venue 50 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 50 with the docking port and carefully push into place.

Figure 2-19. Mount to Docking Station/Cart

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

Figure 2-20. Press the locking lever

Release Venue 50 from the Docking Station/Cart

1. Pull the release trigger. The locking lever pops up and the Venue 50 can be removed.

Figure 2-21. Release system from Docking Station/Cart

WARNING

Please make sure to turn off the Venue 50 before releasing it from the Docking Station/Cart.

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. Press the **Power On/Off** switch to power off the system.
2. Unplug the Docking Station/Cart power cord (if the system is plugged in).
3. Release the Venue 50 from the Docking Station/Cart.
4. Store all probes in their original cases or in soft cloth or foam to prevent from 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 a steep incline (>5 degrees) or loading the system 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 plastic shelf.
- Wrap the power cord around the power cable hook at the rear panel of the Docking Cart.

NOTE: If the 3-probe port is attached to the system, please see "3-probe Port User Instructions" for more information.

Figure 2-22. 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

For extra safety, the Venue 50 may be attached to the docking station/cart with a security cable as follows.

1. Wrap the cable around an immovable object.
2. Insert the lock into the security slot on the back of the system.

Figure 2-23. Insert the security lock

NOTE: Be sure that the security lock is rotated to the unlocked position before inserting the lock.

Attaching the Security Cable (continued)

3. Rotate the key to the locked position.

Figure 2-24. Security cable attached

Powering the System

Connecting and Using the System

To connect the Docking Station/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 50 on plastic foam, paper or similar type surfaces. The system could overheat and slow down. Ensure that the Venue 50 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 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)

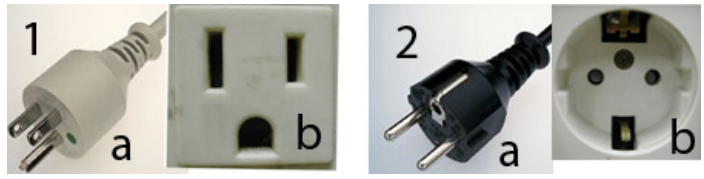


Figure 2-25. Example Plug and Outlet Configurations

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/South Africa, China, Brazil, Australia/ New Zealand, and Argentina.

Power On

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

Figure 2-26. Power On/Off Switch Location

Press the **Power On/Off**, then press **Lock Screen** to lock the screen.

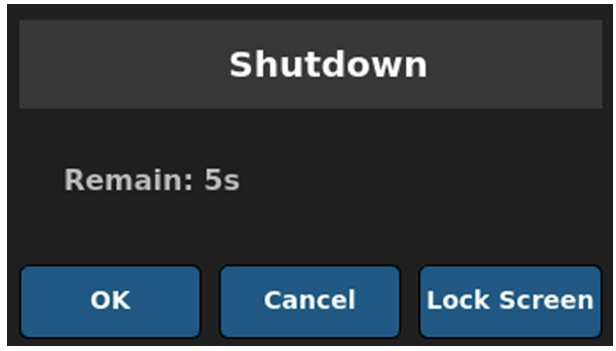


Figure 2-27. Lock the Screen

LED

Figure 2-28. LED Indicators (Docking Station/Cart)

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

   Color: Green

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

   Color: Green

Figure 2-29. LED Indicators (Venue 50)

3. Indicates power status. After pressing the Power On/Off switch, the system power is on and this Power On/Off 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 Shutdown 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 **OK** on the Shutdown window.*

The shutdown process takes a few seconds.

NOTE: If the system does 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/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 degrees.

Figure 2-30. 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 2-31. Adjust Docking Cart Height

CAUTION

Be sure to lock the wheels before adjusting the Docking Cart height.

Adjusting the Docking Cart (continued)

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.

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

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

Brightness

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

To adjust the brightness:

1. Select **Utility** -> **Settings** -> **Common**, then choose the desired brightness in the **Brightness** select box.

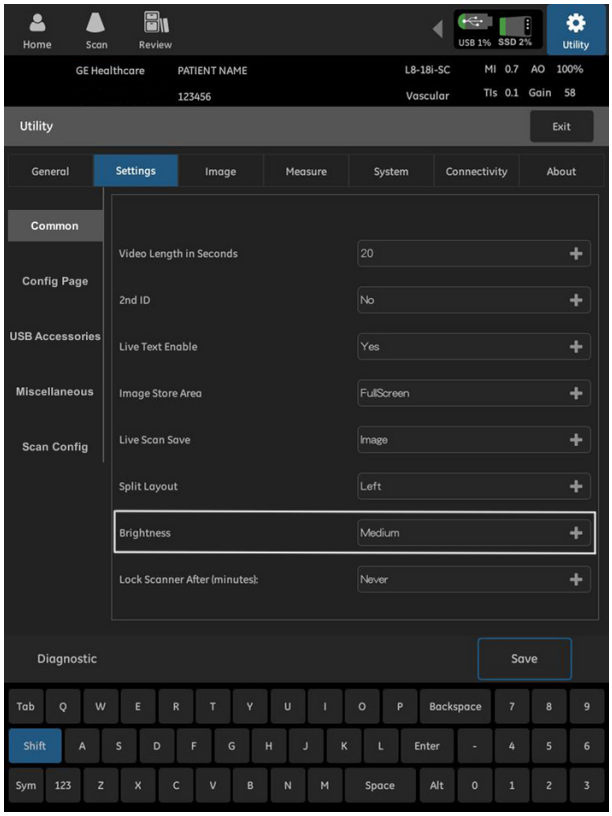


Figure 2-32. Brightness Adjustment

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 50.

See ‘Probe Applications’ on *page 5-20 for more information.*

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 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. Ensure the system is in freeze mode or powered off. 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 2-33. Connect probe to Venue 50

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:

- If the system in on the docking cart, please keep the probe cable free from wheels and use the cable hooks on the docking cart.
- DO NOT bend the cable acutely.
- Avoid crossing cables between probes.

Deactivating the Probe

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

To deactivate a probe:

1. Ensure the Venue 50 is in freeze mode or powered off.
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 2-34. Pop up connector locking lever

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

Figure 2-35. Disconnect probe from Venue 50

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

Secure the probe in its holder for moving a short distance.

When transporting a probe for 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.

Touch Panel

You interact with Venue 50 using your fingers to tap, double-tap, swipe, and pinch objects on the touch panel. Multi-touch with fingers is supported by Venue 50.

Exam Function Controls

The touch panel contains exam function and mode/function specific controls.

Figure 2-36. Venue 50 Menu Bar

1. Home: Enter home page
2. Scan, Review: Perform various functions
3. : eSmart Trainer (option)
4. Utility: Activate system configuration menus
5. TGC, Gain, Depth: Adjust the image information
6. B, Color, PDI, M: Switch to different modes
7. : configurable parameters
8. Needle: Enhance visualization of the needle
9. Split: Split the screen into two
10. Zoom: Magnify a region of interest
11. Guide: Display the biopsy guidelines
12. End Exam: Press to end an exam
13. Dataflow Button: Store the patient information or print the scanning images.
14. Freeze: Stop the acquisition of ultrasound data and freeze the image in system memory.

CAUTION

Use only fingers, or fingers with gloves to operate on the system. Never use any sharp tools to scratch the LCD.

Monitor Display

Monitor Display

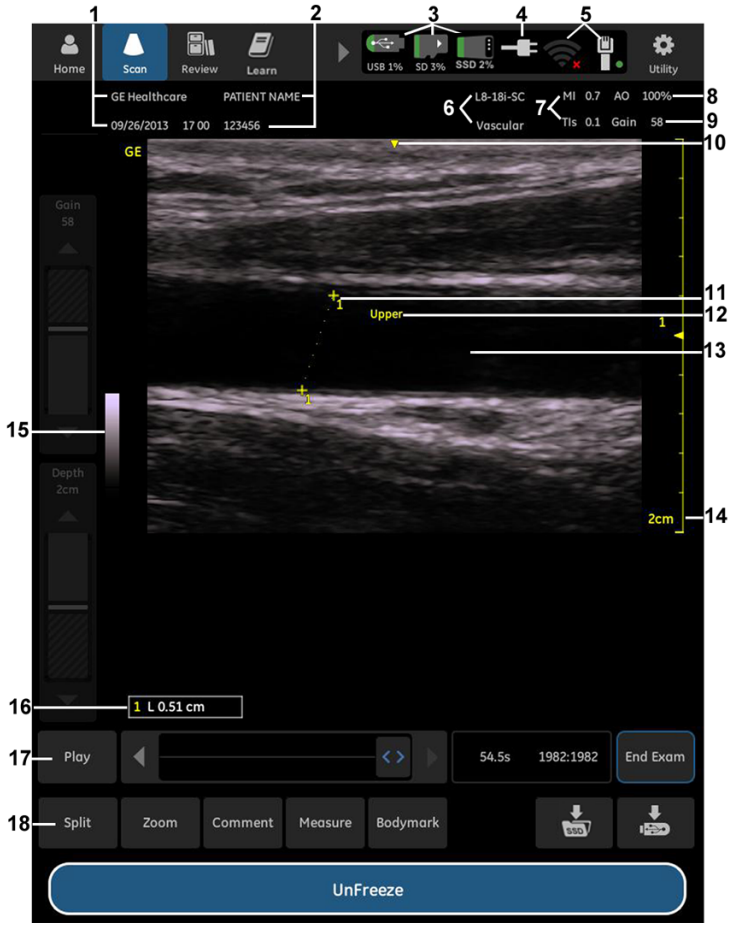


Figure 2-37. Monitor Display

1. Institution/Hospital Name, Date, Time
2. Patient Name, Patient ID
3. Storage device status
4. Battery status
5. Wireless and local network connection status
6. Probe and application
7. MI, TI
8. Acoustic Output
9. Gain
10. Center line mark
11. Measurement caliper
12. Comment
13. Image area
14. Depth scale
15. Gray/Color bar
16. Measurement result window
17. Cine Gauge
18. Function controls

Chapter 3

Performing an Exam

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

Performing an Exam

Overview

A 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 Name
2. Patient ID
3. Study Description
4. Date of Birth (DOB)
5. LMP (if applicable)
6. Performing Physician
7. Patient Gender

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 of the patient. Make sure the correct patient identification appears on all screens and hard copy prints.

Beginning a New Patient

Tap **Home** to display the Home screen on the monitor.

Enter new patient information. Select the desired application. Press **Scan** to begin the exam. At the end of each exam, all patient data, annotations, measurements and images will be stored in the patient files.

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

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

Home Screen

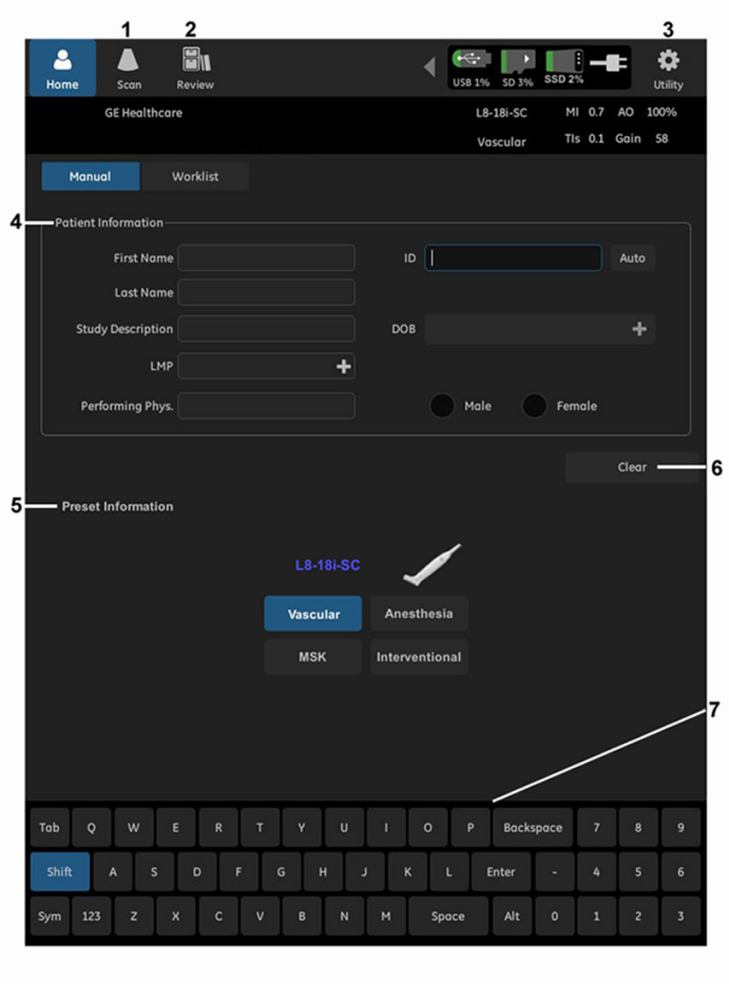


Figure 3-1. Home Screen

1. Scan
2. Review
3. Utility
4. Patient Information
5. Preset Information
6. Clear
7. Soft Keyboard

Home Screen (continued)

The Home Screen details are:

1. Scan: To begin scanning.
2. Review: To review the desired patient from the archive.
3. Utility - To display the system configuration page.
4. Patient Information
   - 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 fingers.

   - Patient ID

     Type the 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** --> **Settings** -> **Common.***

   - Study Description: To describe the scanning area
   - DOB: Date of Birth
   - LMP: Last Menstrual Period. You may find LMP in Obstetrics. 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** -> **Date and Time**.
   - Performing Phys: Physician who performs the study
   - Gender: Male or Female
5. Preset Information: To choose the desired application.
6. Clear: To clear the patient information.
7. Soft Keyboard - To type text.

Scanning a New Patient

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

1. Press **Home**. The patient screen is displayed.
2. Fill in patient information by means of the following:
   a. Fill in the patient information manually.
   b. Press **Worklist** to select the desired patient from worklist server and press **Select** or **Select EM**. The patient information will show on the home screen.
   c. If the last patient exam does not end, press **New Patient** and fill in the patient information manually.
3. Select the application from **Preset Information** (if not automatically selected).
4. Press **Scan** to perform the exam.
5. Store data to patient files.

You may choose more applications for the same patient by tapping **Home**-> **Preset Information** in live scanning mode.

Scanning without entering any patient data

To scan a patient without entering any patient data:

1. Press **Scan** to perform the exam and save images/videos.
2. Patient images/videos are stored in the storage device, refer to 'Image Storage' on *page 3-88*.

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.

B Mode Controls

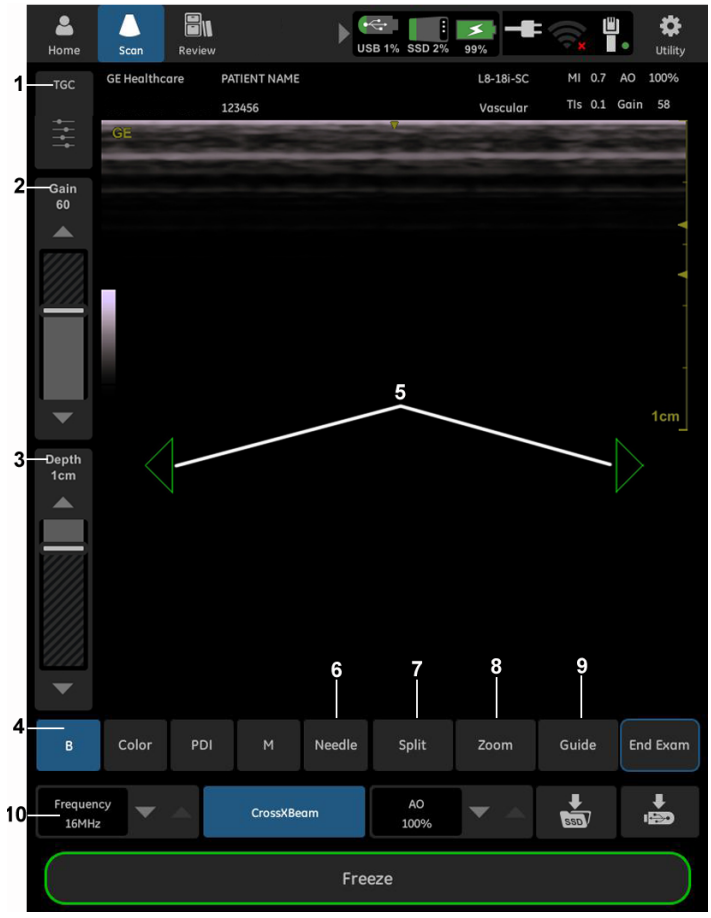


Figure 3-2. B Mode Controls

Table 3-1: B Mode Controls

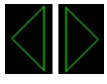
Controls	Affect on Image
TGC	Adjust TGC to balance the image so that the density of echoes is the same throughout the image.
Gain	Makes images brighter or darker.
Depth	Press to increase or decrease scanning depth.
B/Color/PDI/M	Switch to PDI/Color Flow/M mode, different option for different packages.
	Press left or right justification pointer to show more image area. Note: The justification pointers are available only when the scanning depth is equal to or less than 1cm. Note: The justification pointers are only available for linear probes.

Table 3-1: B Mode Controls

Controls	Affect on Image
Needle	Press to activate the Needle mode. Gain, Angle and Tilt  can be activated. The needle function only applies to linear probes. Caution: Before activating the Needle, please make sure to select Interventional related preset first.
Split	Press to split the screen into two.
Zoom	Press to magnify the region of interest.
Guide	Press to display the biopsy guidelines.
Configurable Parameters	• LiveGain: To balance echo contrast so that cystic structures appear echo-free and reflecting tissue fills in. • Frequency: This optimizes the probe's wide band imaging capabilities at multiple frequencies to image at greater depths. • CrossXBeam: Improve contrast resolution with increased conspicuity of low contrast lesions, better detection of calcifications, biopsy needle visualization, and cystic boundary definition. • Gray Map: Affects the presentation of B Mode information. • Focus Pos: Focus optimizes the image by increasing the resolution for a specific area. • Reverse: Used for anatomical correctness. • ATO Level: Select the Auto Tissue Optimize Level to pick a preference for the contrast enhancement in the resulting image. • Dynamic Range: It is useful for optimizing tissue texture for different anatomy. • Compression: Suppress the noise in the image. • Rejection: Allow for the elimination from the display of low level echoes caused by noise. • Frame Aver: Smooth the image. • SRI HD: Smooth the image when image speckle interferes with the desired image detail • Edge Enhance: Make the image edge clearer/sharper. • FOV: Adjust field of view • AO: Adjust acoustic output
Note: The configurable parameters can be configured in Utility -> Settings -> ScanConfig.	

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.

Color Flow Mode Controls

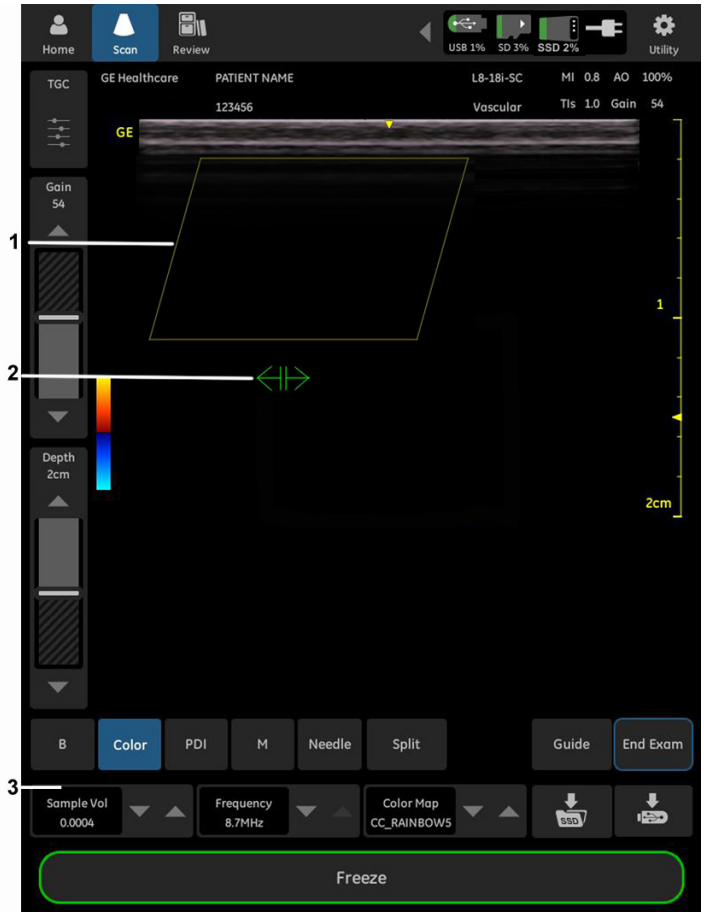


Figure 3-3. CF Mode Controls

Table 3-2: CF Mode Controls

Controls	Affect on Image
ROI	Use two fingers to adjust the size of the ROI. Or press the ROI and move it to the desired position.
	Hold the pointer and move left or right to adjust the angle of the ROI. Note: The justification pointers are available only when the scanning depth is equal to or less than 1cm. Note: The justification pointers are only available for linear probes.

Table 3-2: CF Mode Controls

Controls	Affect on Image
Configurable Parameters	• Scale: Imaging of higher velocity flow requires increased scale values to avoid aliasing. • Threshold: Limit color flow overlay to low level echoes inside vessel walls. Help to minimize color 'bleeding' outside vessel walls. • Sample Vol: Place the sample volume gate to sample blood flow. • Steer: Provide a doppler cursor angle suitable for linear probe orientation. • Wall Filter: Decrease, unnecessary low frequency signals caused by motion. • Color Map: Show the direction of the flow and highlight the higher velocity flows. • Invert: Allow to view blood flow according to personal preference, without flipping the probe.
See Table 3-1 for more information.	

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.

PDI Mode Controls

Figure 3-4. PDI Mode Controls

Table 3-3: PDI Mode Controls

Controls	Affect on Image
Configurable Parameters	• PDI Map: Show the power of the flow and highlight the stronger power flows.
See Table 3-1 and Table 3-2 for more information.	

M Mode

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.

M Mode Controls

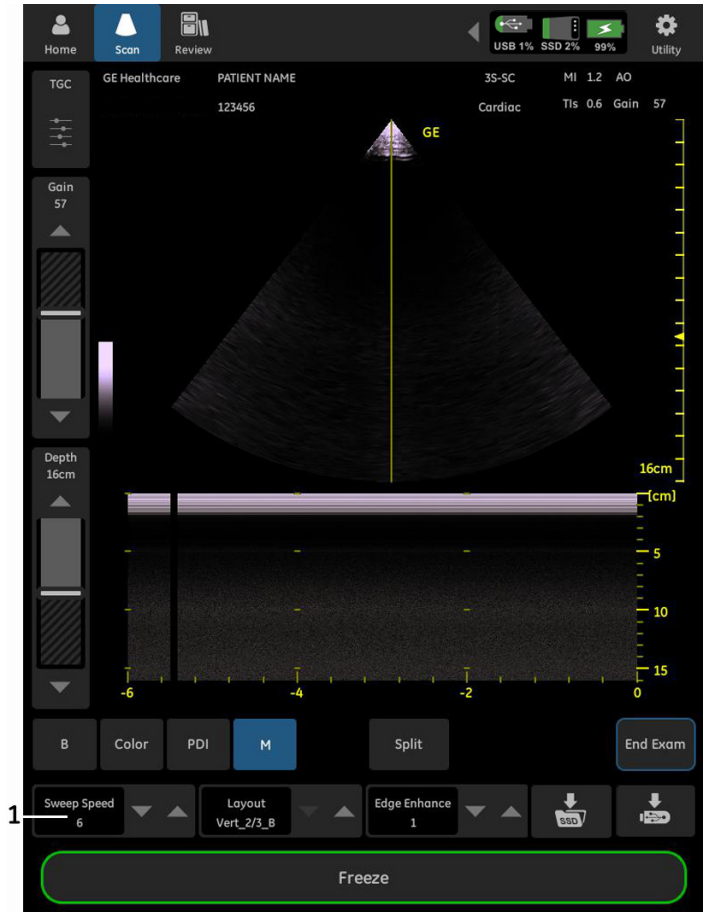


Figure 3-5. M Mode Controls

Table 3-4: M Mode Controls

Controls	Affect on Image
Configurable Parameters	• Sweep Speed: Change the speed of the timeline. • Layout: Change the Horizontal/Vertical layout between B Mode and M Mode.
See Table 3-1 for more information.	

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 operator. 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

Below measurements can be made in B-Mode.

- Distance
- Ellipse
- Volume
- Trace
- Open Trace
- Angle

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

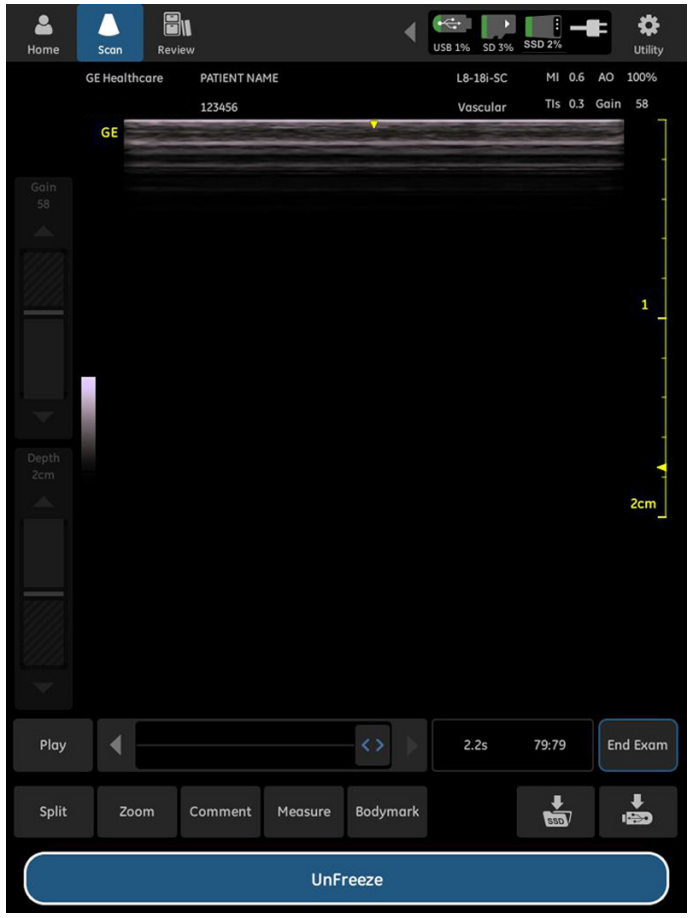


Figure 3-6. Frozen Mode

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

Distance Measurement

To make a distance measurement:

1. Press **Measure**.

Figure 3-7. Measure Screen

2. Select **Distance**.

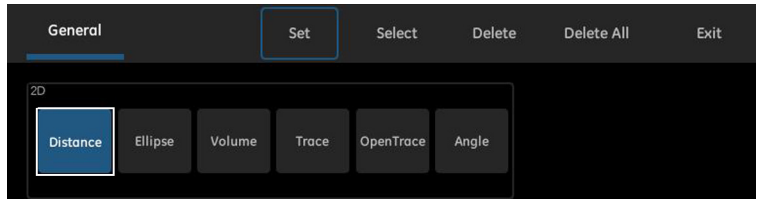


Figure 3-8. Distance Screen

3. Touch the screen, and two active calipers display.
4. Move the calipers to the desired position.

Distance Measurement (continued)

5. Press **Set**.

   The system displays the value in the Results Window.

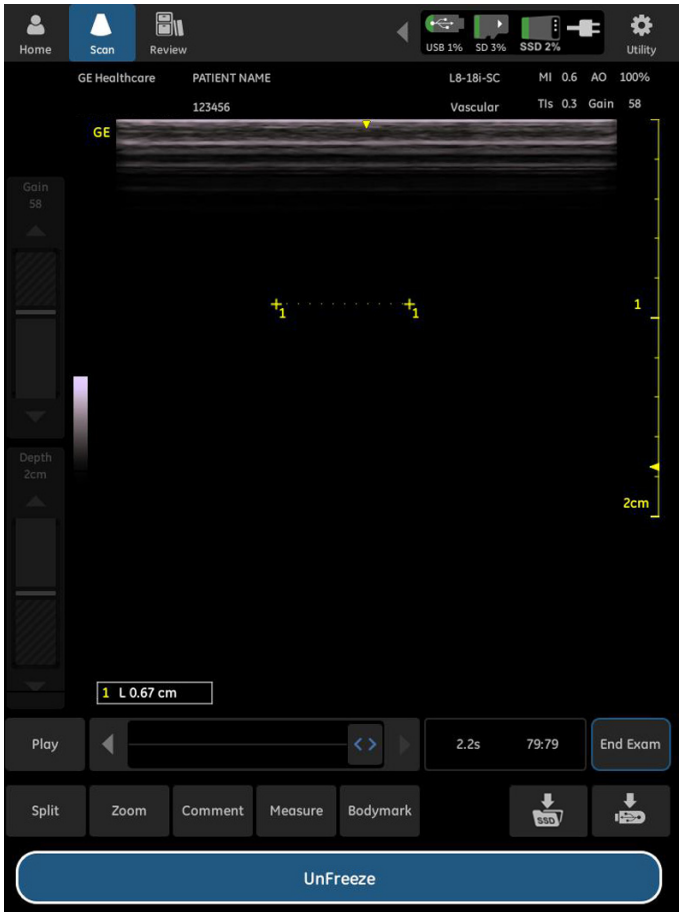


Figure 3-9. Distance Measurement

NOTE: If you touch the very edge of the scanning screen, the calipers will display at the center of the screen. You may move the calipers to the desired position to do the measurement.

Ellipse Measurement

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

1. Press **Measure**, then select **Ellipse**.

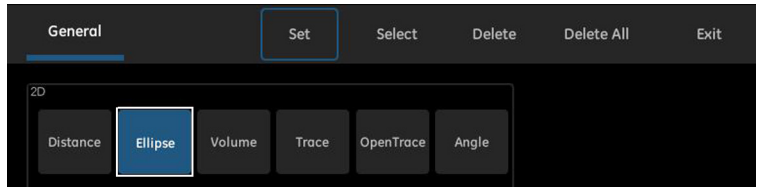


Figure 3-10. Ellipse Screen

2. Touch the screen, and three active calipers display.
3. Move the calipers to the desired position.
4. Press **Set**.

   The system displays the value in the Results Window.

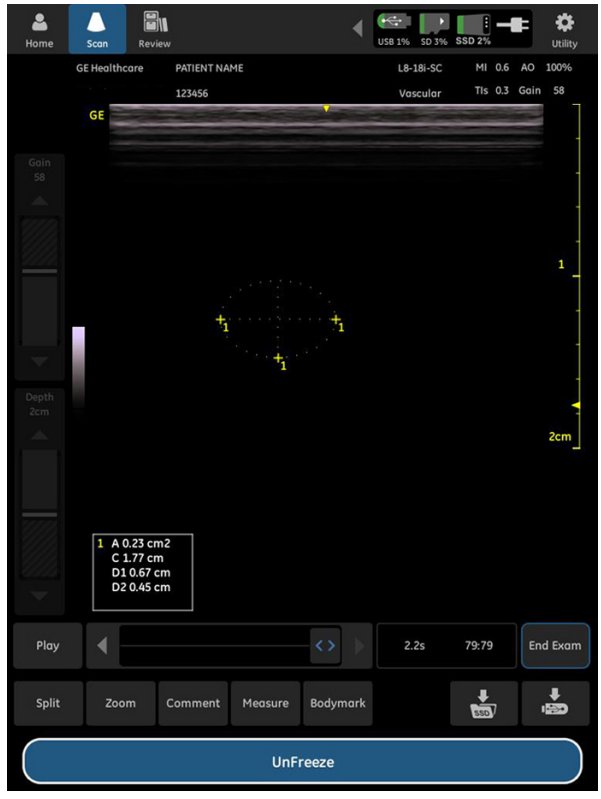


Figure 3-11. Ellipse Measurement

Volume Measurement

To make a volume measurement:

1. Press **Measure**, then select **Volume**.

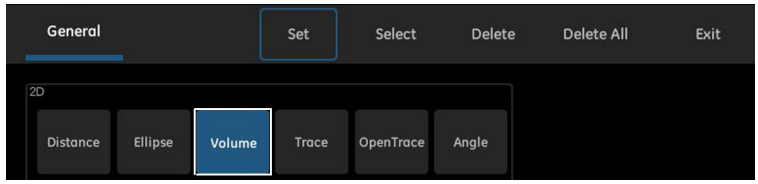


Figure 3-12. Volume Screen

2. Touch the screen, and two active calipers display.
3. Move the calipers to the desired position.
4. Press **Set** and the first distance value appears in the Results Window.
5. Repeat Step 1-4 twice and the system displays the volume value in the Results Window.

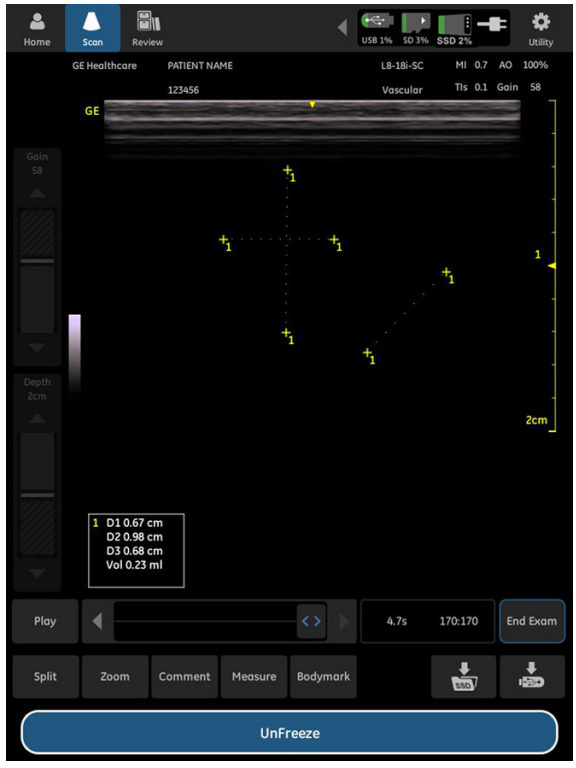


Figure 3-13. Volume Measurement

Trace Measurement

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

1. Press **Measure**, then select **Trace**.

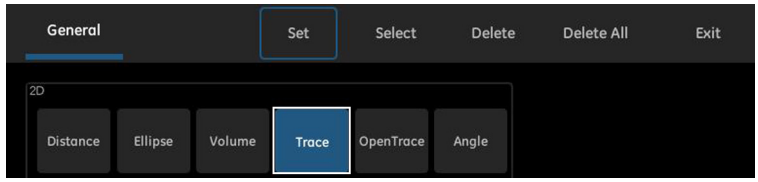


Figure 3-14. Trace Screen

2. Touch the screen, and an active caliper displays.
3. Move the caliper to the start position and press **Set** to fix the trace start point.
4. Move the caliper around the anatomy. A dotted line shows the traced area.
5. Press **Set**.

   The system displays the value in the Results Window.

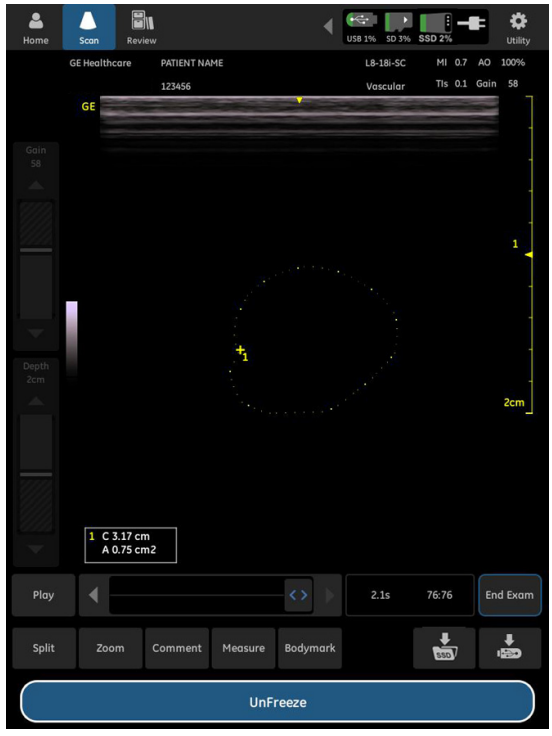


Figure 3-15. Trace Measurement

Open Trace Measurement

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

1. Press **Measure**, then select **Open Trace**.

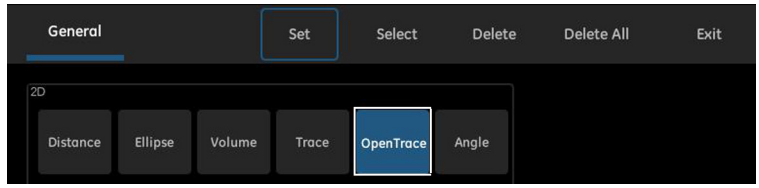


Figure 3-16. Trace Screen

2. Touch the screen, and an active caliper displays.
3. Move the caliper to the start position and press **Set** to fix the trace start point.
4. Move the caliper around the anatomy. A dotted line shows the traced area.
5. Press **Set**.

   The system displays the value in the Results Window.

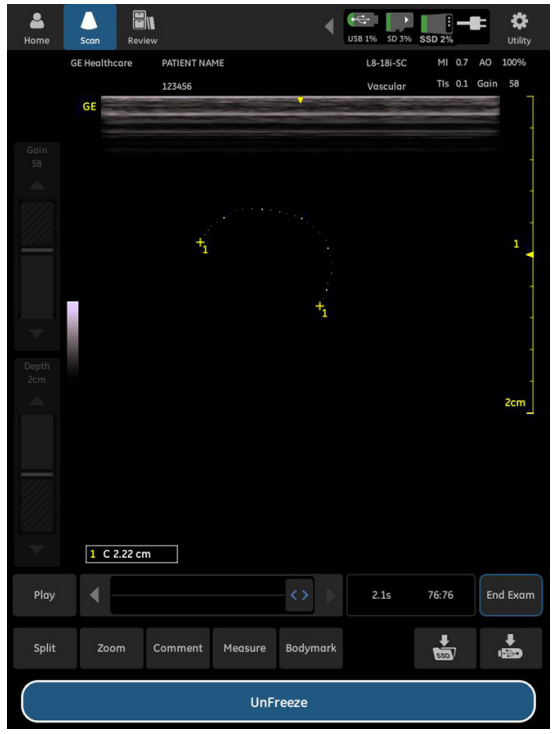


Figure 3-17. Open Trace Measurement

Angle Measurement

This function measures the angle between two intersecting planes:

1. Press **Measure**, then select **Angle**.

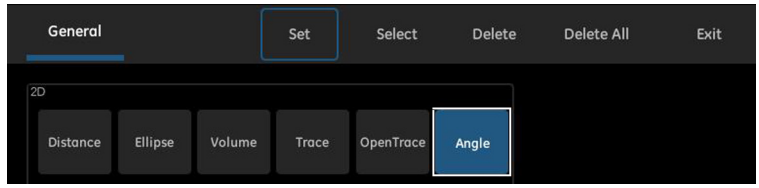


Figure 3-18. Angle Screen

2. Touch the screen, and three active calipers display.
3. Move the calipers to the desired position.
4. Press **Set**.

   The system displays the value in the Results Window.

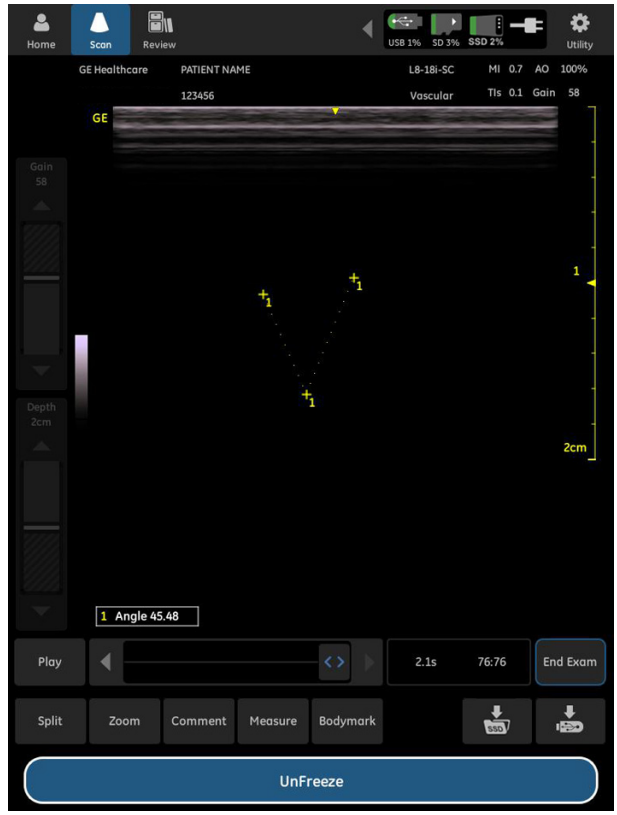


Figure 3-19. Angle Measurement

M Mode Measurements

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

- Depth
- Heart Rate

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

1. In B Mode, scan the desired anatomy you wish to measure.
2. Go to the M Mode part of the display.
3. Press **Freeze**.

Depth

To make a distance measurement:

1. Press **Measure**, then select **Depth**.

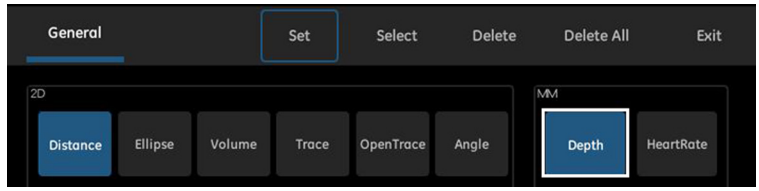


Figure 3-20. Depth Screen

2. Touch the screen, and two active calipers display.
3. Move the calipers to the desired position.
4. Press **Set**.

   The system displays the value in the Results Window.

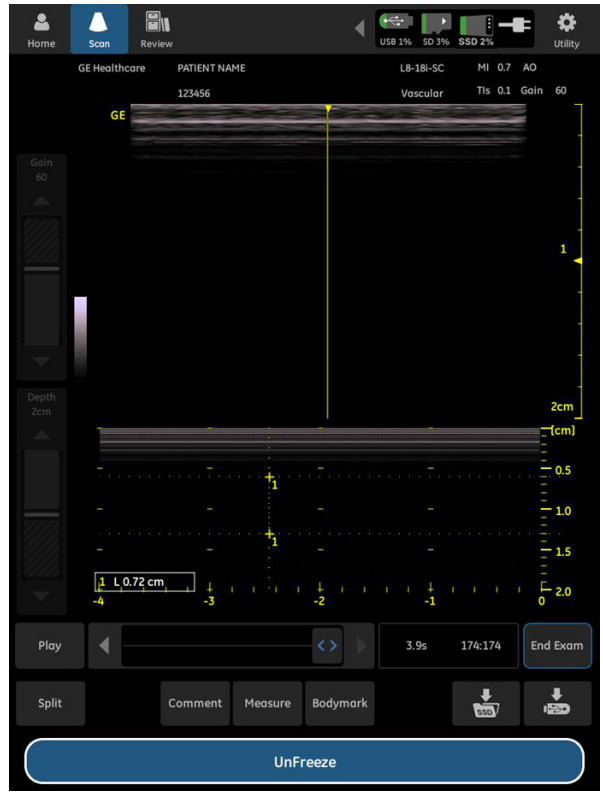


Figure 3-21. Depth Measurement

Heart Rate

To measure time and velocity between two points:

1. Press **Measure**, then select **Heart Rate**.

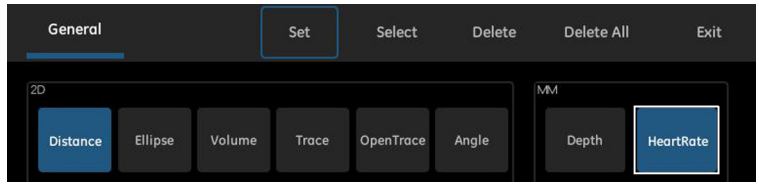


Figure 3-22. Heart Rate Screen

2. Touch the screen, and two active calipers display.
3. Move the calipers to the desired position.
4. Press **Set**.

   The system displays the value in the Results Window.

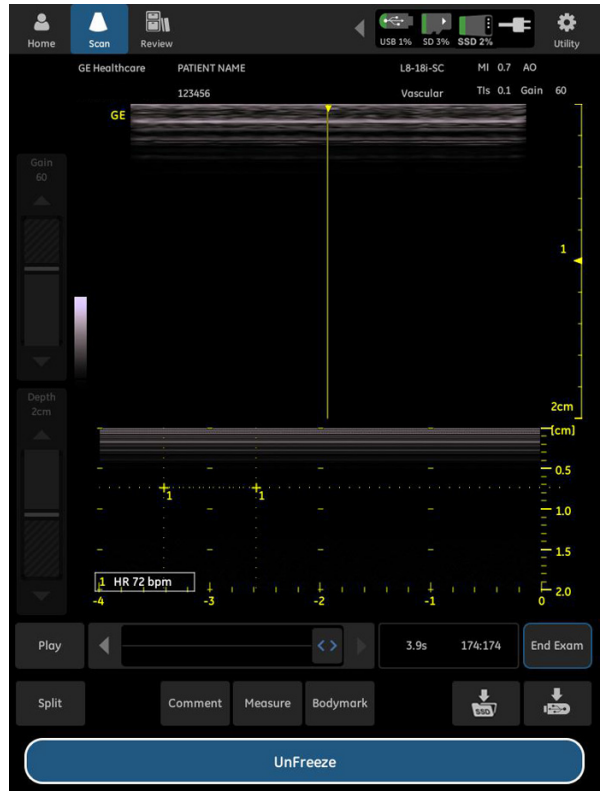


Figure 3-23. Heart Rate Measurement

Measurement Controls

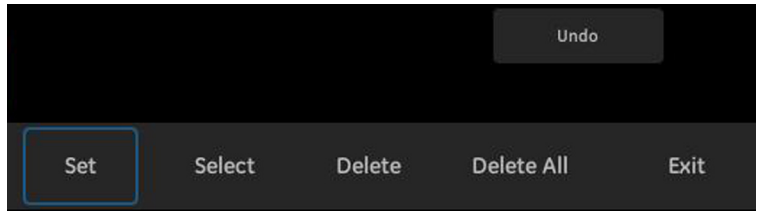


Figure 3-24. Measurement controls

Table 3-5: Measurement Controls

Controls	Affect on Image
Set	Set measurements
Select	Select the desired measurements
Delete	Delete the selected measurements
Delete All	Delete all measurements
Exit	Exit the measurement window
Undo	Undo the trace measurement bit by bit. (It is only applied for Trace and Open Trace measurement.)
Note: Press **Select** for one time to select the first measurement; Press **Select** for the second time to select the second measurement, and so on.	

Obstetrics Measurements

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 measurements can be configured in **Utility** -> **Measure** -> **Measure**.*

NOTE: Operators may choose different measurement types based on their regional preferences.

WARNING

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

*NOTE: The following instructions assume that you first go to **Home** -> **Preset Information** -> **OB1/OB2/3**, press **Scan** and then **Freeze**.*

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 **Measure**, then select **GS (1 Caliper)**.

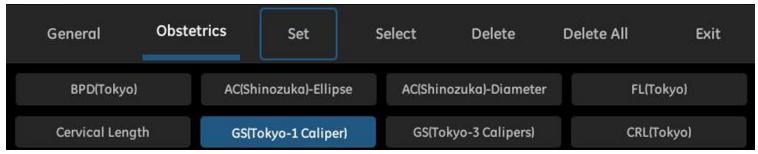


Figure 3-25. GS (1 Caliper) Screen

2. Touch the screen, and two active calipers display.
3. Move the calipers to the desired position.
4. Press **Set**.

   The system displays the value in the Results Window.

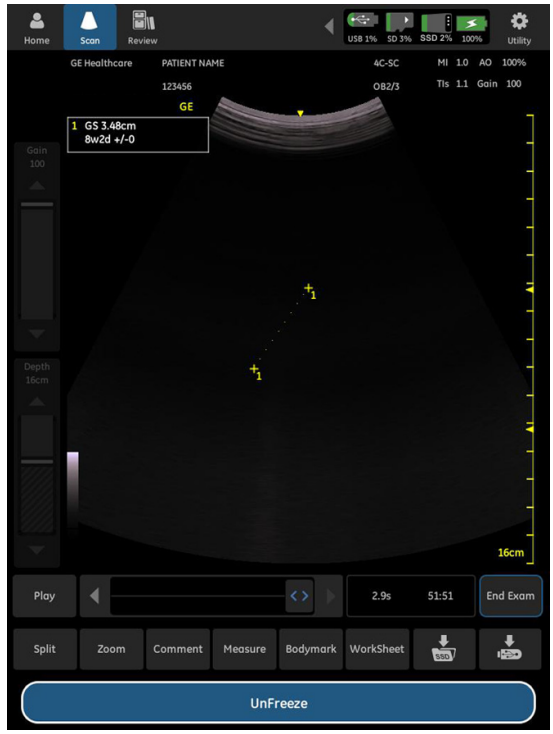


Figure 3-26. GS (1 Caliper) Measurement

GS(3 Calipers)

To make a GS(3 Calipers) measurement:

1. Press **Measure**, then select **GS (3 Calipers)**.

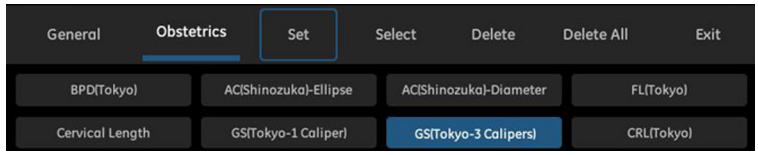


Figure 3-27. GS (3 Calipers) Screen

2. Touch the screen, and two active calipers display.
3. Move the calipers to the desired position.
4. Press **Set** and the first distance value appears in the Results Window.
5. Repeat Step 1-4 twice and the system displays the GS value in the Results Window.

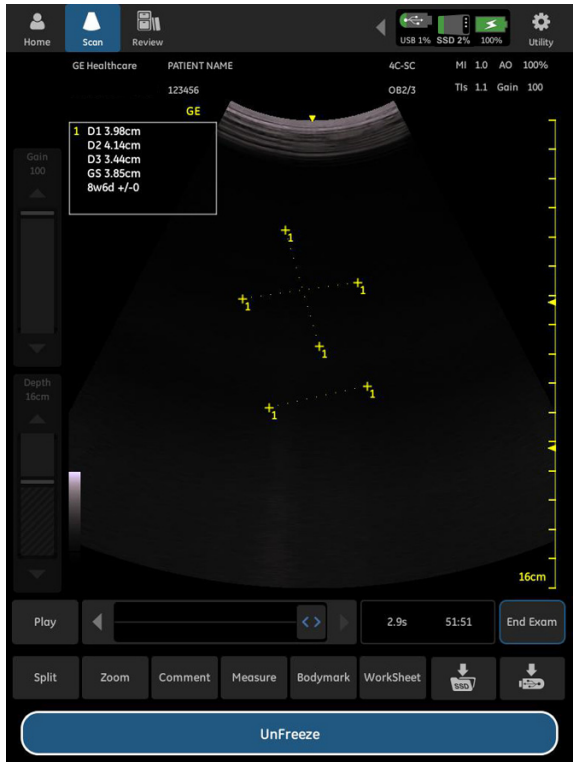


Figure 3-28. GS (3 Calipers) Measurement

Crown Rump Length (CRL)

To measure crown rump length, make one distance measurement:

1. Press **Measure**, then select **CRL**.

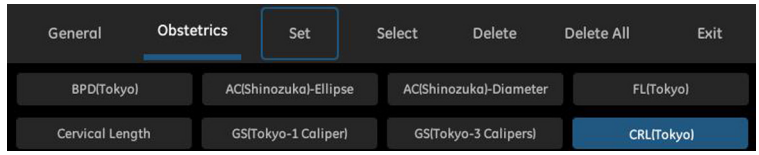


Figure 3-29. CRL Screen

2. Touch the screen, and two active calipers display.
3. Move the calipers to the desired position.
4. Press **Set**.

   The system displays the value in the Results Window.

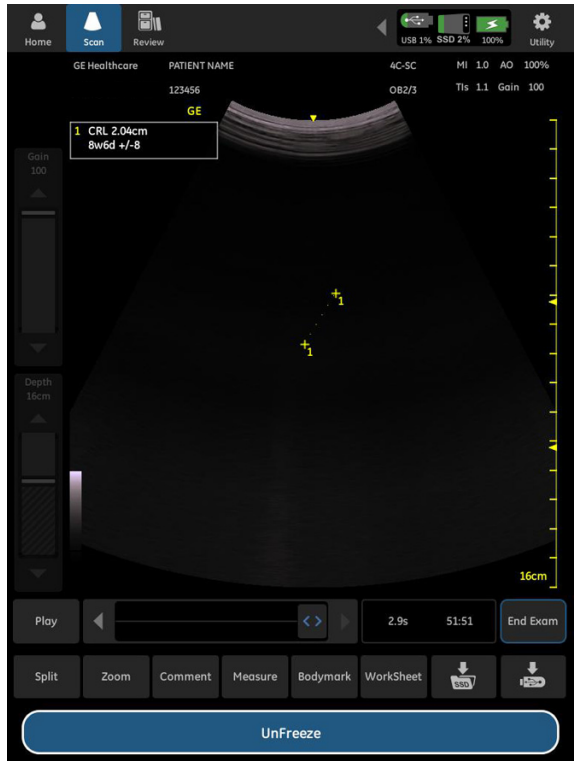


Figure 3-30. CRL Measurement

Biparietal Diameter (BPD)

To measure biparietal diameter, make one distance measurement:

1. Press **Measure**, then select **BPD**.

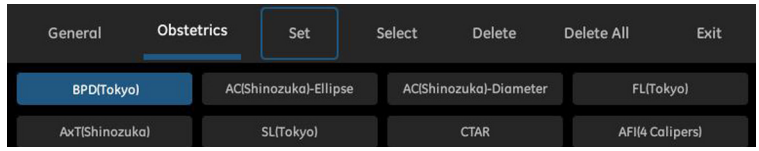


Figure 3-31. BPD Screen

2. Touch the screen, and two active calipers display.
3. Move the calipers to the desired position.
4. Press **Set**.

   The system displays the value in the Results Window.

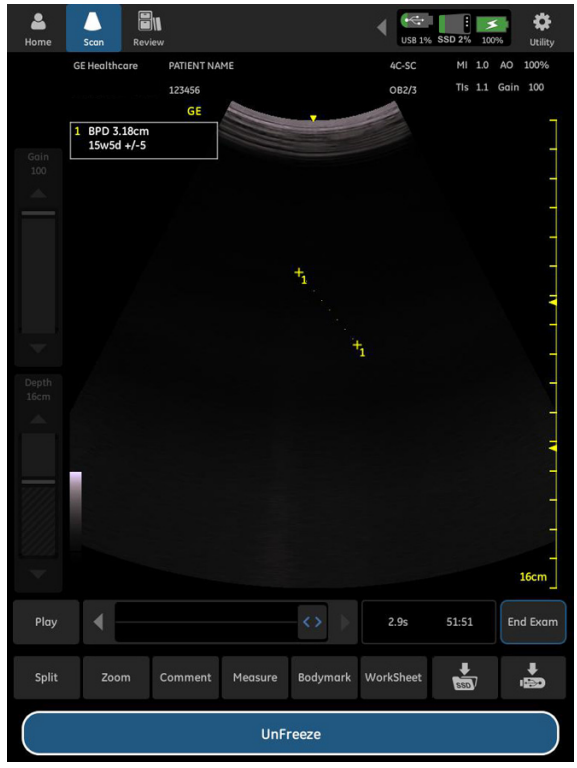


Figure 3-32. BPD Measurement

Abdominal Circumference (AC)

To measure abdominal circumference, make a diameter measurement.

1. Press **Measure**, then select **AC (Diameter)**.

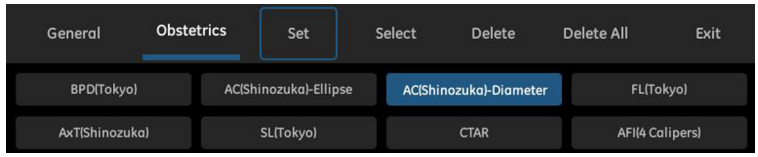


Figure 3-33. AC (Diameter) Screen

2. Touch the screen, and two active calipers display.
3. Move the calipers to the desired position.
4. Press **Set** to get the first diameter.
5. Repeat Step 1-4 to get the second diameter.

   The system displays the value in the Results Window.

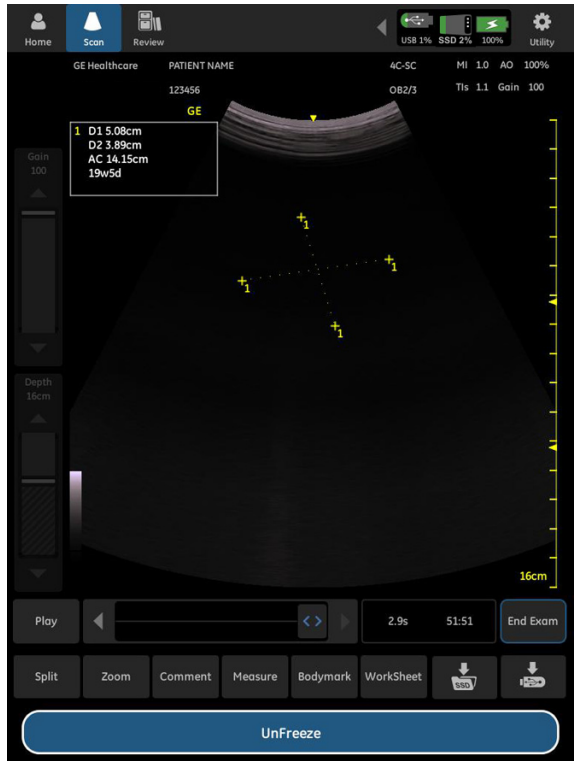


Figure 3-34. AC (Diameter) Measurement

Abdominal Circumference (AC) (continued)

To measure abdominal circumference, make an ellipse measurement.

1. Press **Measure**, then select **AC (Ellipse)**.

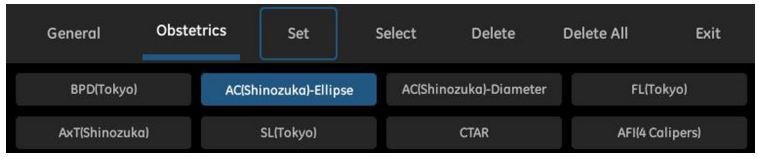


Figure 3-35. AC (Ellipse) Screen

2. Touch the screen, and three active calipers display.
3. Move the calipers to the desired position.
4. Press **Set**.

   The system displays the value in the Results Window.

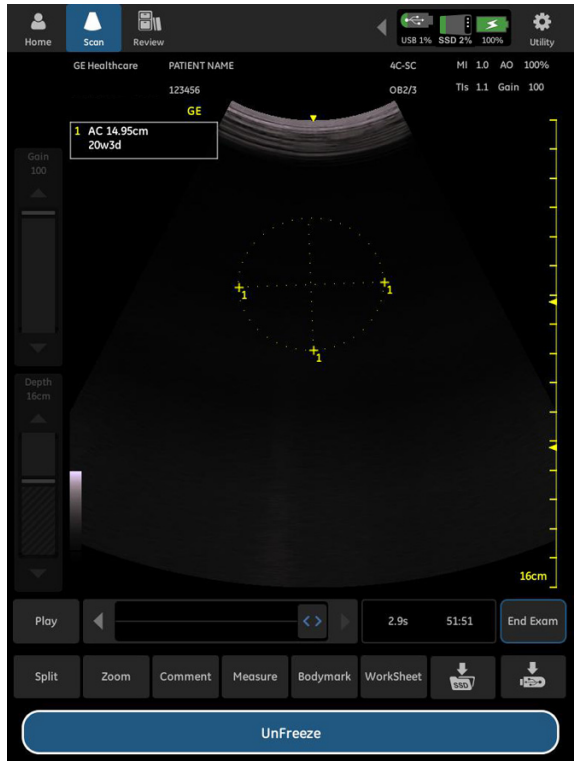


Figure 3-36. AC (Ellipse) Measurement

Femur Length (FL)

To measure femur length, make one distance measurement:

1. Press **Measure**, then select **FL**.

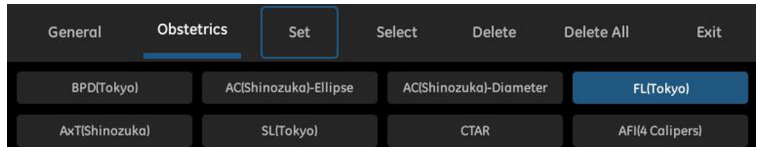


Figure 3-37. FL Screen

2. Touch the screen, and two active calipers display.
3. Move the calipers to the desired position.
4. Press **Set**.

   The system displays the value in the Results Window.

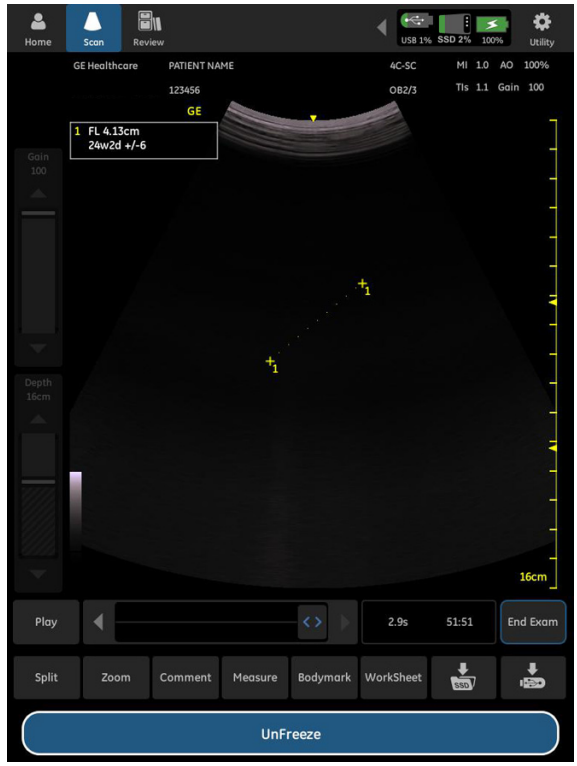


Figure 3-38. FL Measurement

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

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

1. Press **Measure**, then select **AxT**.

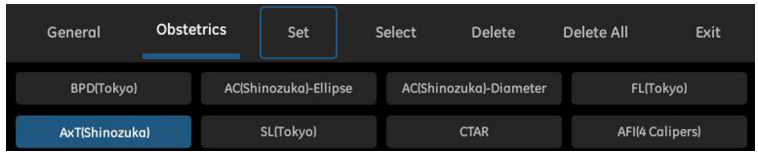


Figure 3-39. AxT Screen

2. Make a distance measurement of the antero-postero trunk diameter (APTD).
   a. Touch the screen, and two active calipers display.
   b. Move the calipers to the desired position.
   c. Press **Set**.

      The system displays the distance value in the Results Window.
3. Make a distance measurement of the transverse trunk diameter (TTD), repeat steps a-c above.

The system displays the AxT value in the Results Window.

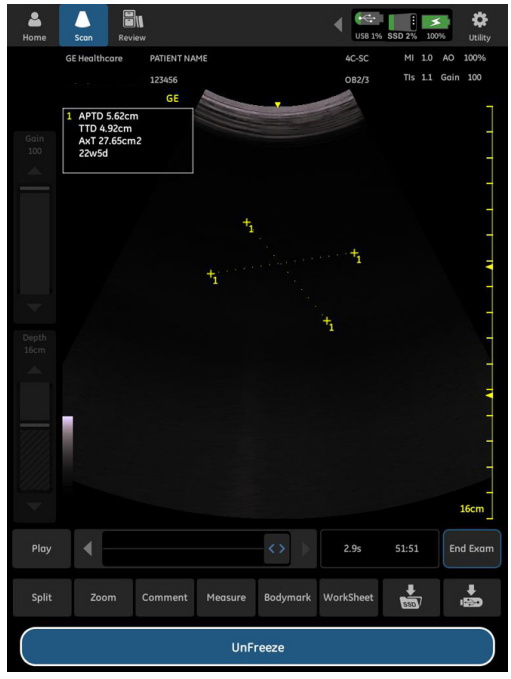


Figure 3-40. AxT Measurement

Spine Length (SL)

To measure spine length, make one distance measurement:

1. Press **Measure**, then select **SL**.

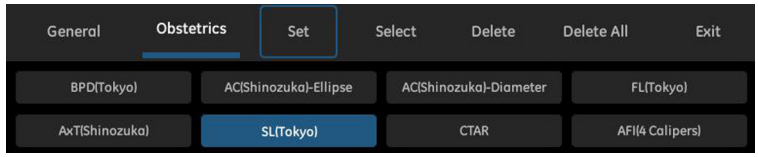


Figure 3-41. SL Screen

2. Touch the screen, and two active calipers display.
3. Move the calipers to the desired position.
4. Press **Set**.

   The system displays the value in the Results Window.

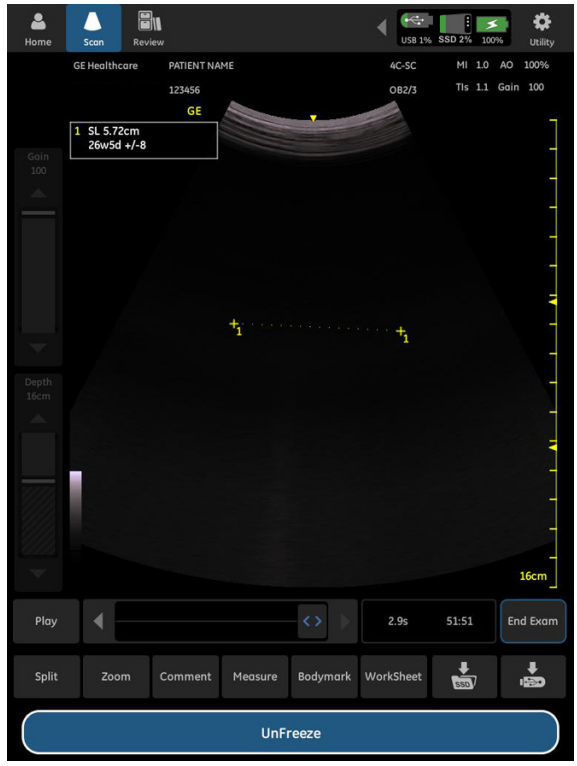


Figure 3-42. SL Measurement

Cardio-Thoracic Area Ratio (CTAR)

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

1. Press **Measure**, then select **CTAR**.

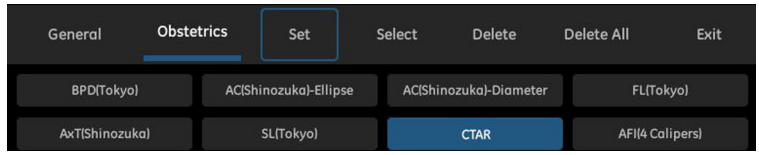


Figure 3-43. CTAR Screen

2. Make an ellipse measurement of the cardiac area.
   a. Touch the screen, and three active calipers display.
   b. Move the calipers to the desired position.
   c. Press **Set**.

      The system displays the cardiac area value in the Results Window.
3. Make an ellipse measurement of the thoracic area, repeat step a-c above.

The system displays the CTAR value in the Results Window.

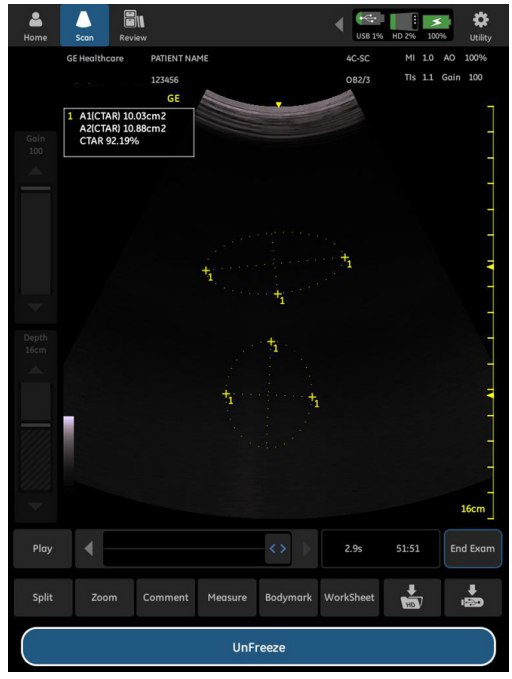


Figure 3-44. CTAR Measurement

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 **Measure**, then select **AFI (1 Caliper)**.

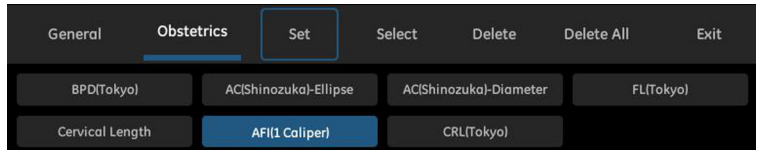


Figure 3-45. AFI (1 Caliper) Screen

2. Touch the screen, and two active calipers display.
3. Move the calipers to the desired position.
4. Press **Set**.

   The system displays the value in the Results Window.

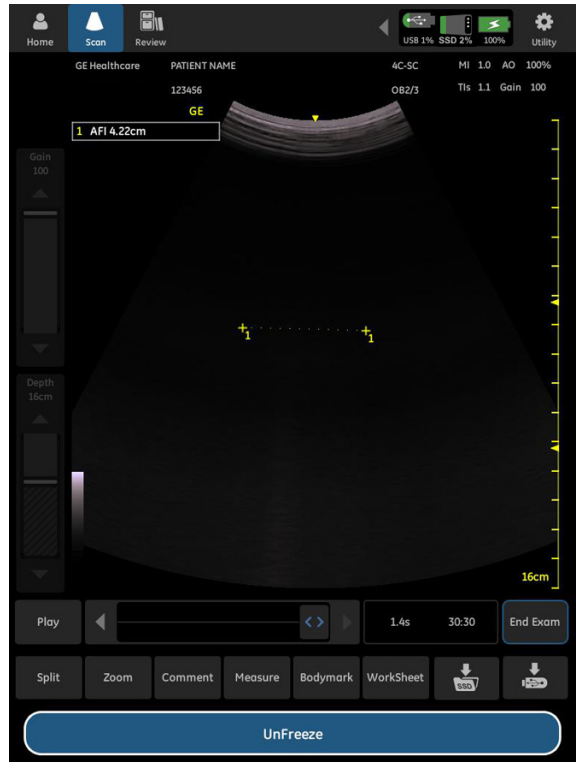


Figure 3-46. AFI (1 Caliper) Measurement

AFI(4 Calipers)

To make a AFI(4 Calipers) measurement:

1. Press **Measure**, then select **AFI (4 Calipers)**.

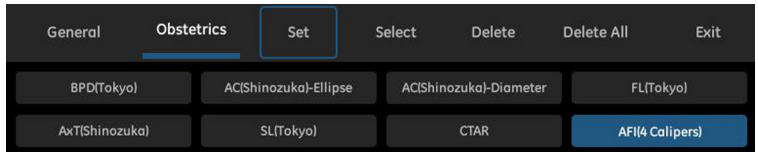


Figure 3-47. AFI (4 Calipers) Screen

2. Touch the screen, and two active calipers display.
3. Move the calipers to the desired position.
4. Press **Set** and the first distance value appears in the Results Window.
5. Repeat Step 1-4 three times and the system displays the AFI value in the Results Window.

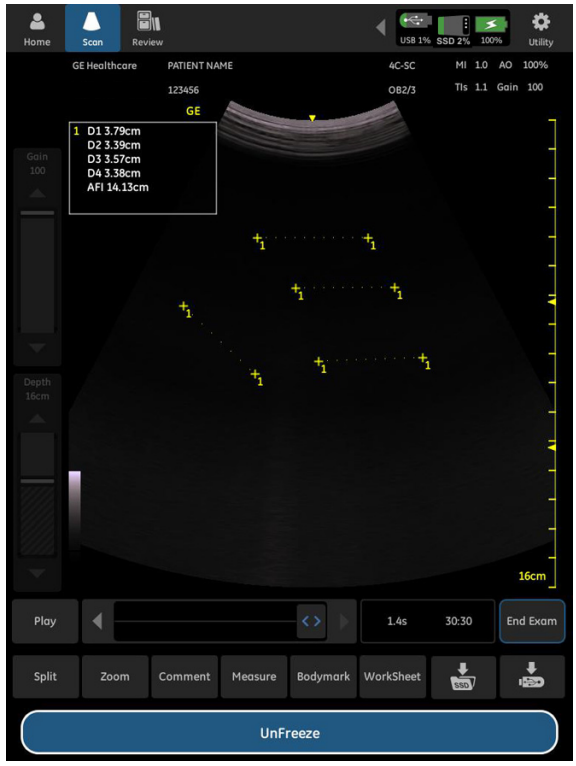


Figure 3-48. AFI (4 Calipers) Measurement

Cervical Length (CL)

To measure cervical length, make one distance measurement:

1. Press **Measure**, then select **CL**.

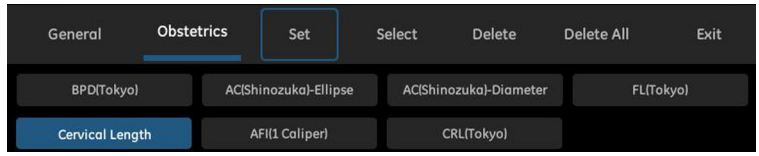


Figure 3-49. CL Screen

2. Touch the screen, and two active calipers display.
3. Move the calipers to the desired position.
4. Press **Set**.

   The system displays the value in the Results Window.

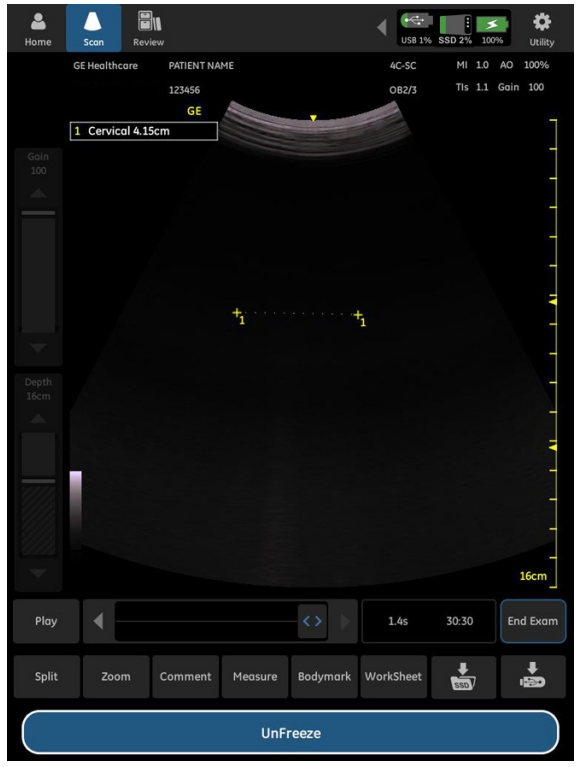


Figure 3-50. CL Measurement

Humerus Length (HL)

To measure humerus length, make one distance measurement:

1. Press **Measure**, then select **HL**.

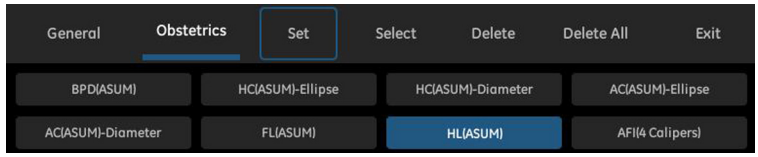


Figure 3-51. HL Screen

2. Touch the screen, and two active calipers display.
3. Move the calipers to the desired position.
4. Press **Set**.

   The system displays the value in the Results Window.

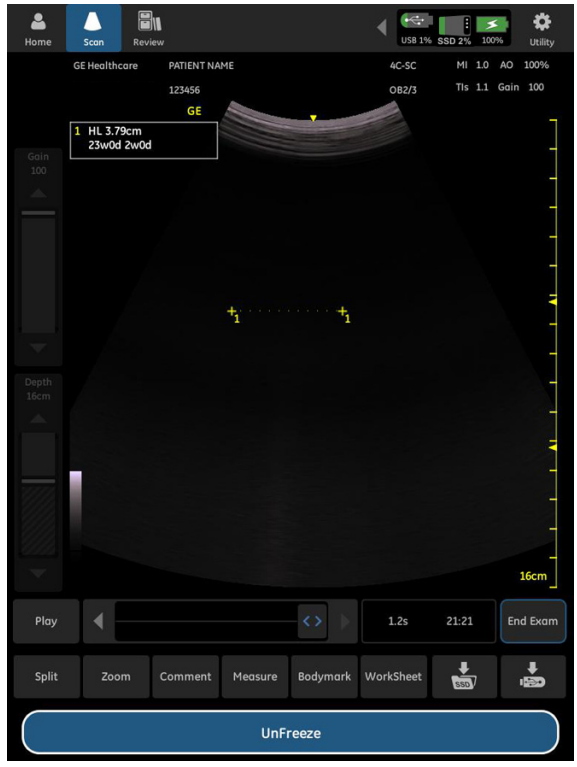


Figure 3-52. HL Measurement

Head Circumference (HC)

To make a HC (Hadlock) - Diameter measurement:

1. Press **Measure**, then select **HC (Diameter)**.

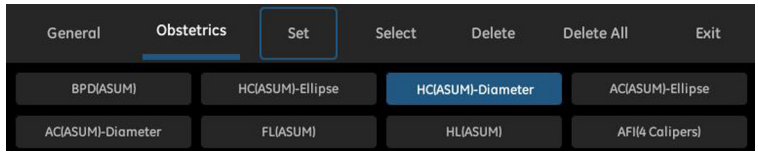


Figure 3-53. HC (Diameter) Screen

2. Touch the screen, and two active calipers display.
3. Move the calipers to the desired position.
4. Press **Set** to get the first diameter.
5. Repeat Step 1-4 to get the second diameter.

   The system displays the value in the Results Window.

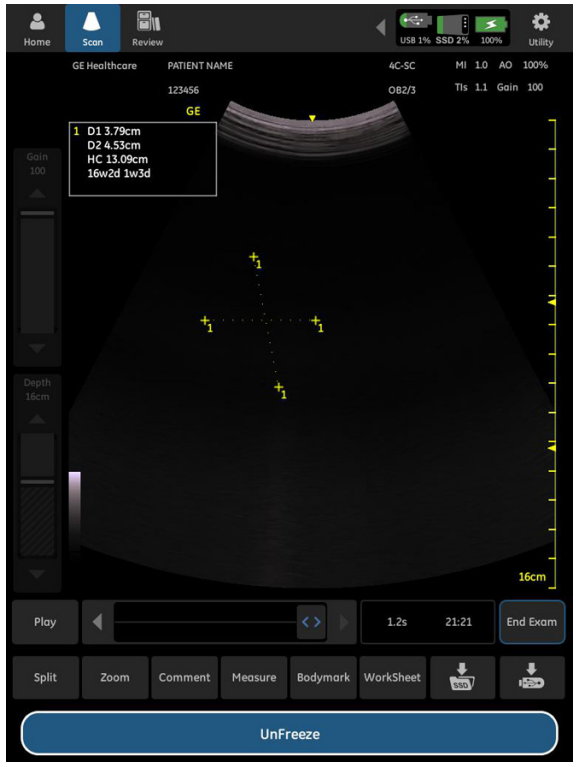


Figure 3-54. HC (Diameter) Measurement

Head Circumference (HC) (continued)

To make a HC (Hadlock) - Ellipse measurement:

1. Press **Measure**, then select **HC (Ellipse)**.

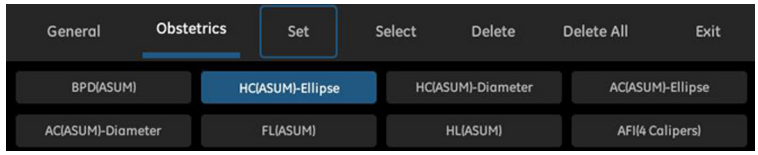


Figure 3-55. HC (Ellipse) Screen

2. Touch the screen, and three active calipers display.
3. Move the calipers to the desired position.
4. Press **Set**.

   The system displays the value in the Results Window.

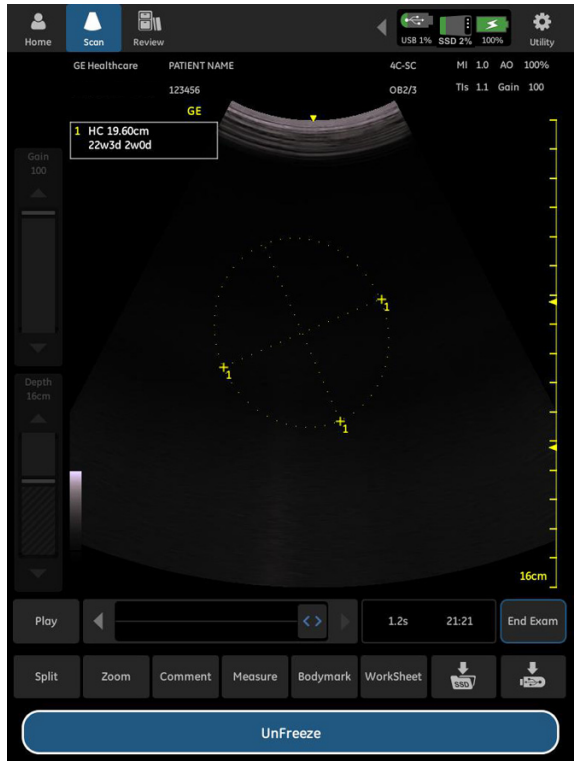


Figure 3-56. HC (Ellipse) Measurement

Fetal Trunk Cross-Sectional Area (FTA)

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

1. Press **Measure**, then select **FTA**.

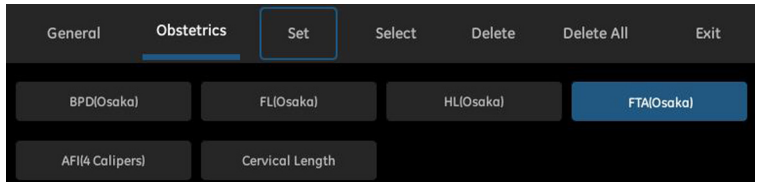


Figure 3-57. FTA Screen

2. Touch the screen, and two active calipers display.
3. Move the calipers to the desired position.
4. Press **Set**.

   The system displays the value in the Results Window.

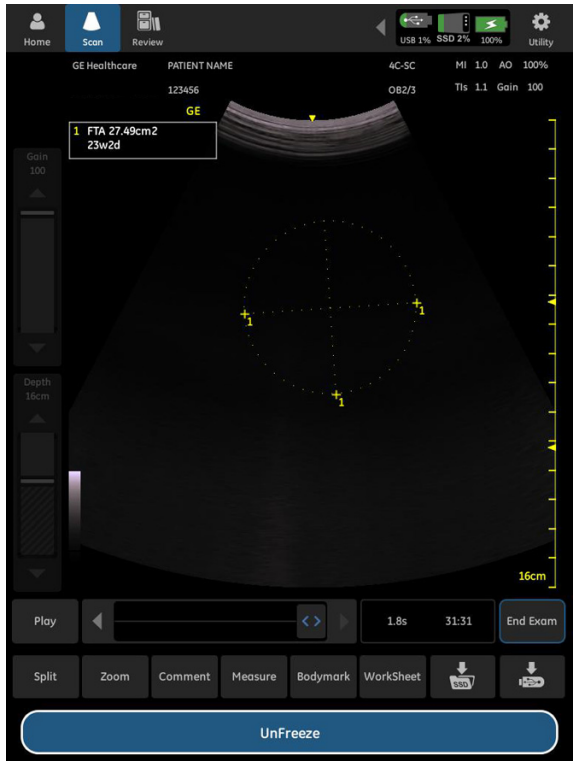


Figure 3-58. FTA Measurement

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 can be configured in **Utility** -> **Measure** -> **Obstetrics**.*

Annotations

Introduction

Select **Comment** to activate comment mode.

The comment function provides the capability to type the comments of free text and/or add the comments from the comment library. It also provides the operator with bodymark and arrow pointers.

NOTE: Annotations are only available in frozen mode.

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

Comment Retention

Comments will be retained and carried over when switching to multi-image mode.

The position of the comments is adjusted so that it is at the same relative position with respect to the display window in the new format as it was in the single image format.

Annotating an image using the library

Annotating an image using the system preset library

1. Press **Comment**, then press **Annotation**.
2. Choose the desired comment from the system preset library.

NOTE: You may swipe the screen to see more comments in the preset library.

3. Move the annotation box to the desired position. Press anywhere on the scanning screen to set the comment or select  to clear the comment.

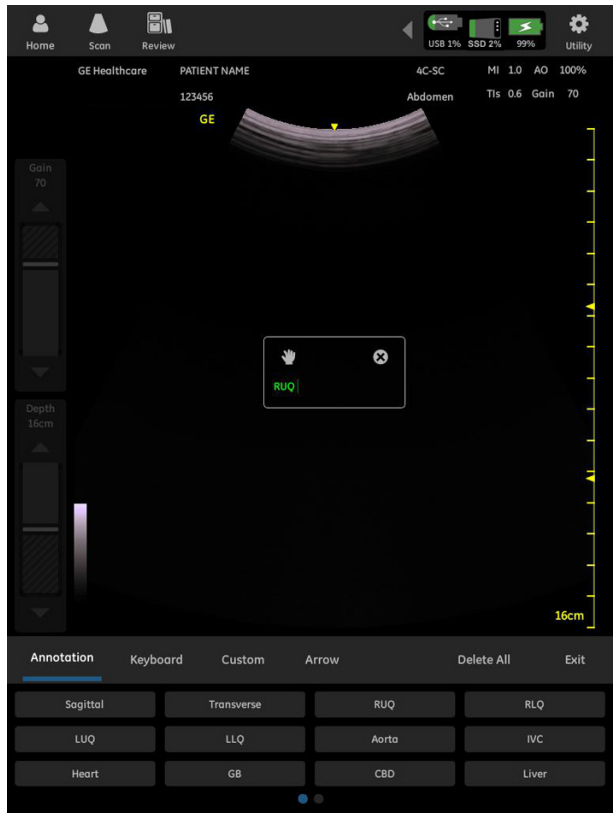


Figure 3-59. Preset Library

Annotating an image using the customer defined library

Creating/Editing comments for customer defined library

To create or edit comments for customer defined library:

1. Press **Comment**, then press **Custom**.
2. Select  .

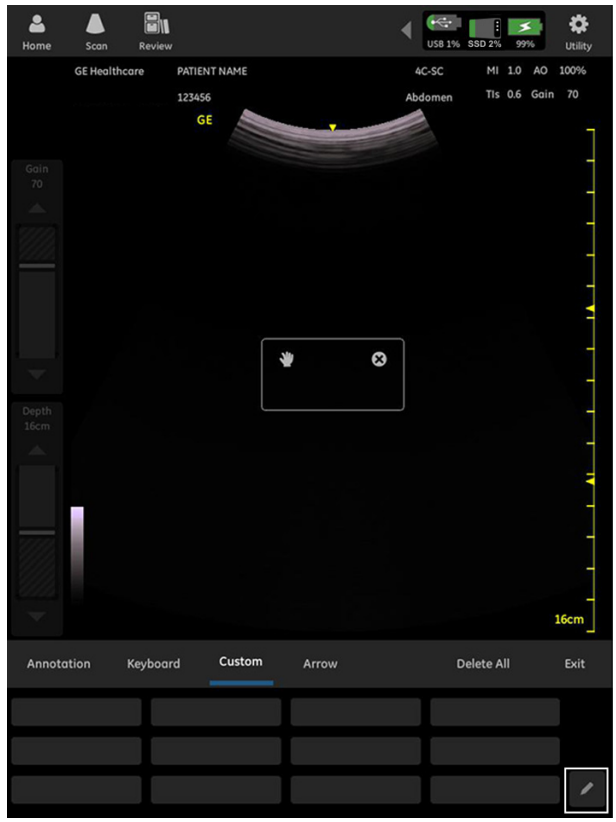


Figure 3-60. Customer Defined Library

Creating/Editing comments for customer defined library (continued)

3. Select a blank tab to create a new comment or select a defined tab to edit the comment, then press **Save** to save the new or edited comments.

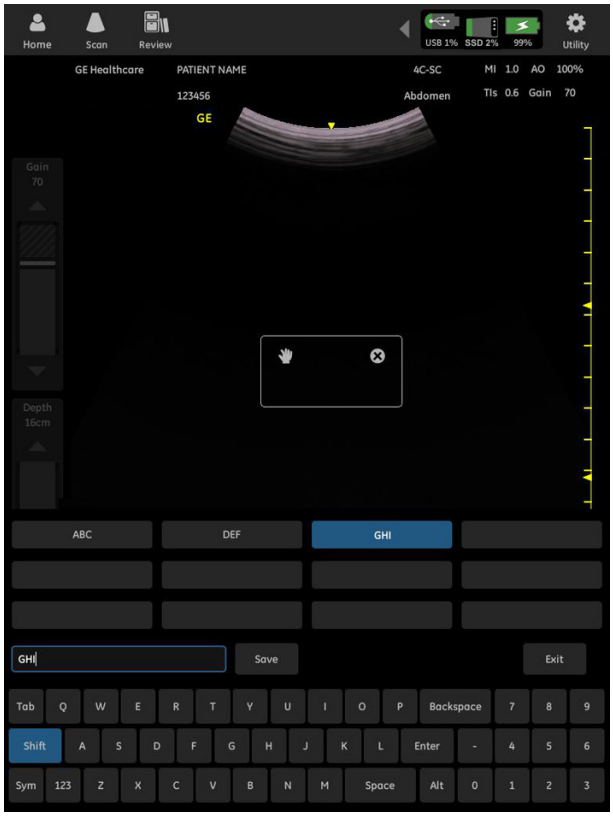


Figure 3-61. Customer Defined Library

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

Annotating an image using the customer defined library

1. Press **Comment**, then press **Custom**.
2. Choose the desired comment from the customer defined library.
3. Move the annotation box to the desired position. Press anywhere on the scanning screen to set the comment or select  to clear the comment.

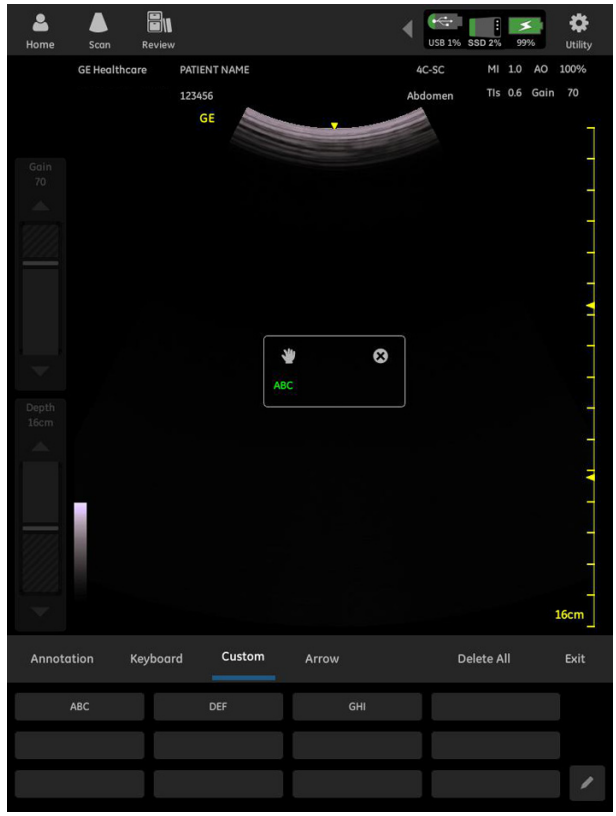


Figure 3-62. Customer Defined Library

Annotating an image with typed words

1. Press **Comment.**
2. Press **Keyboard**, then type comments.
3. Move the annotation box to the desired position. Press anywhere on the scanning screen to set the comment or select  to clear the comment.

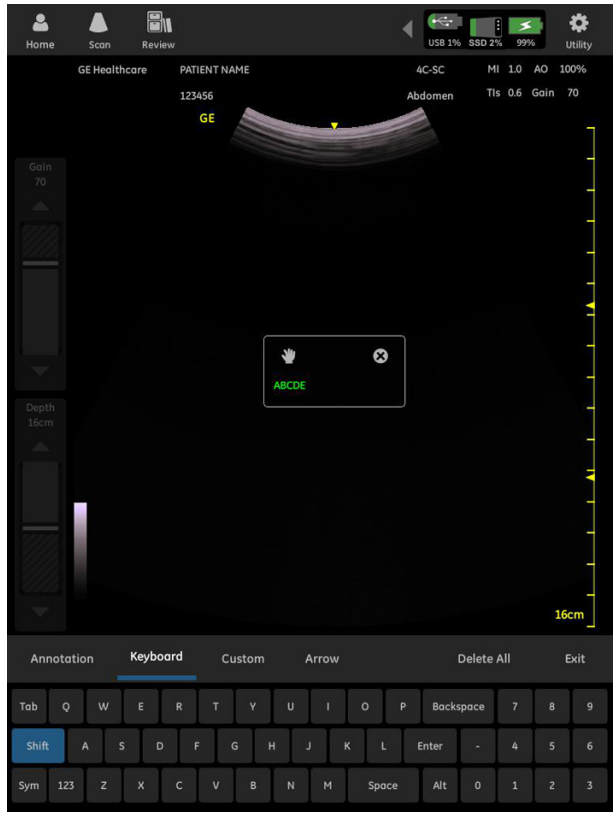


Figure 3-63. Keyboard

Bodymark

1. Press **Bodymark**.
2. Select the desired bodymark and move it to the desired position on the screen.
3. Press anywhere on the scanning screen to set the bodymark or press to delete it.

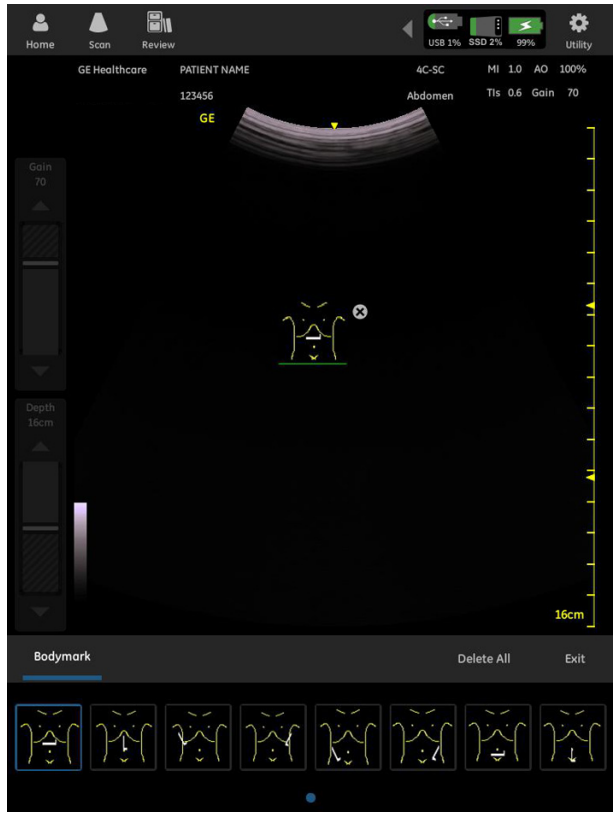


Figure 3-64. Bodymark

Arrow Pointers

1. Press **Comment**, then select **Arrow**.
2. Select the desired arrow pointer and move it to the target position on the screen.

*NOTE: You may change the size of the arrow pointers by selecting **Small**, **Medium** or **Large**.*

3. Press anywhere on the scanning screen to set the arrow pointer or press  to delete it.

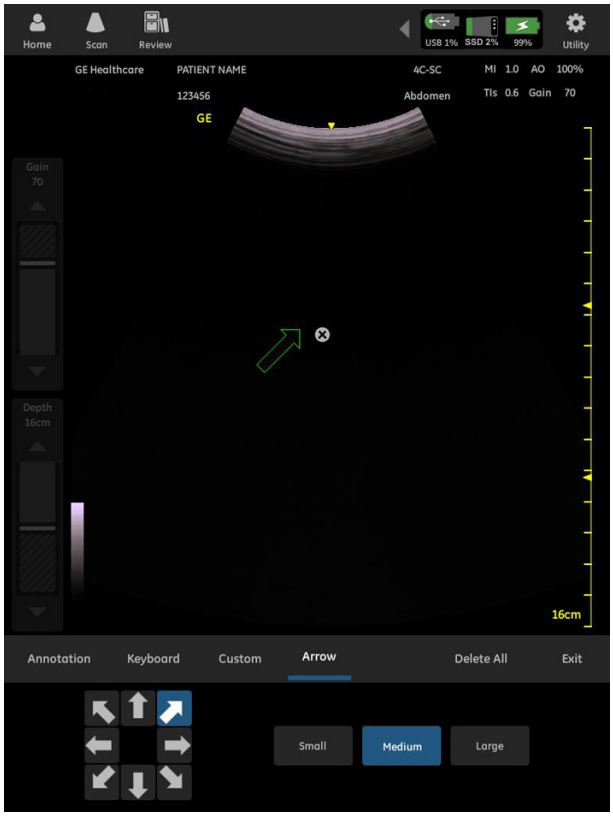


Figure 3-65. Arrow

Edit while annotating

There are two modes 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 mode.

To delete the annotation

1. Press **Freeze**.
2. Select **Comment**.
3. Select the desired comment and press  to delete it.
4. To delete all the comments, select **Delete All**.

*NOTE: If you select **Delete All**, all comments, including arrow pointers, bodymarks and text, will be deleted.*

To move the annotation

1. Press **Freeze**.
2. Select **Comment**.
3. Select the desired comment and move it to the target position.

Annotation Controls

Figure 3-66. Annotation mode controls

Table 3-6: Annotation controls

Controls	Affects on image
Annotation	Select the comments from the preset library.
Keyboard	Type the comments with alphabets.
Custom	Create or edit for customer defined library.
Arrow	Select for arrow placement.
Delete All	Delete all annotations.
Exit	Exit the annotation screen.

OB Worksheet

OB Worksheet summarizes 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 when the OB package option is activated.

Activating the Worksheet

Select **Worksheet** in frozen mode.

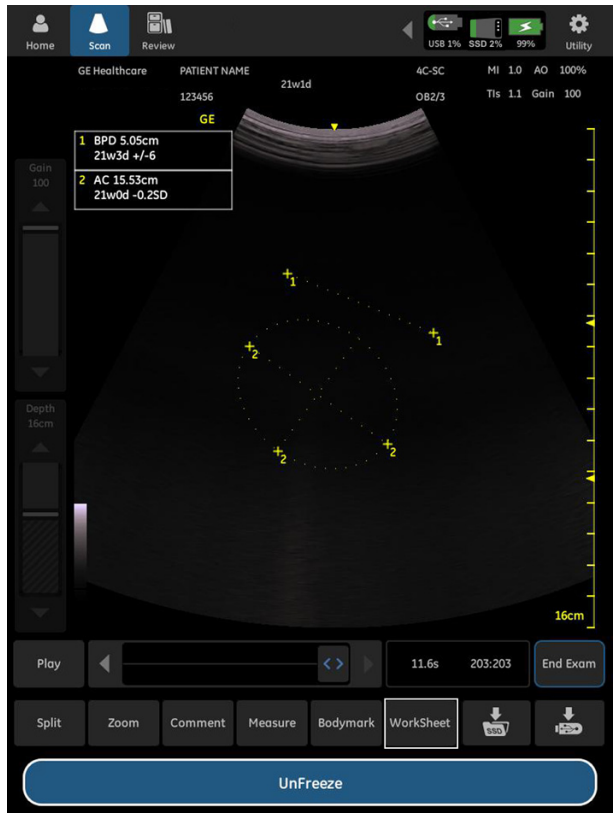


Figure 3-67. Worksheet

OB Worksheet Controls

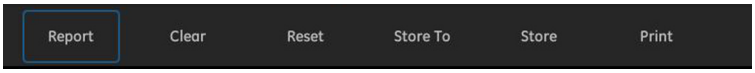


Figure 3-68. OB Worksheet Controls

Table 3-7: OB Worksheet Controls

Controls	Function Description
Report	Press to view the report sheet.
Clear	Press to clear the all the information in OB Worksheet except Patient ID, Name and Age.
Reset	Press to reset the worksheet.
Store to	Press to set store destination.
Store	Press to store the worksheet.
Print	Press to print the worksheet.

OB Worksheet information

OB Worksheet information:

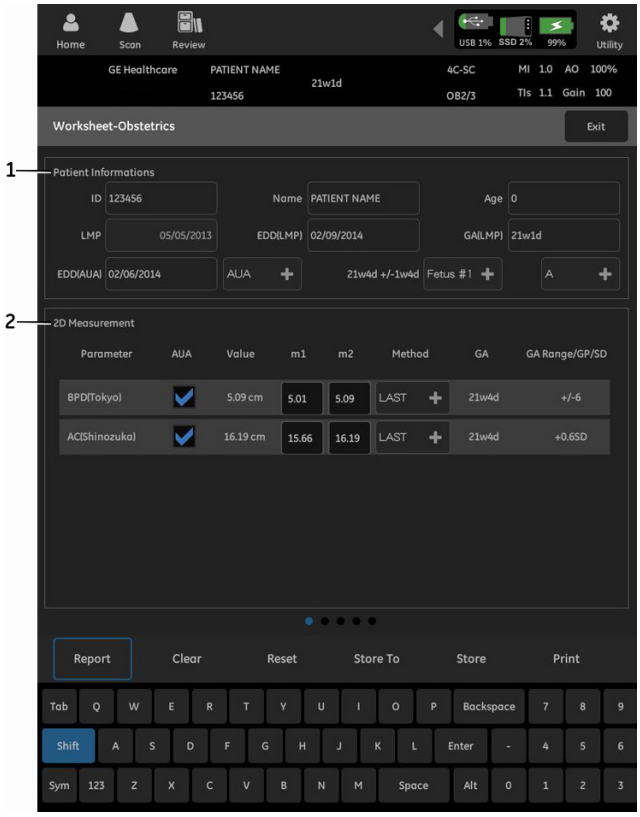


Figure 3-69. OB Worksheet page - page1

1. Patient information

Table 3-8: 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.
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.

Table 3-8: Patient information

Field	Description
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 3-9: 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)

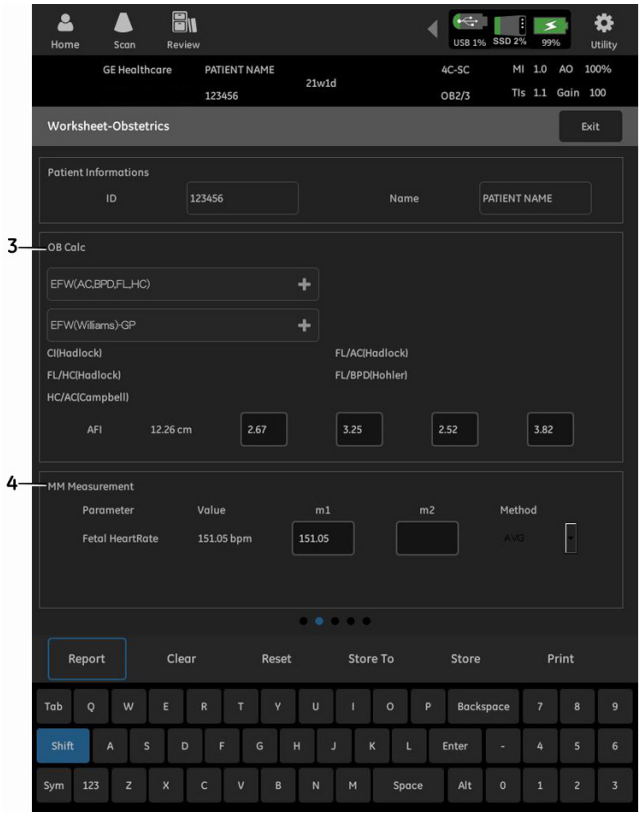


Figure 3-70. OB Worksheet page - page2

3. OB Calculation

Table 3-10: OB 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.
FL/AC, FL/HC, FL/BPD, HC/AC	Ratios for the measurements
AFI	Amniotic Fluid Index.

OB Worksheet information (continued)

4. MM Measurement

Table 3-11: 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)

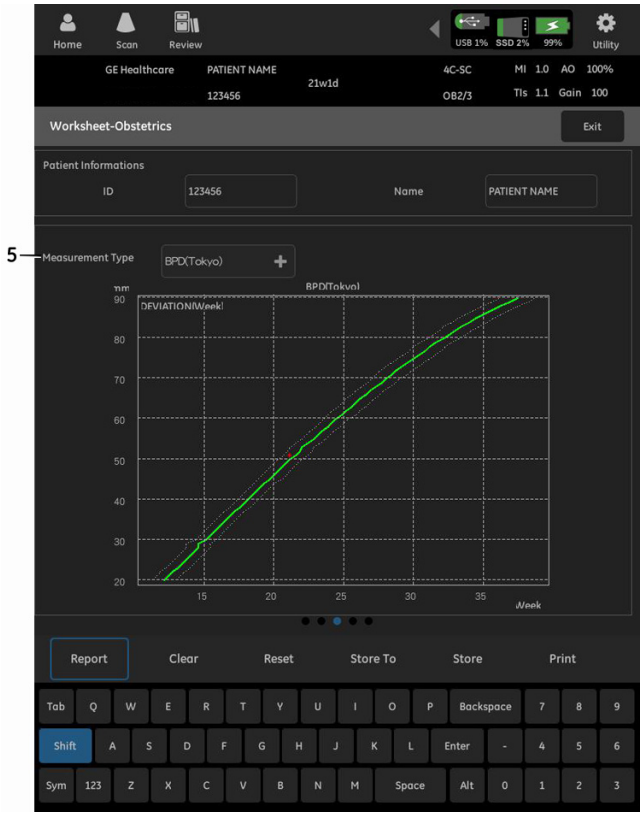


Figure 3-71. OB Worksheet page - page3

5. Measurement Type

NOTE: You may choose the measurement type from the pull-down list and the screen will show the corresponding figure.

OB Worksheet information (continued)

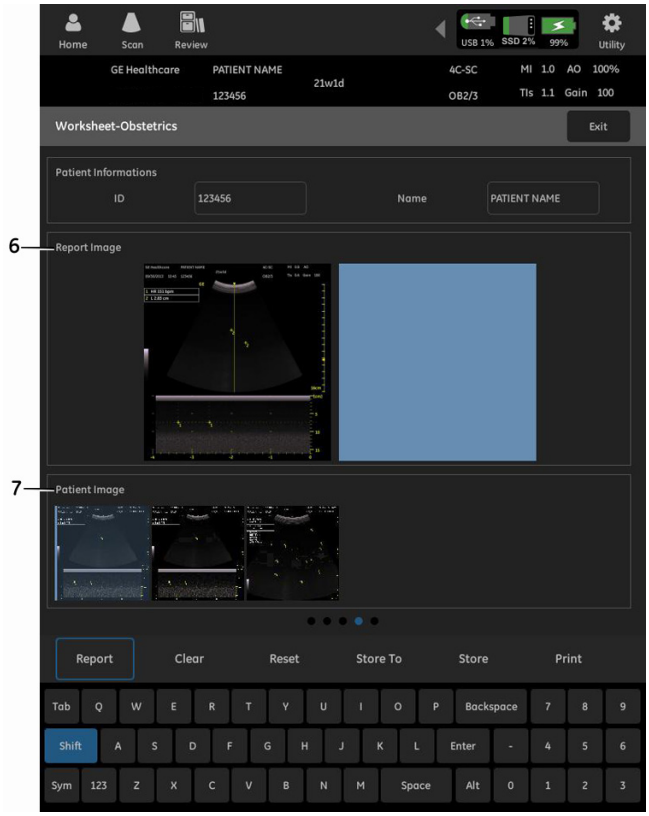


Figure 3-72. OB Worksheet page - page4

6. Report Image
7. Patient Image

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

OB Worksheet information (continued)

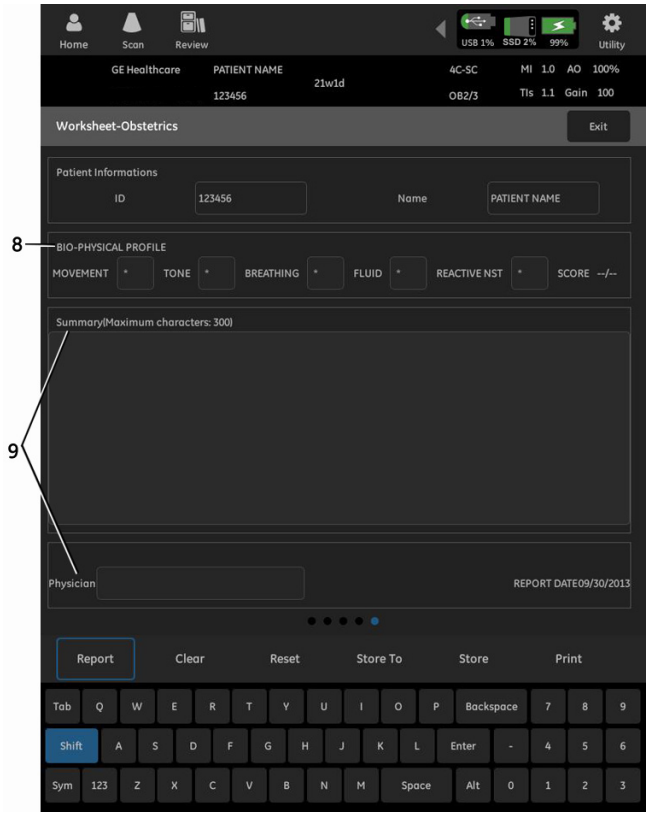


Figure 3-73. OB Worksheet page - page5

8. BIO-PHYSICAL PROFILE

Table 3-12: 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 *
Reactive NST	Type 0, 2 or *

OB Worksheet information (continued)

9. Summary and Physician

Table 3-13: 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.

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 the desired image in the patient image area to copy the image to the report image area.

Double click 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, then the report will be shown on the screen.

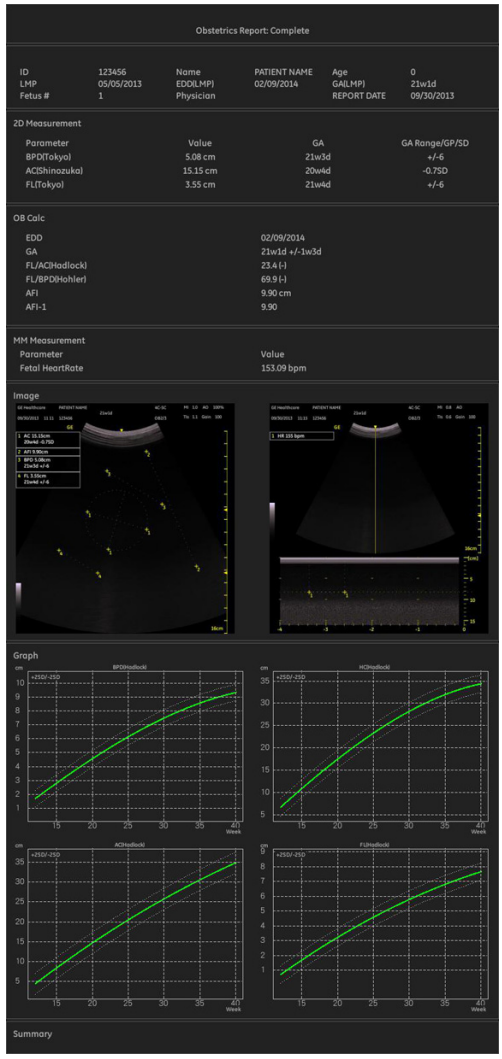


Figure 3-74. OB Report page

OB Report controls

Worksheet

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

Store To

Press to set the store destination.

Store

Press to store the OB Report.

Save Text

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

Save PDF

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

Print

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

Multi gestational

Venue 50 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 defaults to 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, Text or PDF format.

To Store an OB Report:

1. Select **Report** on the OB worksheet page to enter into OB report page.
2. Press **Store To** to set the store destination.

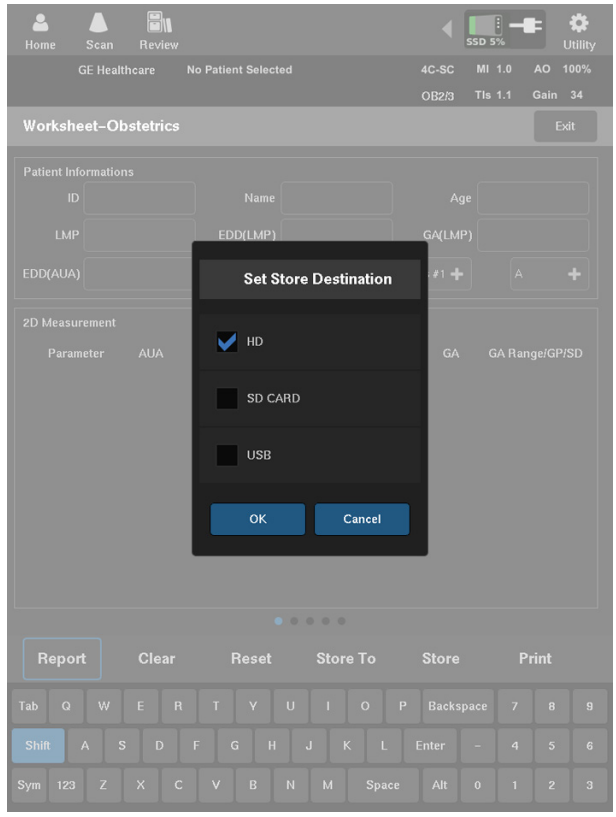


Figure 3-75. Set Store Destination

3. Press **Store** to save the OB report in JPEG format to the patient folder.
4. Press **Save Text** or **Save PDF** to save the OB report in text format or in PDF format to the patient folder.

Image Management

Zooming an Image

Introduction

Zoom is used to magnify a region of interest (ROI). The system adjusts all imaging parameters accordingly. You can zoom a live or frozen image with your fingers.

Bioeffect

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

Acoustic Output Hazard

Observe the output display for possible effects.

To zoom an image, press **Zoom**. A reference image appears in the lower, right-hand section of the display. You may use your fingers to zoom the image.

To exit zoom, press **Zoom** or press **B** Mode if in Live scan mode.

Split Screen

Overview

To activate split screen, press **Split**.

- In live mode

  When you press **Split**, both the latest frame that the system automatically stored and the live image will be on the screen.
- In frozen mode

  When you press **Split**, both the latest image that you stored and the live image will be on the screen.

To exit split, press **Split** or press **B** Mode.

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**

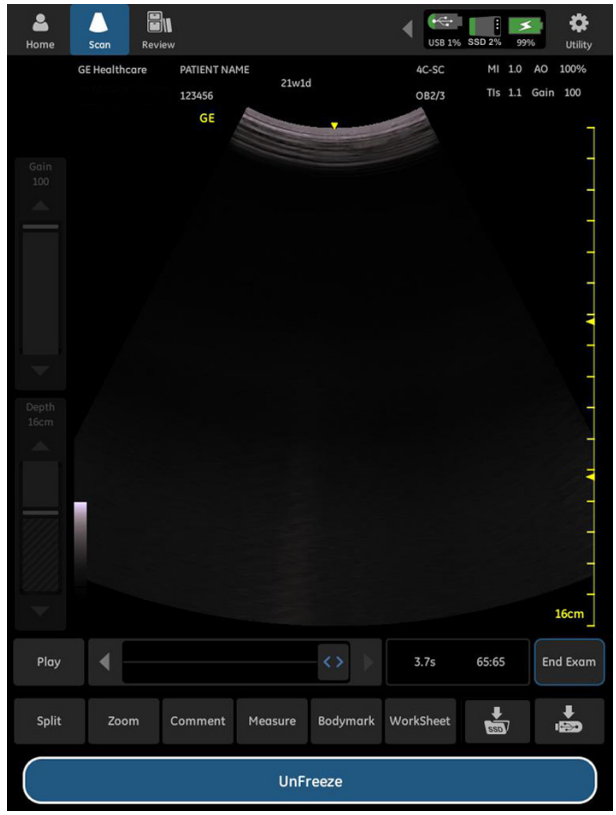


Figure 3-76. Cine screen

Cine controls

Figure 3-77. Cine controls

Table 3-14: Cine controls

Controls	Affects on images
<	View previous frame
>	View next frame
Play/Pause	Playback/Pause the Cine loop

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

Review Archived Information

Searching for an existing patient

1. Select **Review**, then the patient gallery under the storage device displays on the screen.

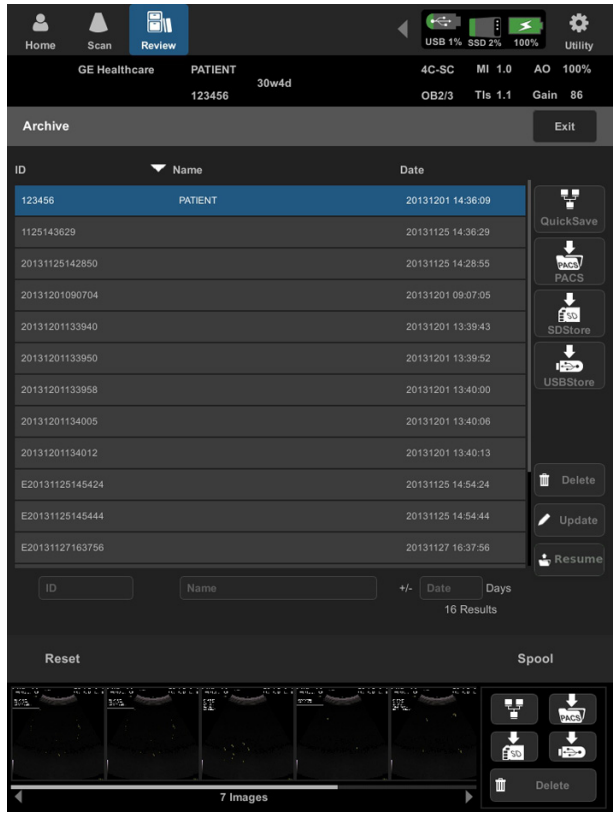


Figure 3-78. Gallery Screen

Searching for an existing patient (continued)

2. Enter Patient ID or Name, then select the desired patient.

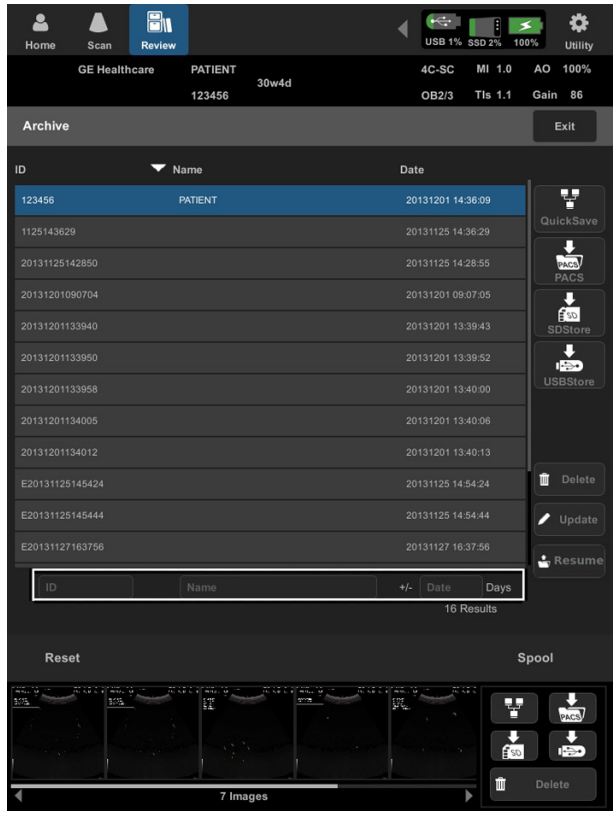


Figure 3-79. Patient Search screen

3. The patient information displays on the screen.

Editing patient information

To edit patient information,

1. Press **Review**, then select the desired patient from the patient gallery.
2. Press **Update** to edit the patient information.

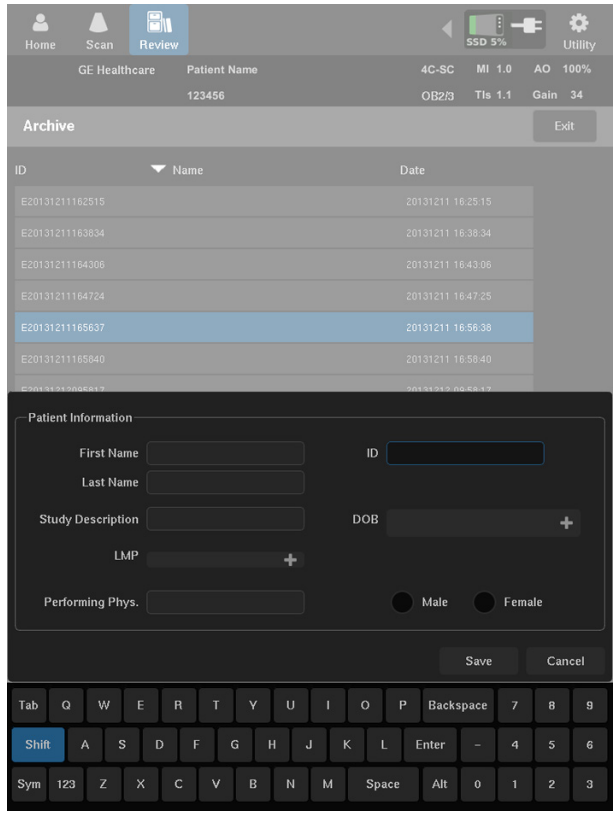


Figure 3-80. Patient Edit page

a. If the patient is an emergency one (i.e. without entering any information before scanning), the operator can edit all the patient information, including patient ID.

NOTE: The patient ID can be revised only once.

b. If the patient is not an emergency patient, the operator can edit all the patient information, excluding the patient ID.

Editing patient information (continued)

If the patient is an emergency patient, you may follow the way to edit patient information as above, or you may do as follows:

1. After the exam, press **Home** -> **Manual** -> **Update Demographic** to edit the patient information.

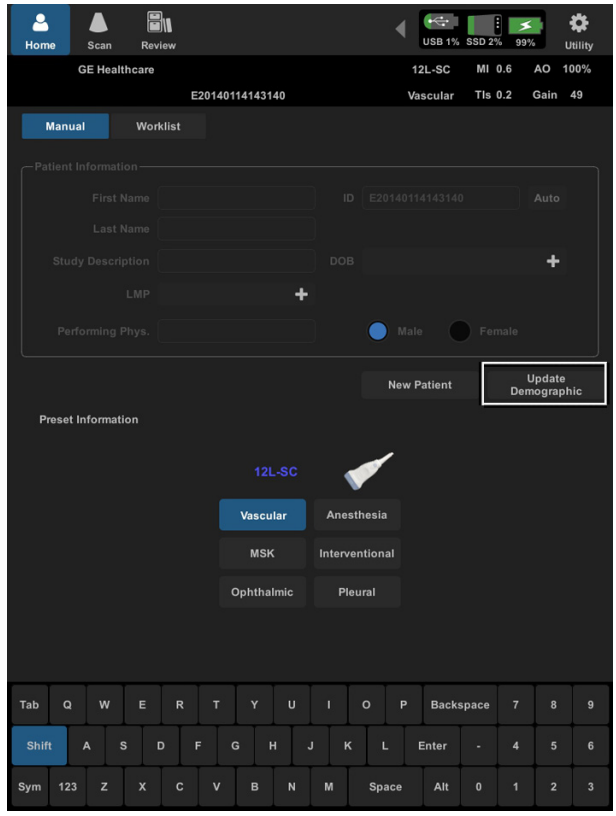


Figure 3-81. Emergency patient edit page

2. Press **Scan** to begin an exam or end an exam. The updated patient information will be stored.

Reviewing the patient exam

To review the patient exam,

1. Press **Review**, then select the desired patient from the **Archive**.

   The images/videos of the selected patient are displayed at the bottom of the screen. You may swipe left or right to see more images/videos.

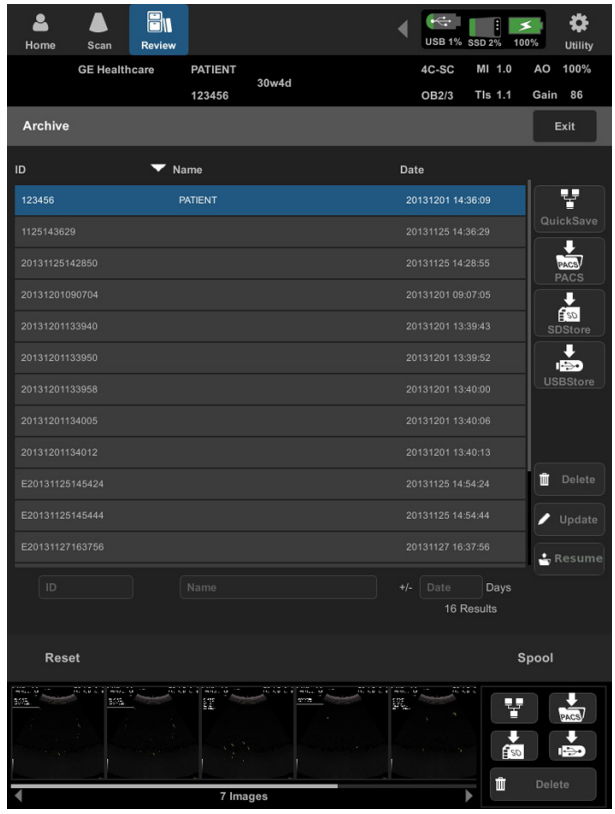


Figure 3-82. Review patient exam

Reviewing the patient exam (continued)

2. Tap the desired image or video, press **Review** and it will be displayed on the review screen.

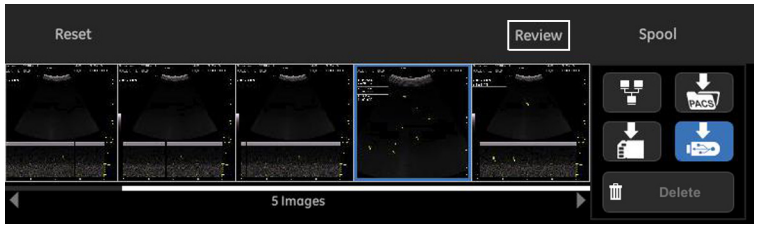


Figure 3-83. Review Patient Exams

3. In the review screen, press **Split** to split the scanning screen. Press **Print** to print the image. Press **Delete** to delete the image or video. Press **Close** to exit to the patient gallery.

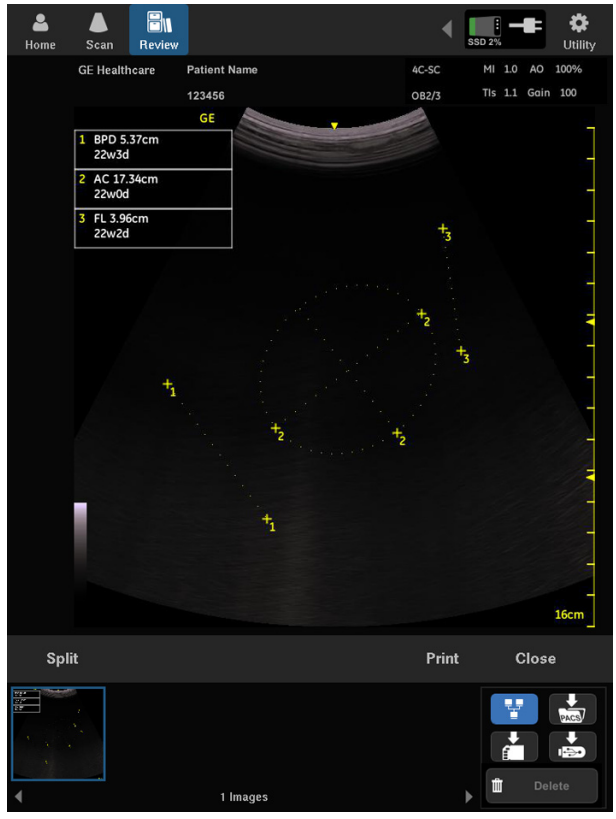


Figure 3-84. Review Screen

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. Press **Delete**. The confirmation dialog box displays.

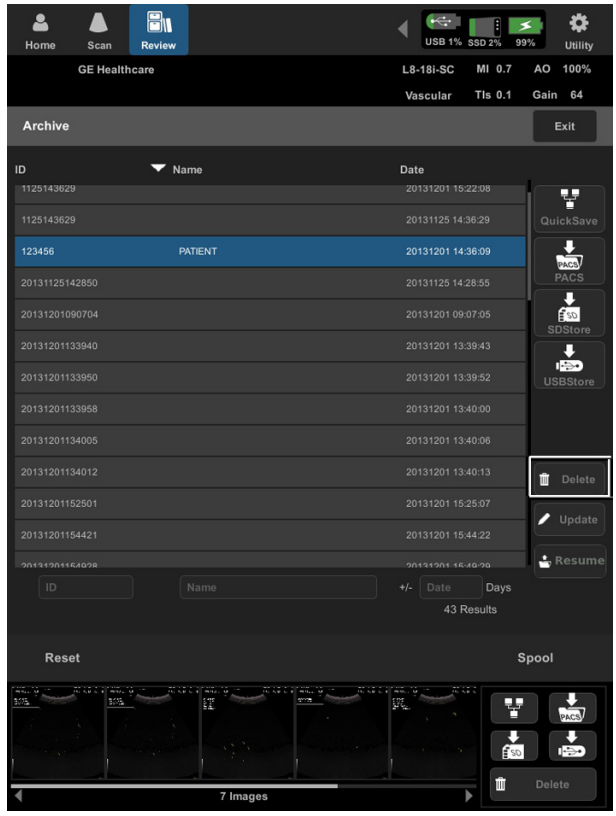


Figure 3-85. Delete Patient

3. Select **OK** to delete or select **Cancel** to exit.

Deleting the existing image/video

1. Select the patient in the patient list.
2. Press the desired image.
3. Press **Delete**. A dialog box displays. Select **OK** to delete or select **Cancel** to exit.

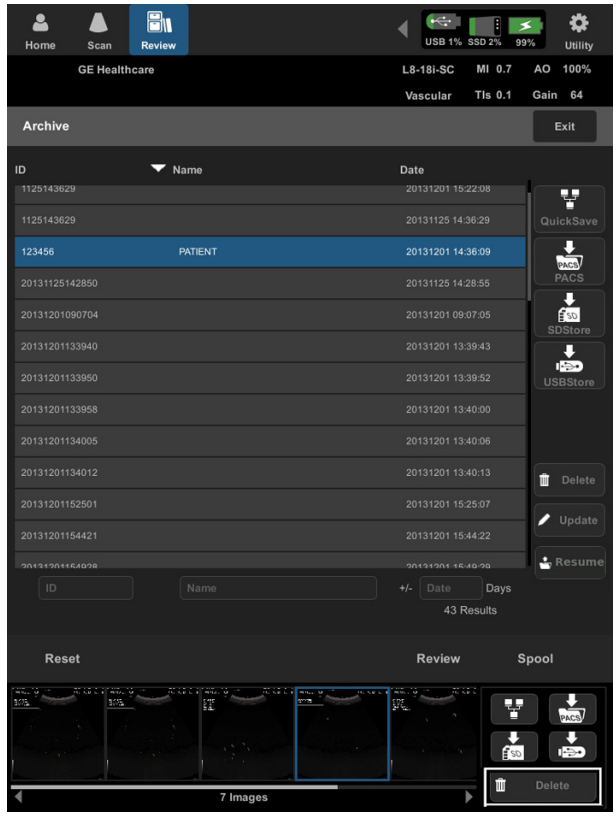


Figure 3-86. Delete Image/Video

Image Storage

Storing an image

Images can be stored in JPEG format.

To store an image in frozen mode:

1. While scanning, press **Freeze**.
2. Scroll through the **Cine Loop** and select the desired image.
3. Press the appropriate **Dataflow Button** to save the image.

To store an image in live scan mode:

1. Go to **Utility** -> **Settings** -> **Common**, then choose **Image** in **Live Scan Save**.
2. Select **Save**, then select **Exit** to enter into scan screen.
3. While scanning press **Dataflow Button** to save the image. A message “Image saved successfully“ displays on the screen.

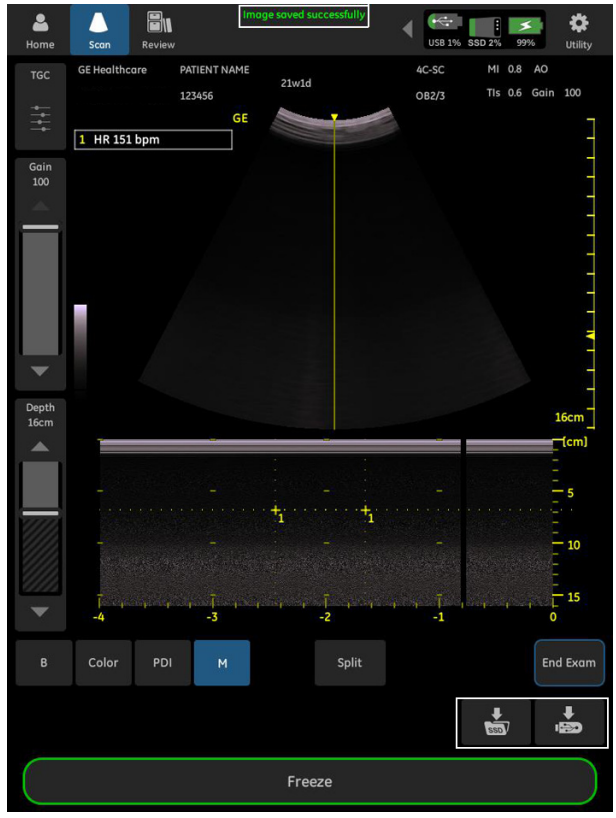


Figure 3-87. Image Saved

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.

1. Go to **Utility** -> **Settings** -> **Common**, then choose **Video** in **Live Scan Save**.
2. Select **Save**, then select **Exit** to enter into scan screen.
3. While scanning or playing back a cineloop, press the **Dataflow Button** to save the video.
4. A processing box showing storing progress displays.
5. A message “Video saved successfully“ displays on the screen.

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 on the screen.

Figure 3-88. Storage device status icon

When the storage device is full

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

Figure 3-89. 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 images/ videos again.

When the storage device is not available

If the selected storage device is not available, the following icon displays:

Figure 3-90. Storage device is not available 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. Tap the storage device status icon, press “Eject SD” or “Eject USB”, then remove the storage device from the system.

DO NOT disconnect the SD Card or USB Memory Stick from Venue 50 without properly ejecting the device; this may result in loss of data.

2. Connect the storage device to the PC.
   - For USB Memory Stick, 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.
   - PatientID@_@_LastName@_FirstName@_UserName@_StudyDate.
   - For those registering with Patient ID and 2nd ID, the folder name is PatientID@_2ndID@_LastName@_FirstName@_UserName@_StudyDate.
   - For those registering with auto Patient ID, the folder name is AutoID@_@_@_@_UserName@_StudyDate.
   - For those scanning without patient registration, the folder name is EAutoID@_@_@_@_UserName@_StudyDate.

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

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 or videos to DICOM image server.
3. **Network QuickSave**: Transfer images and CINE loops to network shared folder.

Network Status

View network status

There are two icons indicating wired and wireless network status.

The following icons indicate that the wired and wireless network are connected:

Figure 3-91. Wired network status icon - connected

Figure 3-92. Wireless network status icon - connected

When the network is disconnected

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

Figure 3-93. Wired network status icon - disconnected

Figure 3-94. Wireless network status icon - disconnected

When the wireless network is limited

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

Figure 3-95. Wireless network status icon - limited or no connection available

DICOM Worklist

1. Select **Home**, then select **Worklist**. The patient list used last time displays.

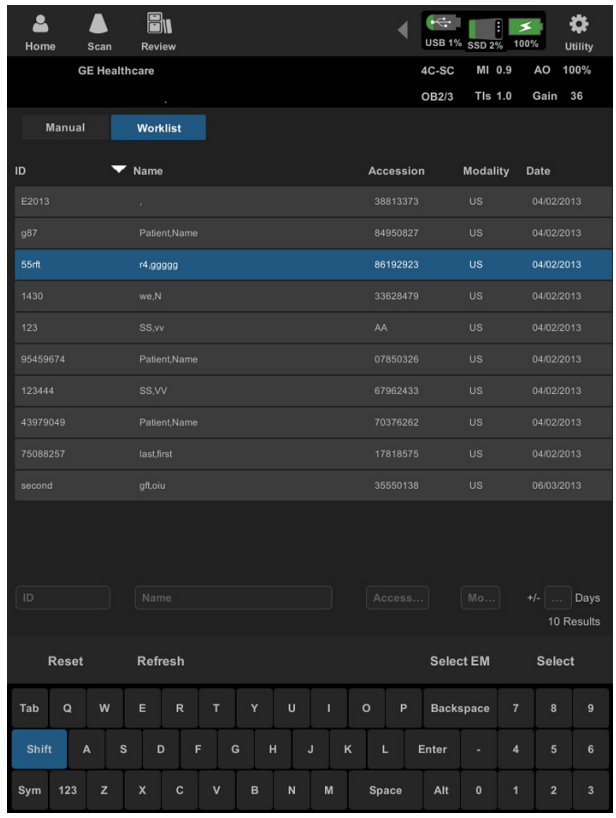


Figure 3-96. Patient list in worklist server

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

DICOM Worklist (continued)

2. Press **Refresh**, the patient list which meets the search criteria in the worklist server displays.

*NOTE: The Search Criteria may be configured in **Utility** -> **Connectivity** -> **DICOM**.*

3. Select the desired patient, press **Select EM** or **Select**, the patient information is automatically populated.

   Or

   Enter Patient ID, Patient Name, Accession, Modality and/or Date to search the patient. Press **Select**, the patient information is automatically populated.

*NOTE: Only when the patient is an emergency one, can the operator press **Select EM**.*

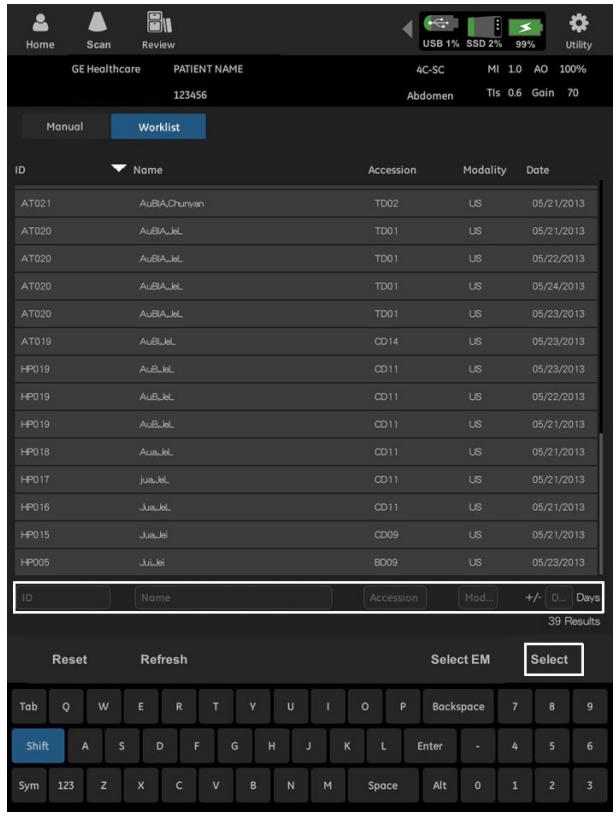


Figure 3-97. Search patient list in worklist server

4. Press **Scan** to begin an exam.

DICOM Image Store

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

NOTE: All still images can be sent to DICOM image server.

*NOTE: Video may be sent to DICOM image server only if **Enable MultiFrame DICOM** is selected.*

NOTE: The multiframe video is limited to 3 seconds.

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

1. Select **Review**. The patient gallery displays on the screen.
2. Select the desired image or video, select (PACS) in the lower right corner. The image or video will be sent to the DICOM image server.

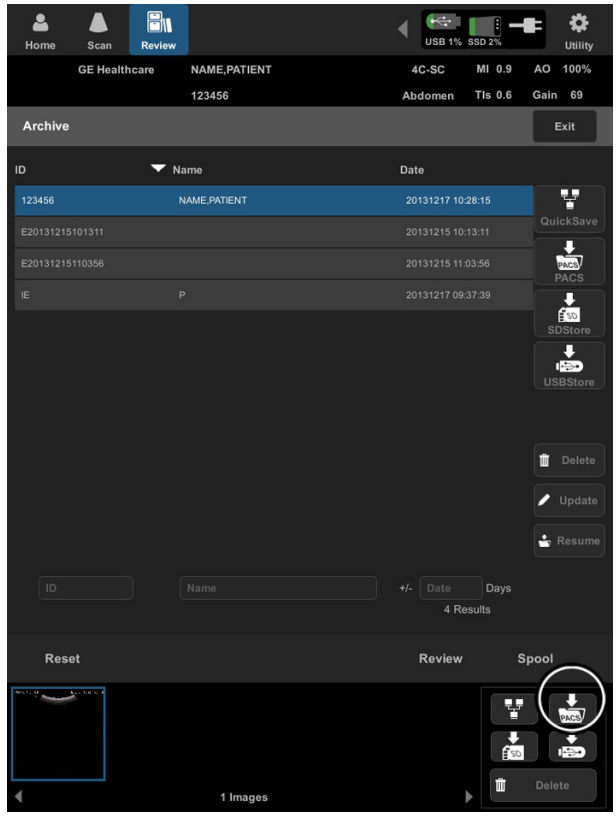


Figure 3-98. DICOM image/video

DICOM Image Store (continued)

Or

Select the desired patient, select  (PACS) on the right side. The images and videos of the patient will be sent to the DICOM image server.

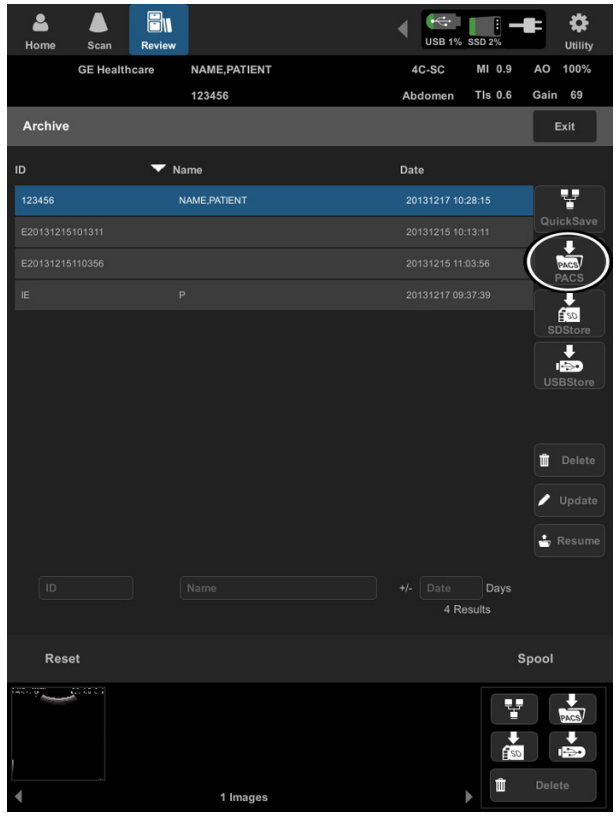


Figure 3-99. DICOM patient data

NOTE: The transfer status can be viewed in Spool, refer to 'Spool' on page 3-100.

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.*

1. Select **Review**. The patient gallery displays on the screen.
2. Select the desired image or Cine loop, select  in the lower right corner. The image or Cine loop will be sent to the network shared folder.

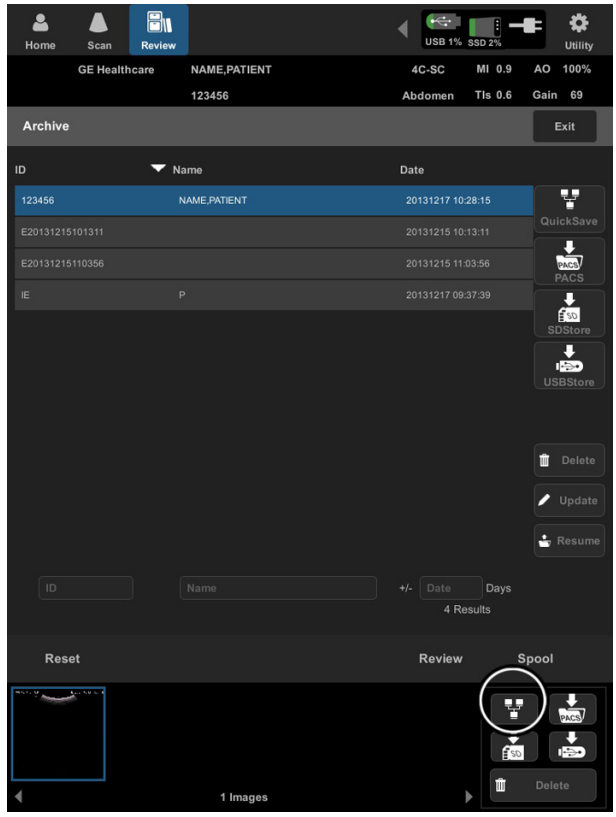


Figure 3-100. Network image/video

Network QuickSave (continued)

Or

Select the desired patient, select  on the right side. The images and Cine loops of the patient will be sent to the network shared folder.

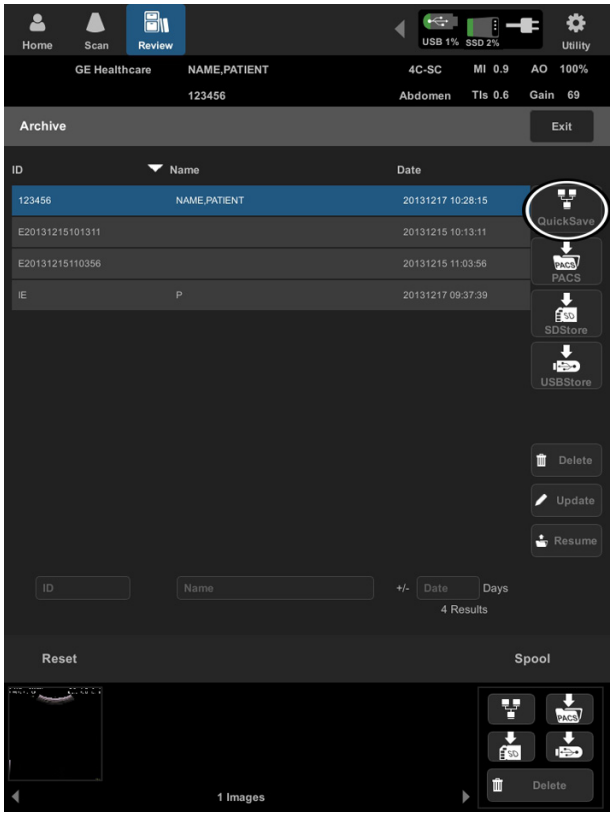


Figure 3-101. Network patient data

Spool

To monitor/control DICOM jobs, select **Review** -> **Spool**. You can view, refresh, resend, and delete images from DICOM spool by selecting a job, then specifying the action to be performed on this job.

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

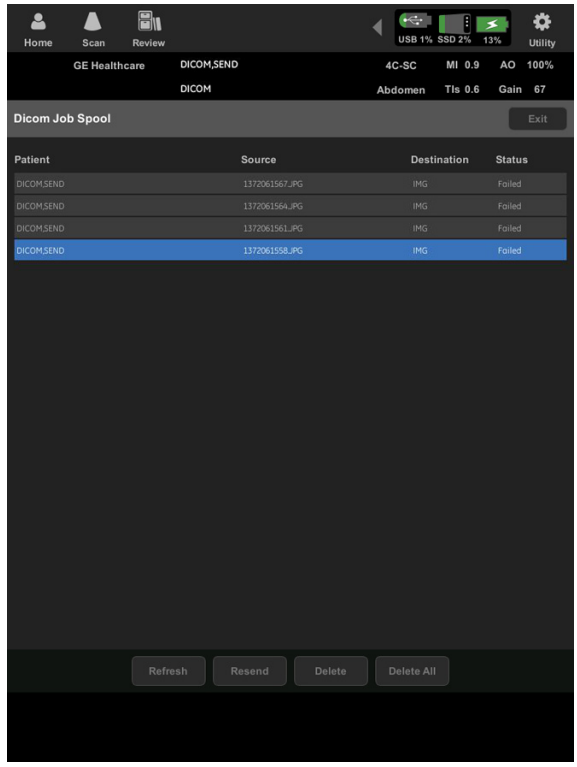


Figure 3-102. Example screen of Spool

Table 3-15: Job status

Status	Description
Ready	The image transfer is ready.
Start	The image transfer has started.
Finished	The image transfer is successfully finished.
Failed	Unsuccessful job attempt. Job stays in spool. Select Resend or Delete to complete the job.

eSmart Trainer (Option)

The system provides eSmart Trainer function.

To activate the eSmart Trainer function:

1. Go to **Utility** -> **Settings** -> **Config Page**, then activate the eSmart Trainer function. Press **Save**.

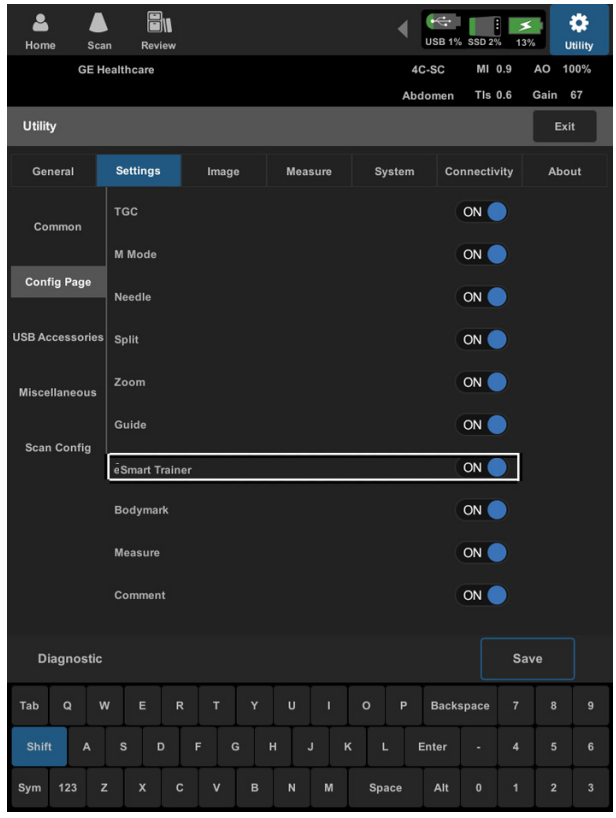


Figure 3-103. Activate eSmart Trainer

eSmart Trainer (Option) (continued)

2. Press **Utility** -> **Settings** -> **Miscellaneous** to choose the desired trainer setting. Press **Save**.

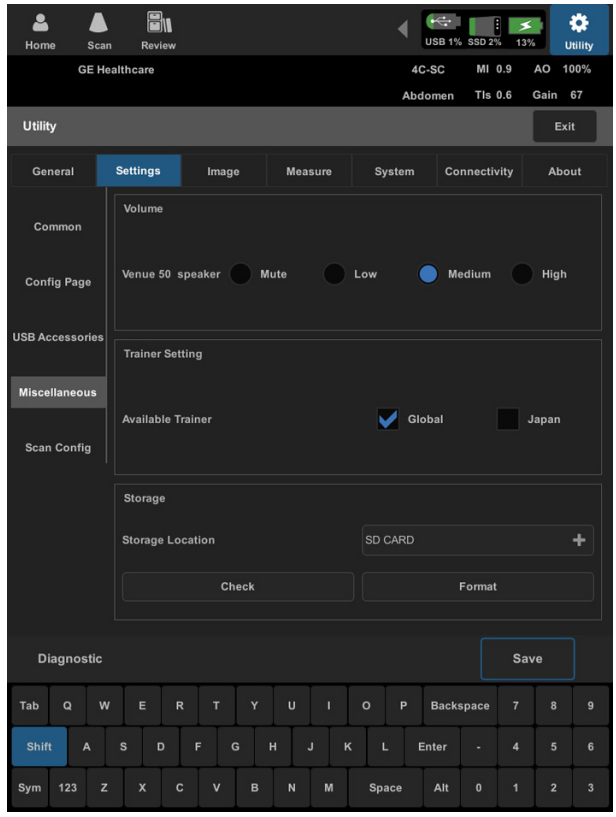


Figure 3-104. Trainer Setting

eSmart Trainer (Option) (continued)

3. Select **Scan**->**eSmart Trainer**.

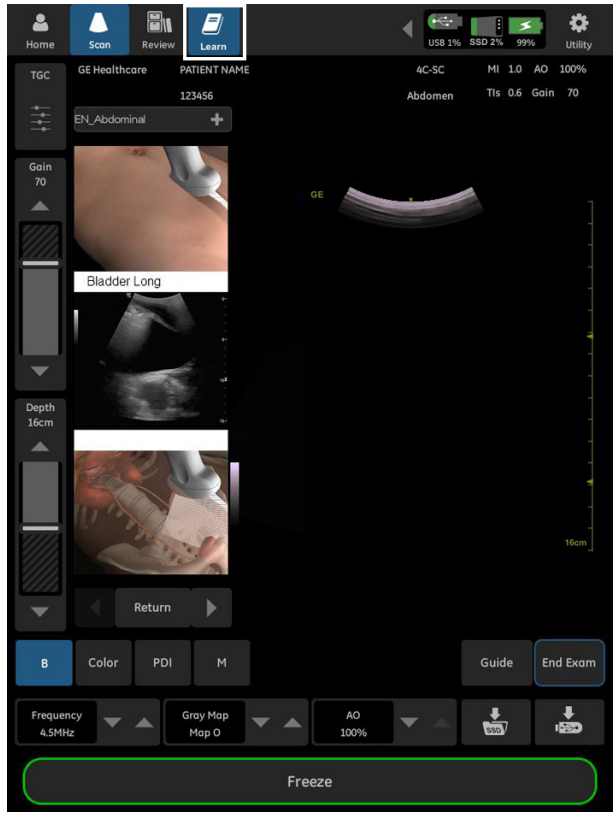


Figure 3-105. Select eSmart Trainer

eSmart Trainer (Option) (continued)

4. Press < or > to see more images in the selected module.
5. Select **Return** to exit the training module.

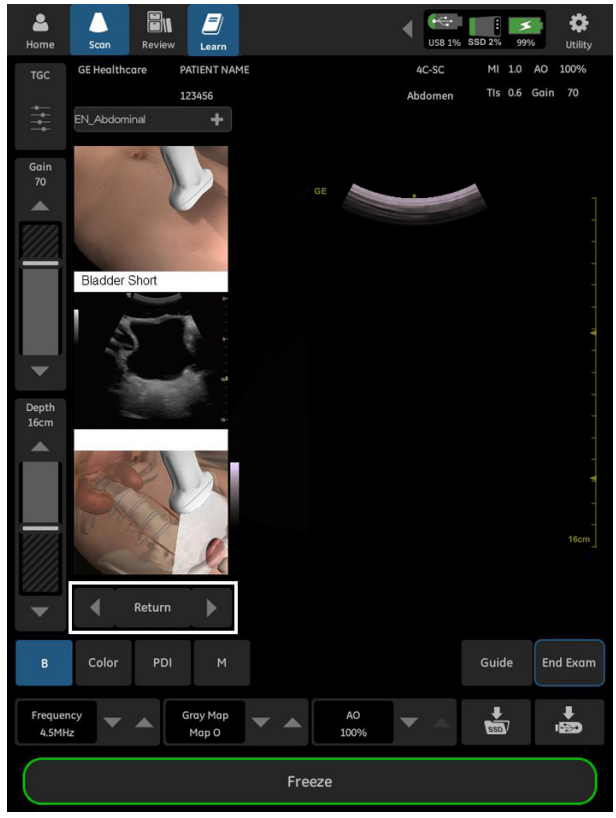


Figure 3-106. eSmartTrainer

Chapter 4

Customizing Your System

Describes how to view system information and configure system settings.

Utility

Overview

Utility Menus provide the following functionality:

- **General -** Configure general system settings
- **Settings** - Configure system settings
- **Image** - Configure image settings
- **Measure** - Configure measurement settings
- **System** - View product information, software option and configure log export storage device
- **Connectivity** - Configure system connectivity settings
- **About** - Software/hardware version and system patents

General

The General screen allows you to specify Facility Name, System Language, Region, Package, Screen Lock Passcode, Data Privacy Passcode, Date Format, Time Format, System Date and System Time.

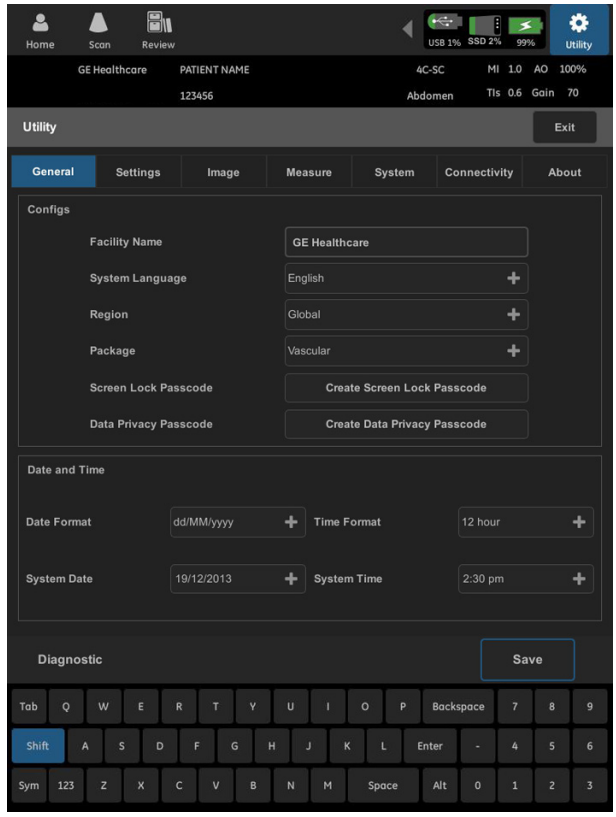


Figure 4-1. Utility - General

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.
Region	Select the region from the drop-down list. Note: If the region is changed, the system will shutdown.
Package	Select the desired software package.
Screen Lock Passcode	Press to create screen lock passcode (4 figures).
Data Privacy Passcode	Press to create data privacy passcode (4 figures). When you press **Review**, you need to input the passcode.
Date Format	Select the appropriate date format from the drop-down list.
Time Format	Select the appropriate time format from the drop-down list.
System Date	Set the appropriate date.
System Time	Set the appropriate time.

It is the institution's responsibility to remember the screen lock passcode. Otherwise, you can not unlock the system. **GE is NOT responsible for the passcode**.

It is the institution's responsibility to remember the data privacy passcode. Otherwise, you can not review, backup, restore or delete the patient information. **GE is NOT responsible for the passcode**.

Settings

Common

Common tab of the Settings screen allows you to specify parameters for the following:

- Video Length in Seconds
- 2nd ID
- Live Text Enable
- Image Store Area
- Live Scan Save
- Split Layout
- Brightness
- Lock Scanner After (minutes)

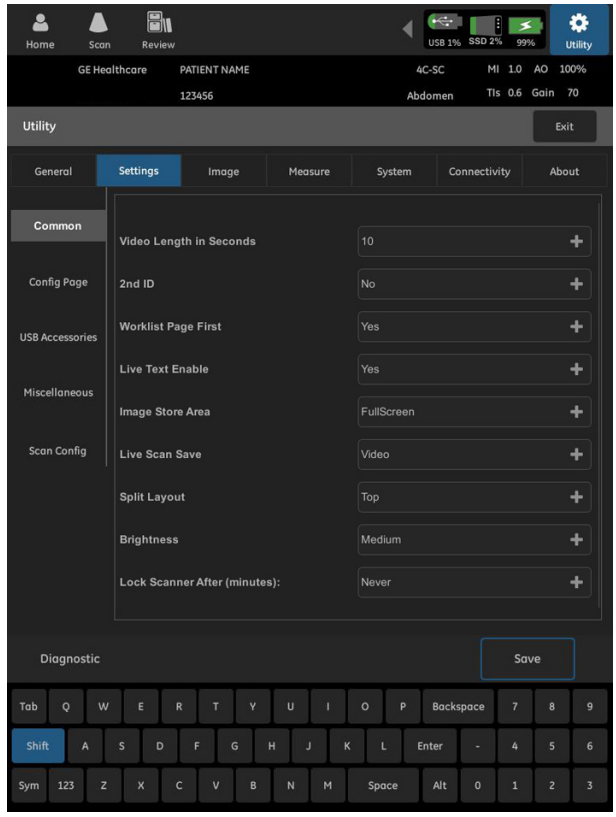


Figure 4-2. Settings - Common

Table 4-2: Setting - Common Parameters

Preset Parameter	Description
Video length in seconds	Select the length of video storage.
2nd ID	Select Yes to enable 2nd ID field in patient screen.
Worklist Page First	Select Yes to enable worklist page to show immediately when pressing **Home**.
Live Text Enable	Select Yes to enable text to be shown in live scanning mode.
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.
Split Layout	Configure the layout of the split screen.
Brightness	Select the brightness degree from the drop-down list.
Lock Scanner After (minutes)	Select the time options to lock the scanner. Note: You may also lock the screen by pressing Power button, then press **Lock Screen**. To unlock the system, please slide to unlock.

Configure Page

Configure Page tab of the Settings screen allows you to activate or deactivate the functions as follows:

- TGC
- M Mode
- Needle
- Split
- Zoom
- Guide
- eSmart Trainer
- Bodymark
- Measure
- Comment

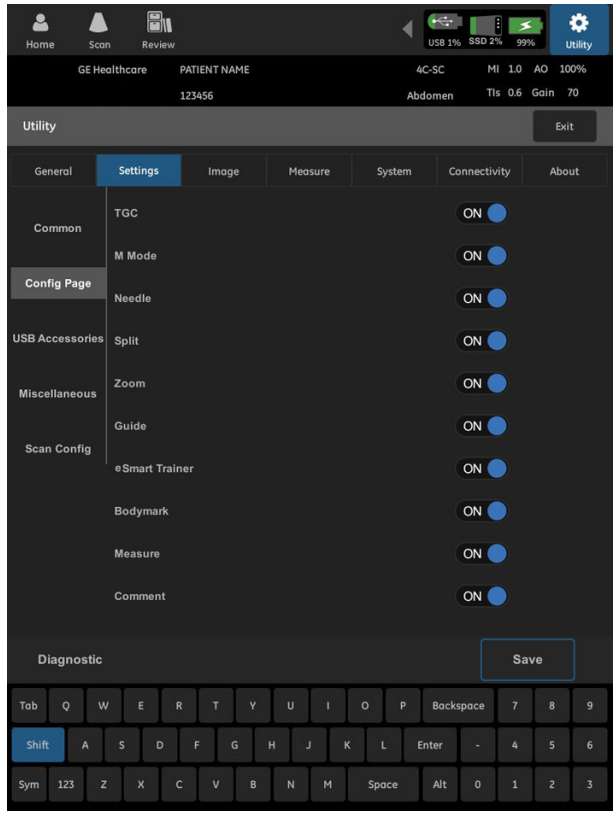


Figure 4-3. Settings - Configure

NOTE: Only the activated function will be shown on the scanning screen.

USB Accessories

USB Accessories tab of the Settings screen allows you to configure the items as follows:

Footswitch:

- Left key
- Middle key
- Right key

Barcode:

- Barcode
- ReadTo

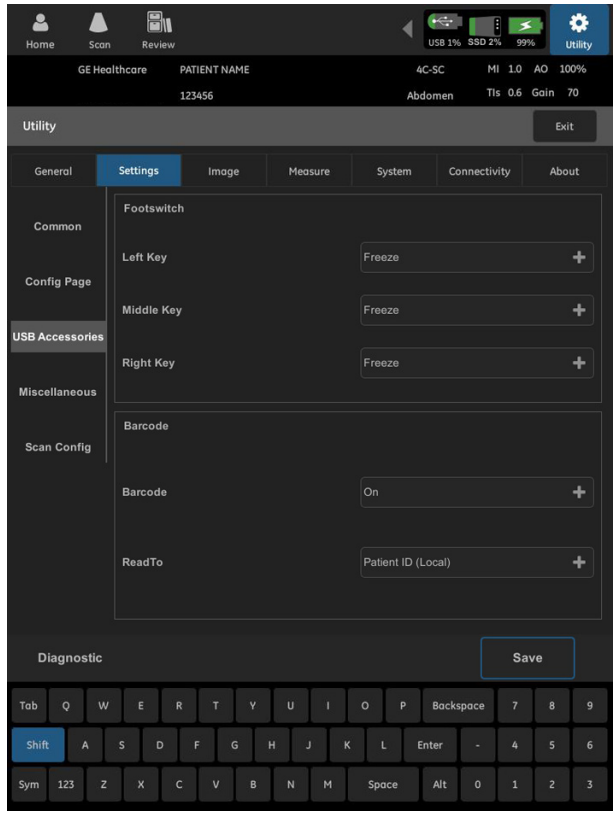


Figure 4-4. Settings - USB Accessories

Table 4-3: Setting-Footswitch Parameters

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

Table 4-4: Barcode Parameters

Preset Parameter	Description
Barcode	Select On or Off to activate or deactivate the barcode reader.
ReadTo	Select the barcode read information.

Miscellaneous

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

Volume:

- Venue 50 speaker

Trainer Setting

- Available Trainer

Storage:

- Storage Location

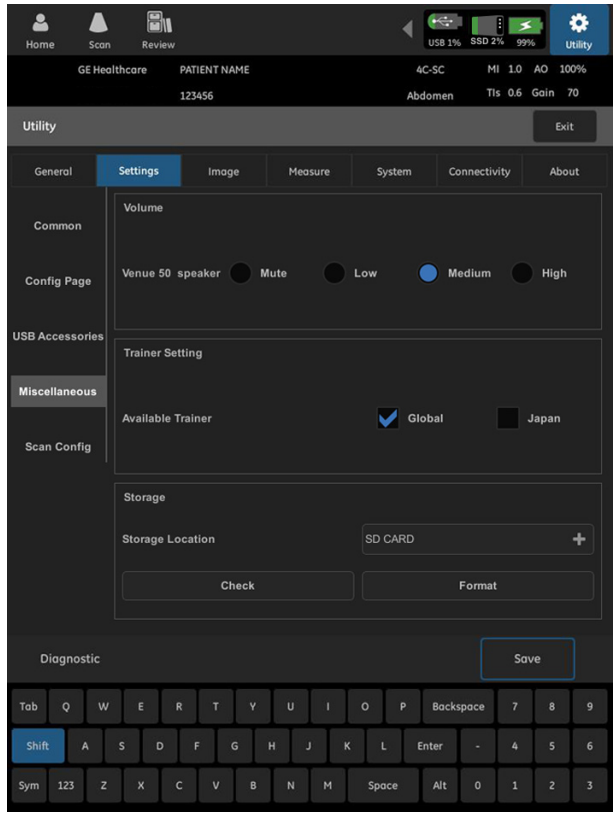


Figure 4-5. Settings - Miscellaneous

Table 4-5: Setting - Miscellaneous Parameters

Preset Parameter	Description
Venue 50 Speaker	Select Mute, Low, Medium or High for Venue 50 speaker volume.
Trainer Setting	Choose the desired eSmart Trainer region.
Storage Location	View and configure storage location.
Check	Select to check and restore current storage device.
Format	Select to format current storage device.

Scan Configuration

Scan Configuration tab of the Settings screen allows you to specify parameters for the following:

- Available Parameters
- Target Parameters

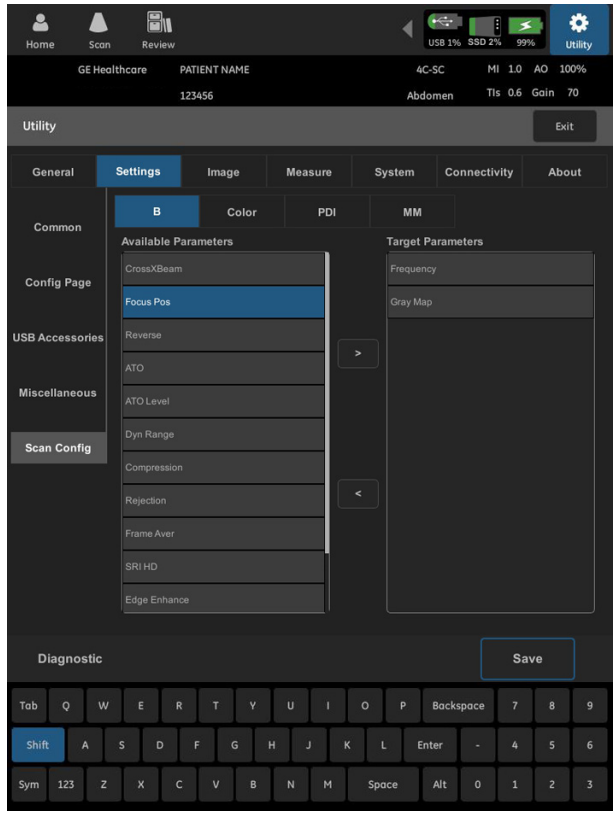


Figure 4-6. Settings - Scan Configuration

Table 4-6: Setting-Scan Configuration Parameters

Preset Parameter	Description
Available Parameters	The available image parameters for current mode.
Target Parameters	The selected image parameters shown on the scanning screen. (Maximum of 3 parameters)

NOTE: Different probes and modes will have different available parameters.

Image

Common

The **Common** screen allows you to configure the items as follows:

- Thermal Name
  - TIC
  - TIS
  - TIB
- Image
  - Auto Zoom
  - Image Style
  - LCD Tint

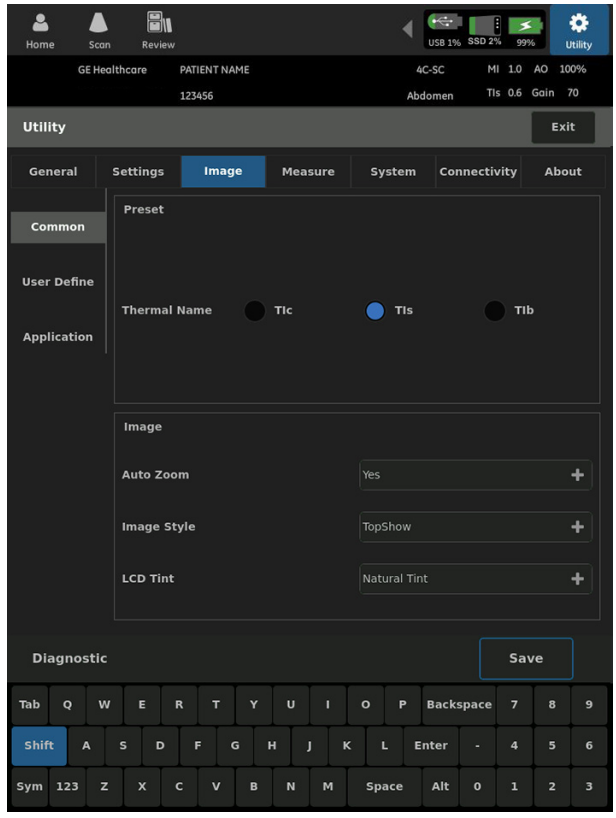


Figure 4-7. Image - Common

Table 4-7: Image - Common settings

Preset Parameter	Description
Thermal Name	Select TIc, TIs, or TIb. • TIc: Used when bone is near the skin surface as in transcranial examination. • TIs: Used when imaging soft tissue only. • TIb: Used when bone is near the focus of the image as in the third trimester OB examination.
Auto Zoom	Select Yes or No to automatically zoom the images or not. It is only available for image depth < 2cm.
Image Style	Select Top or Center to show the image layout.
LCD Tint	Select Natural Tint, Yellow Tint or Blue Tint from the drop-down list to show the preferred image display tint.

User Define

User Define tab of the Settings screen allows you to specify parameters for the following:

- Depth
- B Mode Parameters
- Color Flow Mode Parameters
- PDI Mode Parameters
- M Mode Parameters
- Create New/Overwrite

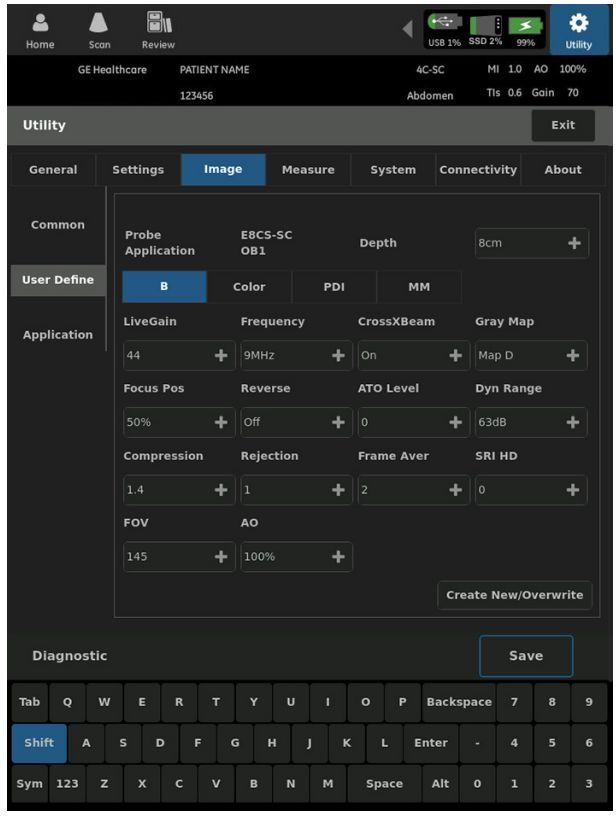


Figure 4-8. Image - User Define

NOTE: When performing an exam with the factory default preset, you may modify and save the scanning parameter values. If you switch to another preset and switch back to the modified one, the parameter values will be restored to the factory default.

User Define (continued)

Create New/Overwrite

Create New/Overwrite allows you to configure your favorite presets.

1. Configure the parameters.
2. Press **Save**.
3. Press **Create New/Overwrite**.
4. Press the blank box and name your favorite preset with the soft keyboard.

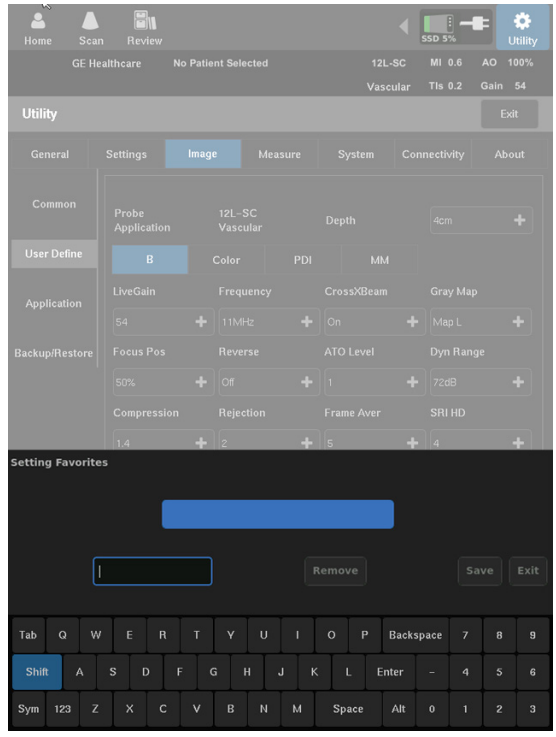


Figure 4-9. UserDefine - Create New

5. Press **Save** to go back to Image screen.

NOTE: All the parameter values in the new preset are available for all depth scanning. You may modify the value while scanning, if needed.

*NOTE: The new preset will be displayed in the **Setting Favorites** after you press **Save**.*

NOTE: You may create a maximum of 10 favorite applications.

Create New/Overwrite (continued)

If you have set your desired preset, it will be displayed under **Utility** -> **Image** -> **Application** -> **Available**.

To overwrite the favorite preset:

1. Configure the parameters.
2. Press **Save**.
3. Press **Create New/Overwrite**.
4. Select the appropriate tab to be overwritten.
5. Press **Overwrite**.

The new preset will overwrite the original one.

To delete the favorite preset:

1. Press **Create New/Overwrite**.
2. Select the appropriate tab to be deleted.
3. Press **Remove** the remove the preset.
4. Press **Save**.

Application

The **Application** screen allows you to configure the items as follows:

- Probe
- Available (application)
- Favorite (application)
- Default (application)

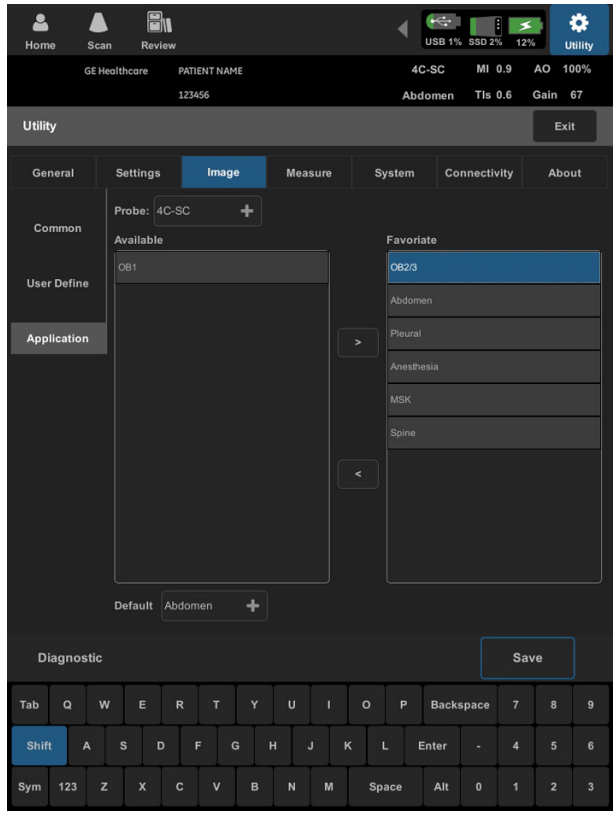


Figure 4-10. Image - Application

Table 4-8: Image - Application settings

Preset Parameter	Description
Probe	Select the available probe.
Available/Favorite	Choose the available application to the favorite or vise verse.
Default	Choose the desired application as the default one for the probe.

Measure

The Measure screen lists measurement configurations.

Obstetrics

The **Obstetrics** tab shows the OB measurement settings of the Venue 50:

- OB Type
- EFW Format
- OB Table
- CUA/AUA

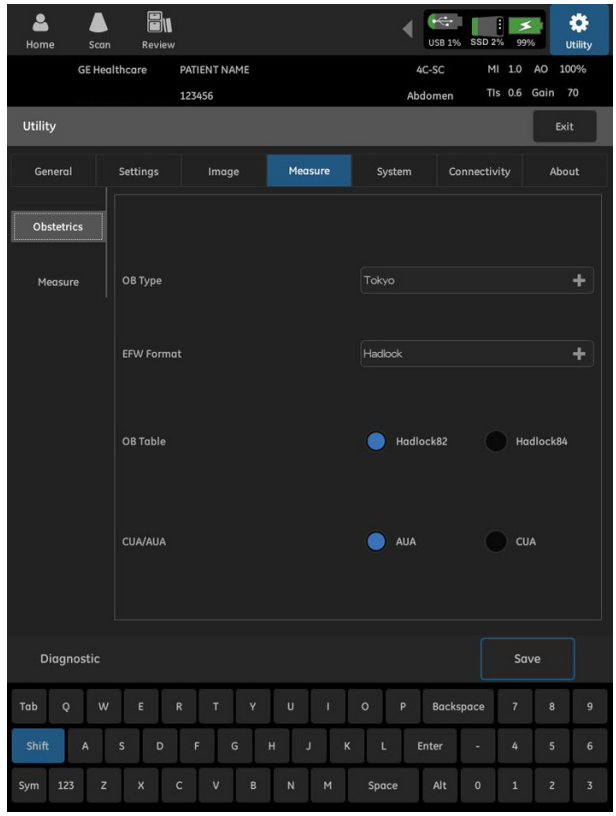


Figure 4-11. Measure - Obstetrics

Table 4-9: 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.
CUA/AUA	Select the ultrasound age calculation method in this field. CUA: Composite Ultrasound Age, regression calculation; AUA: Average Ultrasound Age, an arithmetic average.

Measure

The **Measure** tab shows the configuration of measurement:

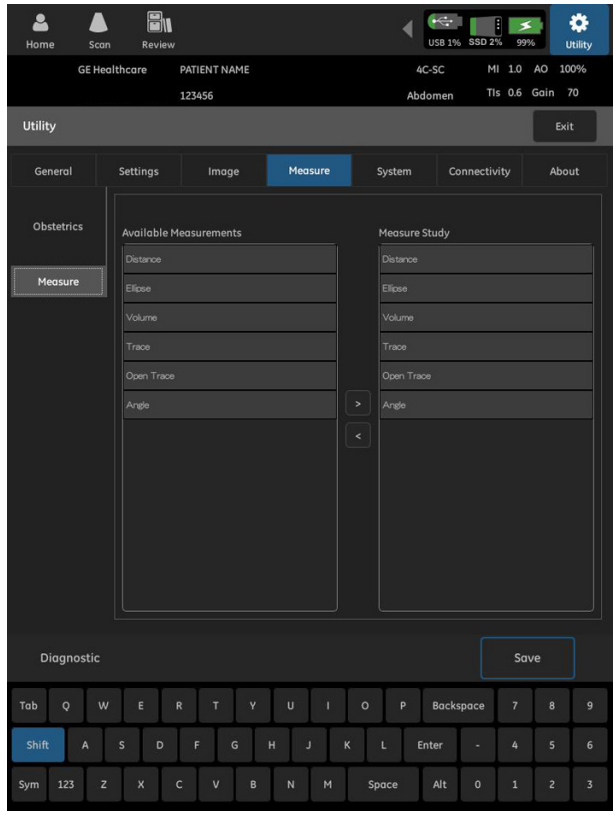


Figure 4-12. Measure - Measure

Table 4-10: Measure settings

Available Measurements	The available measurements for current measurement application.
Measure Study	The selected measurements (maximum of 12 measurements).

System

The **System** screen lists system information.

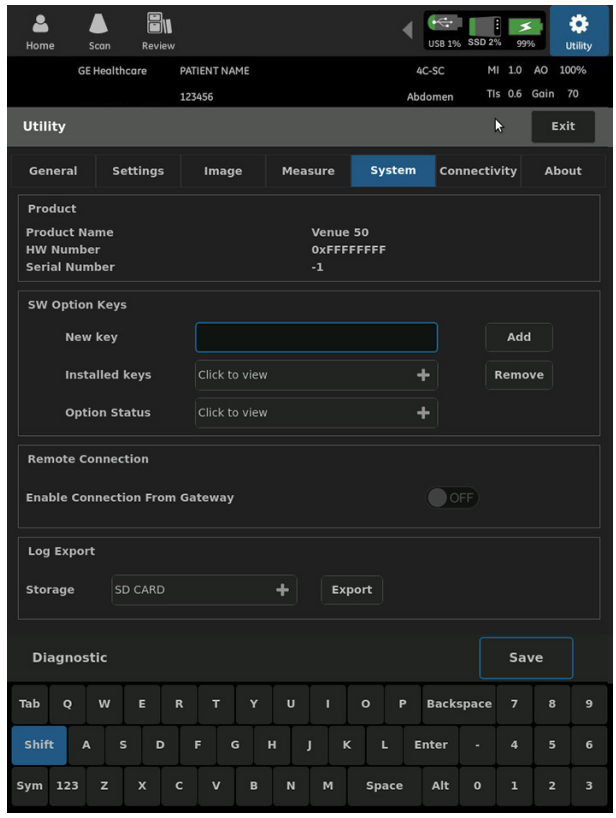


Figure 4-13. Utility - System

Table 4-11: 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 4-12: SW Option Parameters

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

Table 4-13: Remote Connection

Preset Parameter	Description
Enable Connection From Gateway	Turn on/off to connect/disconnect Gateway. Note: The default Gateway connection is off.

Table 4-14: Log Export

Preset Parameter	Description
Storage	Press to choose the storage device.
Export	Press to export the log to the storage device.

Connectivity

The **Connectivity** screen lists connectivity configurations.

TCP/IP

The TCP/IP screen shows the IP status of the Venue 50:

- IP Address
- Subnet Mask
- Default Gateway

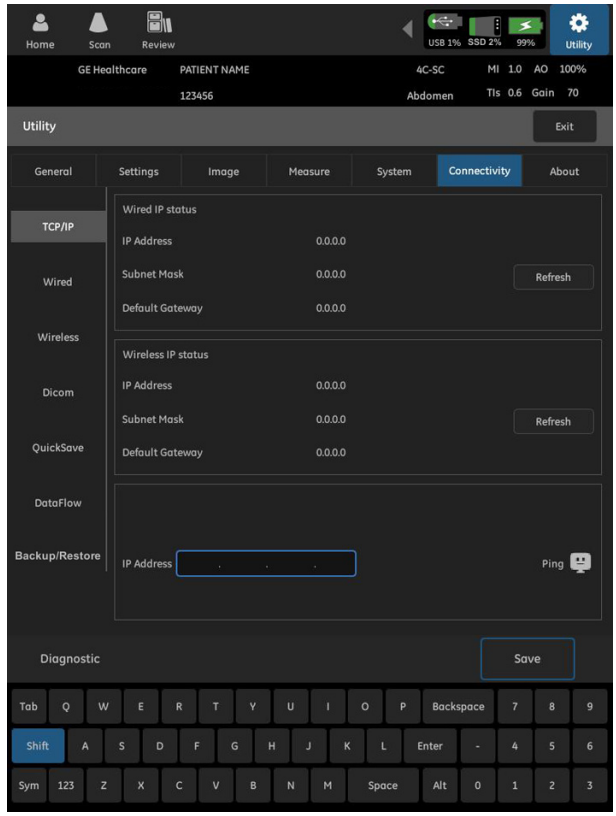


Figure 4-14. Connectivity - TCP/IP

Table 4-15: IP settings

Preset Parameter	Description
IP Address	Type the IP Address.
Subnet Mask	Type the subnet mask address.
Default Gateway	Type the default gateway address.

Wired

The **Wired** screen shows the configuration of wired network:

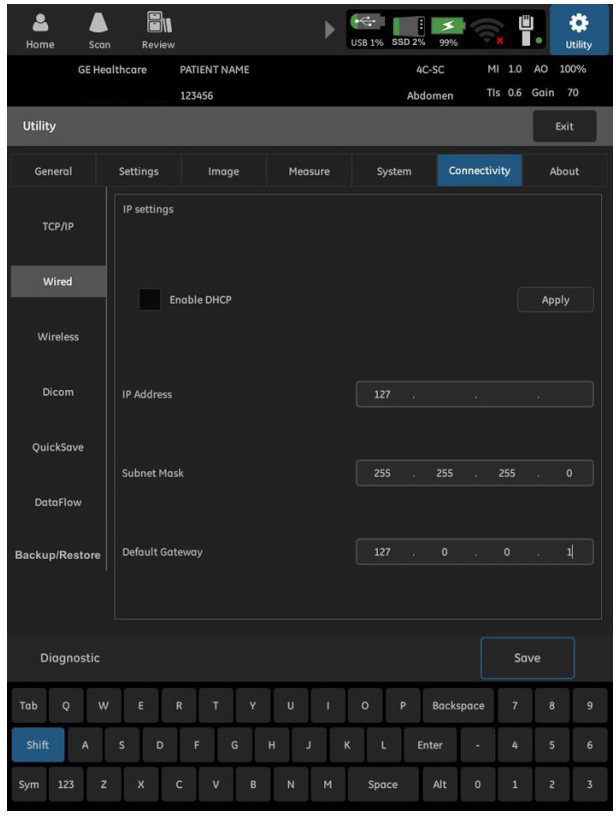


Figure 4-15. Connectivity - Wired

Table 4-16: Wired settings

Preset Parameter	Description
Enable DHCP	Select to enable dynamic IP Address selection.

Wireless

The **Wireless** screen shows the configuration of wireless network:

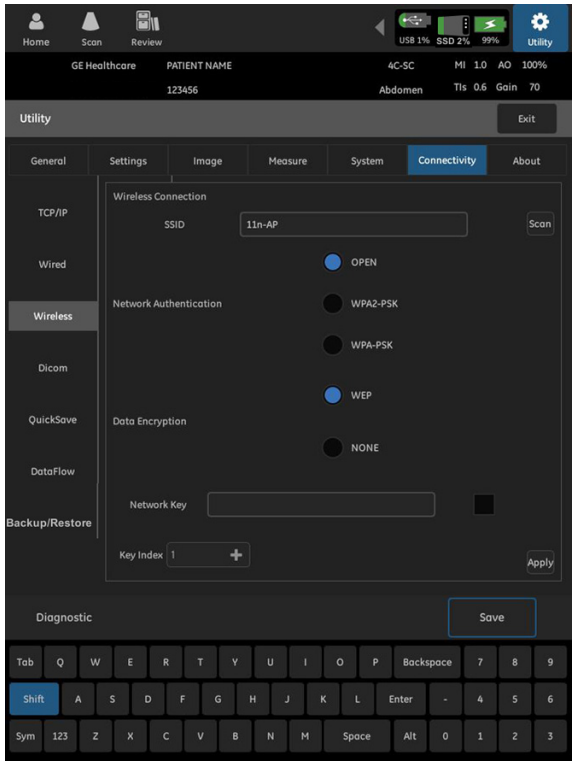


Figure 4-16. Connectivity - Wireless

Table 4-17: Wireless Connection

Preset Parameter	Description
SSID	Select Scan, the list of the available wireless network displays. Select the wireless network that needs to be connected.
Network Authentication	Select OPEN, WPA2-PSK or WPA-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 or WPA-PSK.
Network Key	Type the Network Key.
Key Index	Select 1 to 4 from the drop-down menu for Key Index. NOTE: It is available only when the Network Authentication is OPEN and the Data Encryption is WEP.

DICOM

The **DICOM** screen shows the configuration of DICOM:

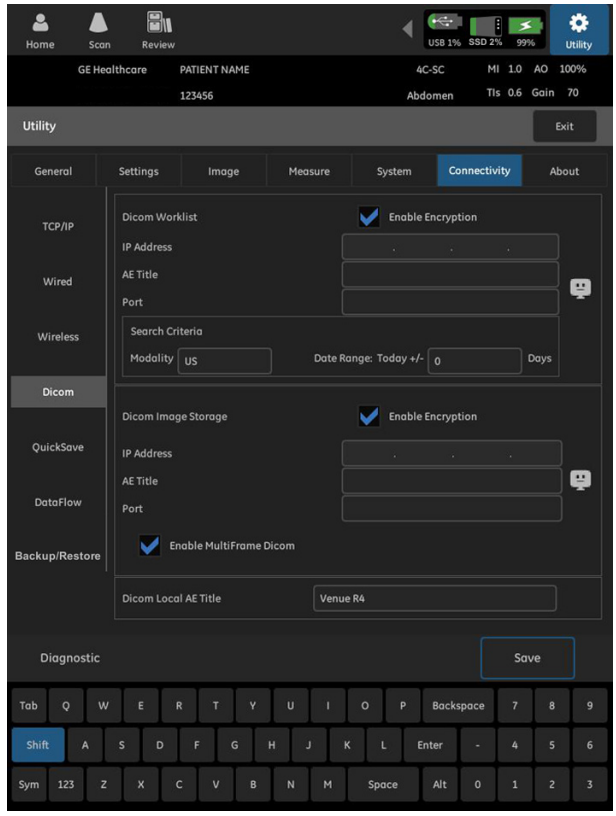


Figure 4-17. Connectivity - DICOM

Table 4-18: 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.

Table 4-19: DICOM Search Criteria settings

Preset Parameter	Description
Modality	Type the exam modality.
Data Range	Type the date range.

Table 4-19: DICOM Search Criteria settings

Preset Parameter	Description
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.	

Table 4-20: 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.
Enable MultiFrame DICOM	Select to enable multiframe DICOM.

Table 4-21: DICOM Local AE Title

Preset Parameter	Description
DICOM local AE Title	Type the local DICOM called AE Title.

QuickSave

The **QuickSave** screen shows the configuration of QuickSave:

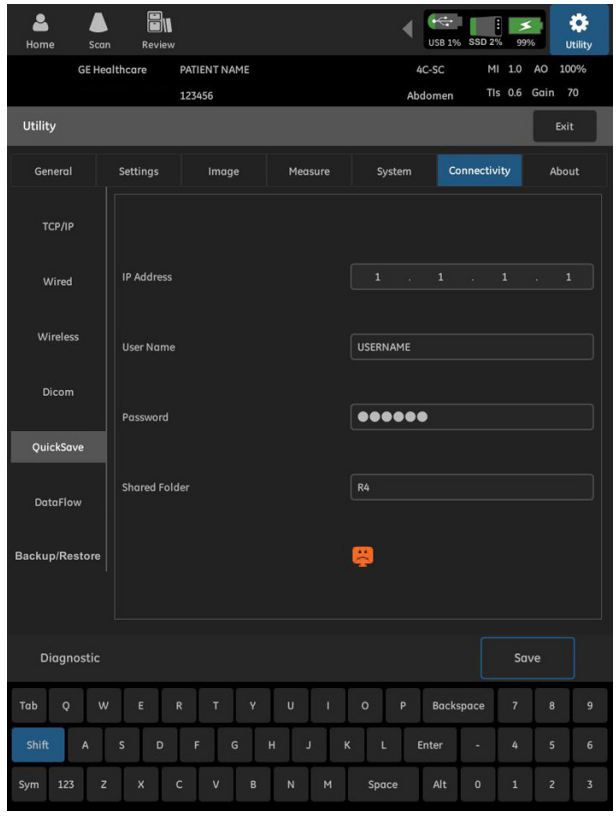


Figure 4-18. Connectivity - QuickSave

Table 4-22: 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.

DataFlow

The **DataFlow** screen shows the configuration of D1 and D2:

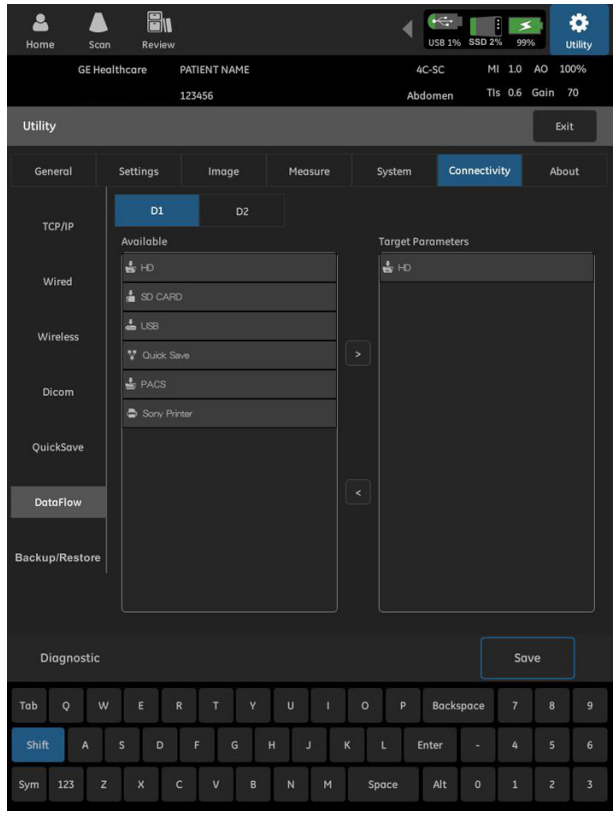


Figure 4-19. Connectivity - DataFlow

Table 4-23: Measure settings

D1, D2	DataFlow button to be configured.
Available parameters	The available storage media.
Target parameters	The selected storage media.

Backup/Restore

The **Backup/Restore** screen allows you to configure the items as follows:

- Storage
- Backup/Restore
  - Patient data/images/videos
  - User defined presets
  - Configuration settings
  - Backup
  - Restore
  - Delete
- Backup remind interval

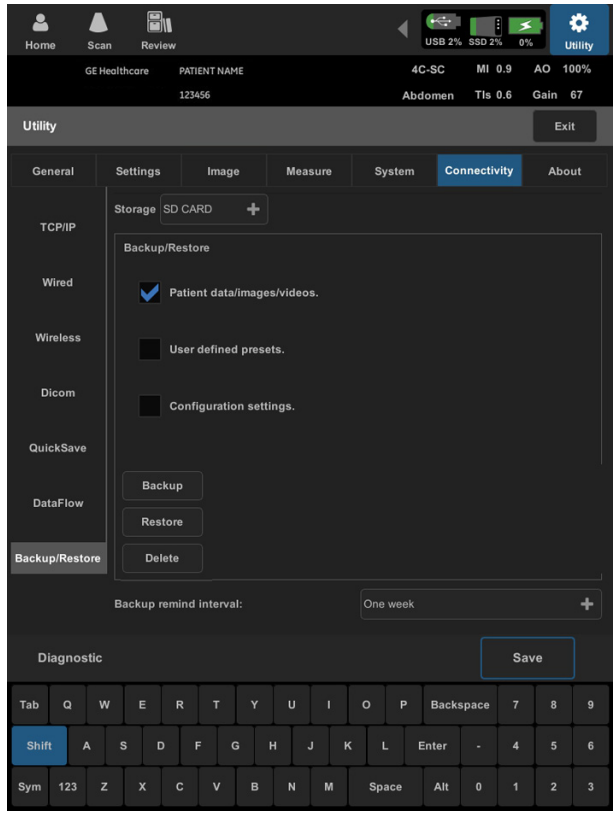


Figure 4-20. Connectivity - Backup/Restore

Backup/Restore (continued)

Table 4-24: Image - Backup/Restore settings

Preset Parameter	Description
Storage	Select the available storage device.
Backup	Backup the Patient data/images/videos, User defined presets or Configuration settings from HDD to the selected storage device.
Restore	Restore the Patient data/images/videos, User defined presets or Configuration settings from the selected storage device to the HDD.
Delete	Delete the Patient data/images/videos, User defined presets or Configuration settings from the HDD.
Backup remind interval	Choose One day, One week or One month from the menu.

NOTE: If you have set the data privacy passcode, you need to input the passcode to backup, restore or delete the information.

CAUTION

It is the institution's responsibility to remember the data privacy passcode. Otherwise, you can not review, backup, restore or delete the information. **GE will NOT aid in the recovery of the information**.

About

The **About** screen allows you to view software version, hardware versions and the system patents.

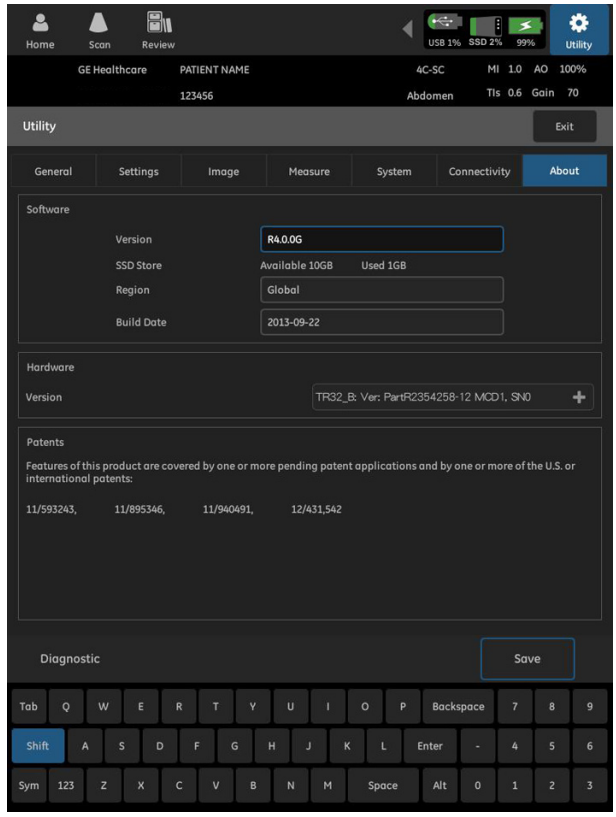


Figure 4-21. Utility - About

Table 4-25: Software version Parameters

Preset Parameter	Description
Version	View software version.
SSD Store	View the SSD available and used storage capacity.
Region	Region of the preset.
Build Date	View software build date.

Table 4-26: Hardware version Parameters

Preset Parameter	Description
Version	View hardware version of main boards.

Chapter 5

Probes and Biopsy

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

Probe Overview

Ergonomics

Probes have been ergonomically designed to:

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

Cables have been designed to:

- Connect to system with appropriate cable length

Cable handling

Take the following precautions with probe cables:

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

Probe orientation

Each probe is provided with an orientation marking. This mark is used to identify the end of the probe corresponding to the side of the image having the orientation mark on the display.

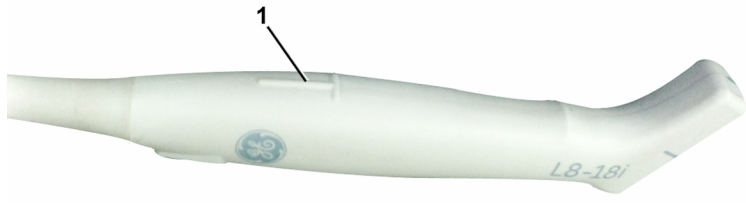


Figure 5-1. Orientation Marking on Probe (Example)

1. Orientation Mark

Labeling

Each probe is labeled with the following information:

- Seller's name and manufacturer
- GE part number
- Probe serial number
- Month and year of manufacture
- Probe designation-provided on the probe grip and the top of the connector housing, so it is easily read when mounted on the system and is also automatically displayed on the screen when the probe is selected.

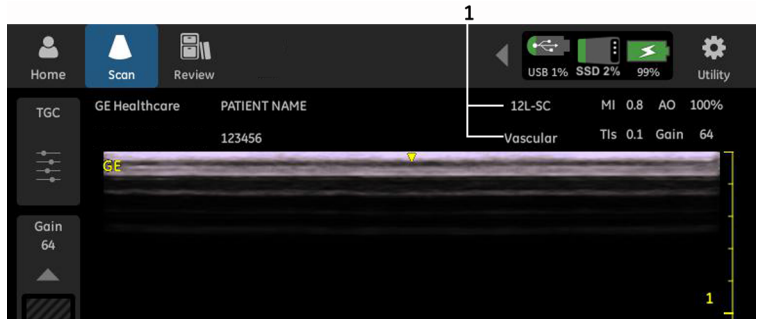


Figure 5-2. Displayed Probe Information

1. Probe Information Location

Probe Naming Conventions

Table 5-1: Probe Naming Convention

Type	Frequency	Connector Type
C=Convex L=Linear S=Sector	“12” in probe “12L-SC”	SC

Probe Usage

For details on connecting, activating, deactivating, disconnecting, transporting and storing the probes, See ‘Probes’ on *page 2-36 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 5-2: Probe Environmental Requirements

	Operational	Storage	Transport
Temperature	3 - 40°C 37 - 104°F	-5 - 50°C 23 - 122°F	-5 - 50°C 23 - 122°F
Humidity	30 - 80% non-condensing	10 - 90% non-condensing	10 - 90% non-condensing
Pressure	700 - 1060hPa	700 - 1060hPa	700 - 1060hPa

Probe Safety

Handling precautions


WARNING

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

Electrical shock hazard


Electrical Hazard

The probe is driven with electrical energy that can injure the patient or operator 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 ‘Preparing for a Biopsy’ on *page 5-25* 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.

Endocavitary Probe Handling Precautions

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

Sterilant Exposure to Patient (e.g., Cidex)—Contact with a sterilant to the patient's skin or mucous membrane may cause an inflammation. If this happens, refer to the sterilant's instruction manual.

Sterilant Exposure from Probe Handle/Connector to Patient (e.g., Cidex)—DO NOT allow the sterilant to contact the patient. Only immerse the probe to its specified level. Ensure that no solution has entered the probe's handle before scanning the patient. If sterilant comes into contact with the patient, refer to the sterilant's instruction manual.

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

Probe handling and infection control

This information is intended to increase operator 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 operator.

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 operator to verify and maintain the effectiveness of the infection control procedures in use. Always use sterile, legally marketed probe sheaths for intra-cavitary and intra-operative procedures.

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

Probe Cleaning Process

Cleaning Probes

To clean the probe:

NOTE: Do not immerse the probe into any liquid beyond the level specified for that probe (See Figure 5-3 on page 5-12 for more information.). Never immerse the transducer connector into any liquid.

1. Inspect the probe's lens, cable, casing, and connector for cracks, cuts, tears, and other signs of physical damage.
2. Disconnect the probe from the ultrasound console. Remove all coupling gel from the probe by wiping with a soft cloth and rinsing with flowing water.

NOTE: DO NOT wipe the probe with a dry cloth.

3. Soak the probe head in water. Scrub the probe as needed using a soft sponge, gauze, or cloth to remove all visible residue from the probe surface.

CAUTION

Take extra care when handling the lens face of the ultrasound transducer. The lens face is especially sensitive and can easily be damaged by rough handling. **NEVER** use excessive force when cleaning the lens face.

4. Rinse the probe with enough clean, potable water.
5. Air dry or dry with a soft cloth.
6. After cleaning, inspect the probe's lens, cable, casing and connector. Look for any damage that would allow liquid to enter the probe. Also, inspect the probe functionality by live scan. If any damage is found, do not use the probe until it has been inspected and repaired/replaced by a GE service representative.

Cleaning Probes (continued)

Figure 5-3. Probe Immersion Levels

1. Fluid Level

Disinfecting probes

Perform After Each Use

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

Table 5-3: Description of Pictogram on Care Card

Pictogram	Description
	“ATTENTION” - Consult accompanying documents is intended to alert the operator 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/operator 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, strictly observe the specified immersing time by the germicide manufacturer. Do not immerse the probe in liquid chemical germicides more than the time prescribed in the care card.
	“Consult accompany document” - Refer to the ultrasound system user manual for important probe care and cleaning instruction.

Disinfecting probes (continued)

Review the probe care card that is packed with each probe. For the GE approved probe disinfectants, please refer to the probe care card.

http://www3.gehealthcare.com/Products/Categories/Ultrasound/Ultrasound_Probes#cleaning

In order for liquid chemical germicides to be effective, all visible residue must be removed during the cleaning process. As described earlier before attempting disinfection, thoroughly clean the probe.

You **MUST** disconnect the probe from the Venue 50 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).

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)

CREUTZFIELD-JACOB DISEASE

Neurological use on patients with this disease must be avoided. If a probe becomes contaminated, there is no adequate way to disinfect the probe.

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. 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. Please refer to the probe care card for GE approved probe gels.

Applying

In order to assure optimal transmission of energy between the patient and probe, a conductive gel or couplant must be applied liberally to the patient where scanning will be performed.

Do not apply gel to the eyes. If there is gel contact to the eye, flush eye thoroughly with water.

Precautions

Coupling gels should not contain the following ingredients as they are known to cause probe damage:

- Methanol, ethanol, isopropanol, or any other alcohol-based product
- Mineral oil
- Iodine
- Lotions
- Lanolin
- Aloe Vera
- Olive Oil
- Methyl or Ethyl Parabens (para hydroxybenzoic acid)
- Dimethylsilicone
- Polyether glycol based
- Petroleum

Sterile Ultrasound Procedures

ONLY ultrasound gel that is labeled as sterile, is sterile.

Ensure you always use sterile ultrasound gel for those procedures that require sterile ultrasound gel.

Once a container of sterile ultrasound gel is opened, it is no longer sterile and contamination during subsequent use is possible.

Planned Maintenance

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

Table 5-4: Planned Maintenance Program

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

Returning/Shipping Probes and Repair Parts

US Department of Transportation and GE 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 50 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".
- **Phased Array Sector.** Phased Array Sector probes are designated by the prefix/suffix "S".

Probe Applications

Table 5-5: Probe Indications for Use

Probe Application	3S-SC	12L-SC	4C-SC	L8-18i-SC	E8CS-SC	10C-SC
Peripheral Vascular		x		x		
Fetal/OB	x		x		x	
Abdominal (GYN & Urology)	x	x	x	x	x	x
Pediatric	x	x	x	x		x
Small Organ (breast, testes, thyroid)		x		x		x
Neonatal Cephalic	x	x		x		x
Adult Cephalic	x					
Cardiac (adult & pediatric)	x					
Conventional Musculoskeletal	x	x	x	x		
Superficial Musculoskeletal		x		x		x
Thoracic/Pleural	x	x	x	x		x
Intraoperative (abdominal, thoracic and peripheral)	x	x	x	x		x
Transvaginal					x	
Ophthalmic	x	x				x
Tissue Biopsy/ Fluid Drainage	x	x	x	x	x	
Vascular Access		x		x		
Nonvascular		x	x	x		

NOTE: Ophthalmic is not available for Japan.

Probe Specifications

Table 5-6: 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
10C-SC	8.0 ± 20%	5.0	4.0

Probe Slice Thickness Specifications

Table 5-7: System Probe Definitions

Probe	Slice Thickness
3S-SC	<=10mm
12L-SC	<=8mm
4C-SC	<=8mm
L8-18i-SC	<=8mm
E8CS-SC	<=13mm
10C-SC	<=13mm

Probe Illustration

Table 5-8: Sector Probes

Probe	Illustration
3S-SC	

Table 5-9: Linear Array Probes

Probe	Illustration	Probe	Illustration
12L-SC		L8-18i-SC	

Table 5-10: Curved Array (Convex) Probes

Probe	Illustration	Probe	Illustration
4C-SC		10C-SC	
E8CS-SC			

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 operator 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, 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 5-6 for more information.*

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

Preparing for a Biopsy

Displaying the Guidezone

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

The available biopsy options appear when Biopsy Kit is selected. There are fixed and adjustable angle biopsy kits available with the Venue 50 depending on the probe. Select the desired biopsy kit.

Displaying the Guidezone (continued)

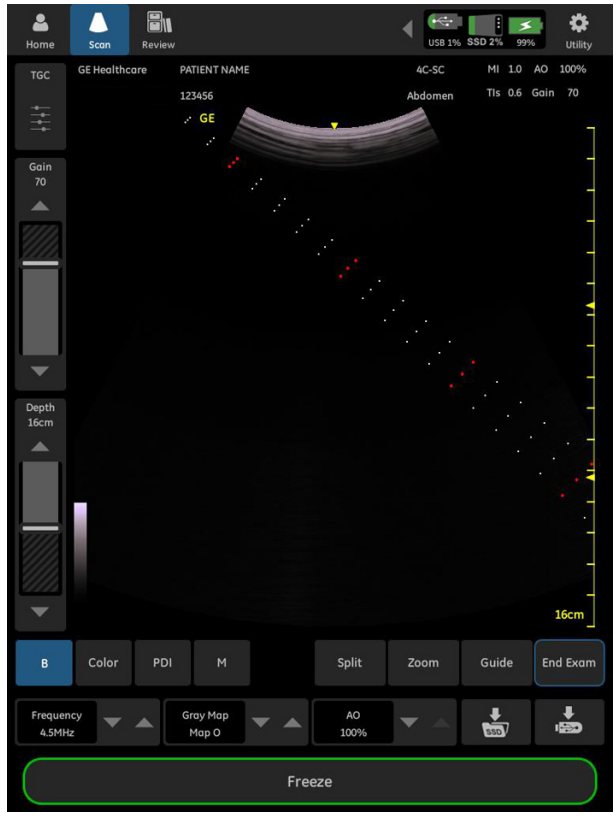


Figure 5-4. Biopsy Guidezones

The biopsy guidezone represents a path of the needle. The dots which make up the guidezones indicates the depth readout where:

- White represents 1 cm increments.
- Red represents 5 cm increments.

The display should be carefully monitored during a biopsy for any needle deviation from the center line or guidezone.

Before scanning, verify the needle can be visualized within the imaging plane. Use the appropriate needle to reach target area.

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 5-11: Biopsy Guide Availability

Probe	Fixed Angle	Multi-Angle		
		MBX1	MBX2	MBX3
3S-SC		4.0cm	5.5cm	8.0cm
12L-SC		1.5cm	2.5cm	3.5cm
4C-SC		4.1cm	6.07cm	10.05cm
E8CS-SC	15.3 (TR5) 15200 (reusable)			

DANGER

Failure to match the guidezone displayed to the guide may cause the needle to track a path outside the zone.

It is extremely important that when using the adjustable angle biopsy guides, the angle displayed on the screen matches the angle set on the guide. Otherwise, the needle will not follow the displayed guidezone which could result in repeated biopsies or patient injury.

Preparing the Biopsy Guide Attachment

Convex, Sector and Linear probes have optional biopsy guide attachments for each probe. The guide consists of a non-disposable bracket to attach to the probe, and a disposable needle clip to attach to the bracket, sheath, gel (sterile gel if necessary) and disposable needle barrels.

The disposable needle barrels are available for a variety of needle sizes.

Please refer to the manufacturer's instructions included in the biopsy kit.

The bracket is packaged non-sterile and is reusable. To avoid possible patient contamination, ensure bracket is properly cleaned, sterilized or disinfected before each use.

Disposable components are packaged sterile and are single-use only. Do not use if integrity of packing is violated or if expiration date has passed.

Fixed Needle Biopsy Guide Assembly


WARNING

DO NOT use the needle with the catheter (soft tube). There is a possibility of breaking the catheter in the body.


CAUTION

Before inserting the needle, scan the patient to determine the correct puncture depth and site. Only the sterile/sanitary sheath, sterile gel and rubber band are on the probe during the pre-needle placement scanning.

Preparation

To prepare the endocavitary probe for use:

1. Remove the probe from the box and carefully examine it for any damage.
2. Clean, then disinfect the probe.

NOTE: Ensure that protective gloves are worn.

Installing the sheath

To install the sheath:

1. Remove the sheath from the package. Do not unroll the sheath.

NOTE: Remember to rinse all sanitary probe sheaths of powder before placing on the probe. Powder can degrade the displayed image.

2. Place an adequate amount of ultrasound gel inside the sheath tip (the gel is between the sheath inner surface and the probe aperture).

NOTE: Ensure that only acoustic coupling gel is used for this purpose.

3. Place the sheath tip over the probe aperture and then pull the sheath end toward the probe handle.
4. Inspect the sheath for nicks, cuts or tears.

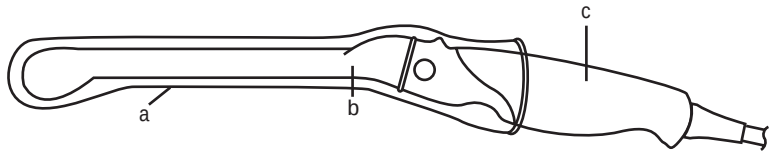


Figure 5-5. Endocavitary Probe with Sheath

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

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

Endocavitary Probe Biopsy Guide Preparation

1. If a biopsy is to be performed, snap the metal or plastic biopsy guide on to the probe over the sheath.

CAUTION

Patient injury or repeated biopsies may result. The needle placement will not be as intended if the needle guide is not properly seated and secure.

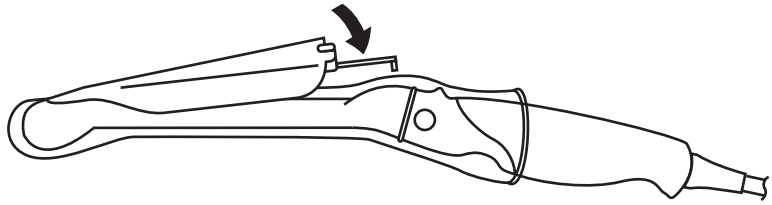


Figure 5-6. Disposable Biopsy Guide 5 degree Angle

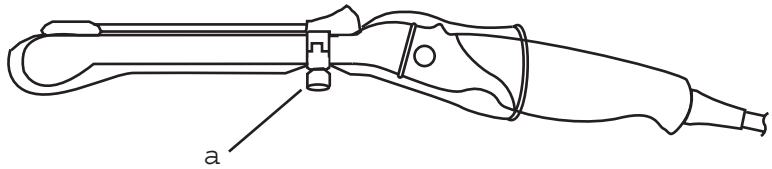


Figure 5-7. Reusable Biopsy Guide

a. Fix with a screw

2. Place an adequate amount of ultrasound gel on the gel-filled sheath tip's outer surface.
3. Ensure the guide is properly seated and secure by pushing forward on the needle insertion end of the guide until the attachment node is firmly in place in its hole.

Multi Angle Biopsy Guide Assembly

WARNING

DO NOT attempt to use the biopsy bracket and needle guide until the manufacturer's instructions, provided with the biopsy bracket and needle guide in the kit, have been read and thoroughly understood.

1. Scan the patient and identify the target for biopsy. Move the probe to locate the target to the center of the image. Enable the system biopsy guidezone and try guidezone angles MBX1 to MBX3 to decide the best angle setting for needle path.

Figure 5-8. Example

2. Pull up on the knob (Figure 5-9 a) to freely move the needle guide attachment. Align the knob with the selected position of the needle guide attachment.

   Push the knob down (Figure 5-9 b) into the desired slot to secure the angle position of the needle guide attachment.

Figure 5-9. Pull up and push down the knob

Multi Angle Biopsy Guide Assembly (continued)

3. Fit a convex of the biopsy bracket (a) in a concave of the probe (b).

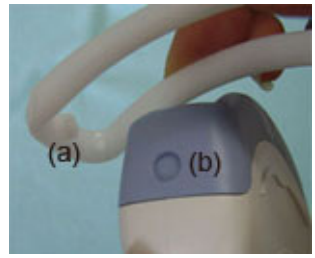


Figure 5-10. Probe/Bracket Alignment

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

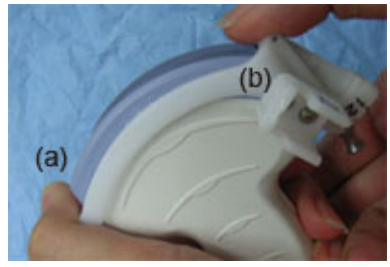


Figure 5-11. Probe/Multi-angle Bracket Alignment 2

4. Place an adequate amount of coupling gel on the face of the probe.

Multi Angle Biopsy Guide Assembly (continued)

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

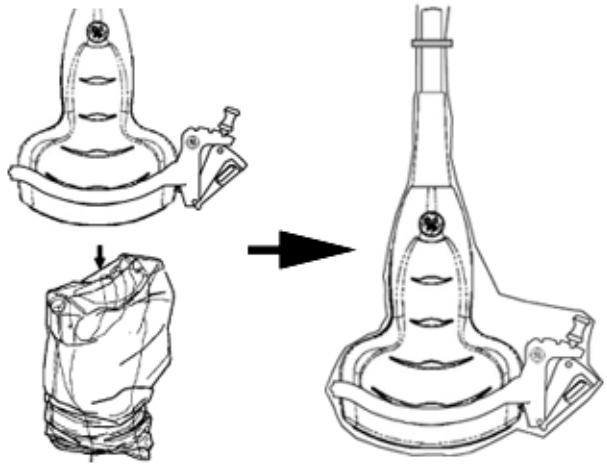


Figure 5-12. Applying Sanitary Sheath

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

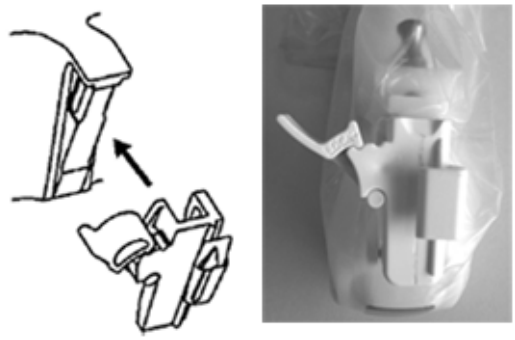


Figure 5-13. Snap the needle guide

Multi Angle Biopsy Guide Assembly (continued)

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

Figure 5-14. Lock the Needle guide

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

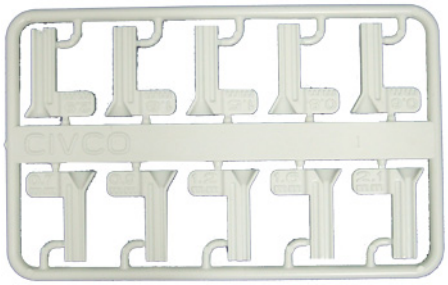


Figure 5-15. Needle Barrel

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

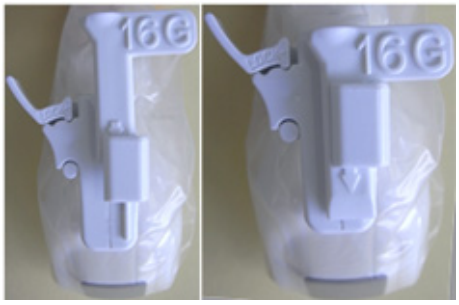


Figure 5-16. Needle Barrel Installation

Multi Angle Biopsy Guide Assembly (continued)

Remove the biopsy guide

1. Hold the other side and push out the needle clip attachment side. See Figure 5-17.

Figure 5-17. Remove the biopsy guide

CAUTION

Avoid finger nail contact with the probe lens to prevent damage.

Releasing the needle

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

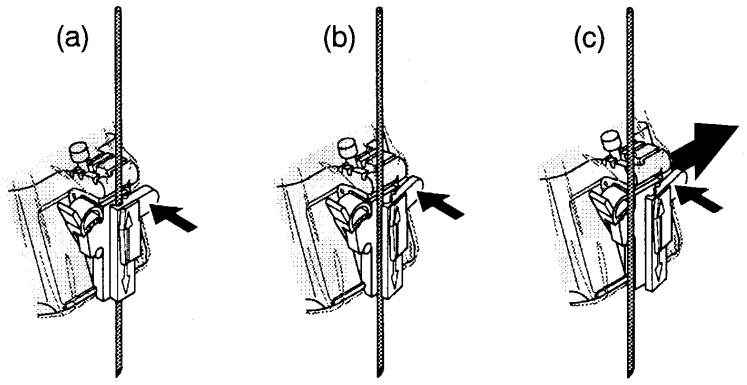


Figure 5-18. Release the needle from assembly

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

Biopsy Needle Path Verification

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

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

The Biopsy Procedure

WARNING Biopsy procedures must only be performed on live images.

CAUTION Before activating the **Guide**, please make sure to select Interventional related preset first.

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.

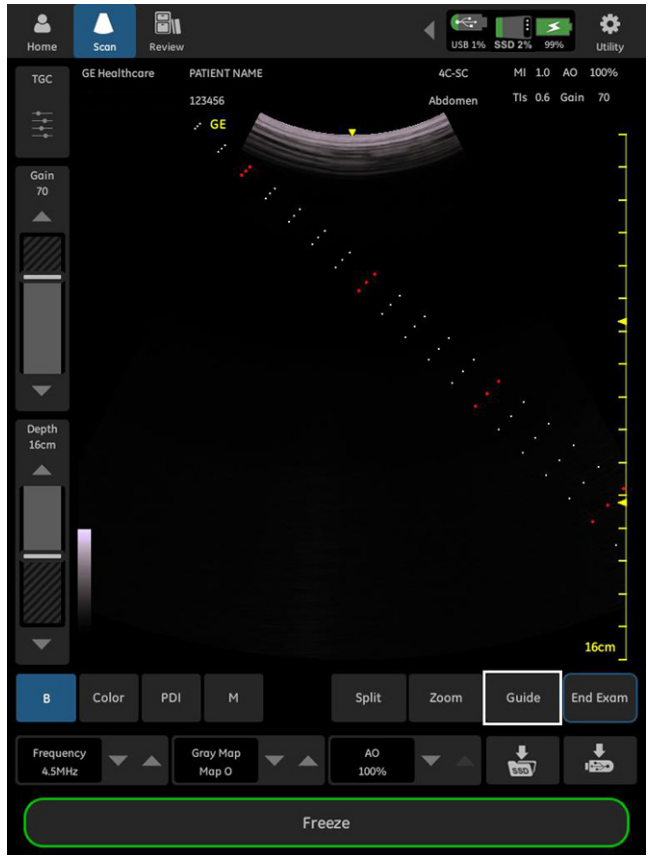


Figure 5-19. Biopsy multi-angle guides

The Biopsy Procedure (continued)

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.

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

Surgery/Intra-operative Use

Preparing for Surgery/Intra-operative Procedures

Preparing the transducer for 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 surgery/intra-operative procedures, a sterile environment is required. Therefore, both the operator and probe need to be sterile.

Preparing for Surgery/Intra-operative Procedures (continued)

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

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

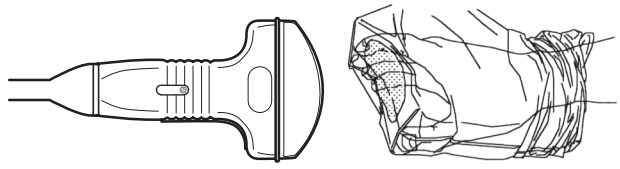


Figure 5-20. Applying Sterile Sheath

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 surgery/ intra-operative procedures for probe cleaning and disinfection.

Chapter 6

User Maintenance

This chapter supplies system data, assistance information, 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: General Specification

Console Dimensions • Height: 282 mm (11.1 in) • Width: 274 mm (10.8 in) • Depth: 56 mm (2.2 in) • Weight: 4.0 kg (8.8 lbs.) with probe Console Electrical Power • Voltage:100-240 V AC • Frequency: 50/60 Hz • Power: Max. 180VA Console Design • Tablet Style • Lithium-ion Battery Pack • Single probe port • Integrated speaker • Docking cart (optional) • Tabletop docking station (optional)	Docking Cart Dimensions • Height: 1152-1442 mm (45.4-56.8 in) • Width: 510mm (20.1 in) • Depth: 480 mm (18.9 in) • Weight: 28.5 kg (62.8 lbs.) Docking Station Dimensions • Height: 375 mm (14.7 in) • Width: 463 mm (18.2 in) • Depth: 243 mm (9.5 in) • Weight: 4.6 kg (10.1 lbs.)

Table 6-2: User Interface

Touch Screen • Multi-touch user-interface with gesture recognition • Mode-specific controls • Alphanumeric Keyboard • Measurement • Annotations • Body marks • Utility settings • Patient information entry	Display Screen • 12.1 in High-Resolution Color LCD • Display: 1024x768 Hard Keys • On/Off button LED • Battery life

Table 6-3: System Overview

Transducer Types • Linear Array • Phased Array • Convex Array Operating Modes • B-Mode • M-Mode • Color Flow Mode (CFM) • Power Doppler Imaging (PDI) • Needle Recognition Standard Features • Automatic Tissue Optimization (ATO) • CrossXBeam™ • Measurement and calculation, editable • Pinch Zoom • Split window • Configurable menu • Standard CINE Memory • Loops storage from memory • Internal solid-state drive (SSD) • Patient data protection • User-define preset Software Options • M-mode • DICOM • OB Package • Needle Recognition • Ophthalmic • eSmart Trainer Hardware Options • Docking Cart • Tabletop Docking Station • Probes • 3-probe port • Extended life battery Media & Peripheral Options • USB thermal B&W printer • USB Memory Stick • SD card • Footswitch • Barcode reader • Wireless card Display Modes • Live image or Stored image • Full size or split screen	Display Annotation • Institution/Hospital Name • Date: MM/DD/YY, DD/MM/YY and YY/MM/DD • Time: configurable 12 or 24 hrs • Patient Name: Last, First • Patient ID: 16 characters • Power Output Readout — MI: Mechanical Index — TIS, TIB, TIC: Thermal Index • System Status (real-time or frozen) • Probe Orientation Marker: Coincides with a probe orientation marking on the probe. • Loop replay • Measurement Results Window • Probe Type • Preset Name • Imaging Parameters by Mode (current mode) — B-mode: Gain, Image Depth, TGC (4 plots), Others (configurable, 3 at most) — M-mode: M Gain, Image Depth, M sample line, TGC (4 plots), Configurable (3 at most) — Color Flow Mode: Color Gain, Image Depth, Color ROI box, TGC (4 plots), Configurable (3 at most) — Power Doppler Imaging Mode: PDI Gain, Image Depth, PDI ROI box, TGC (4 plots), Configurable (3 at most) — Needle Recognition Mode: B Gain, Needle Gain, Beam Angle, Needle Direction, TGC (4 plots) — CINE Mode: Previous Frame, Next Frame, Play/Pause • B Scale Markers: Depth • System Messages Display • Annotation Library: 18-21 preset labels, defined by the application • Customizable annotations: 12 available for each application • Keyboard for free test on screen • Comments available in Live scan mode and Freeze mode • Body marks available for each application • Arrows available in Live scan mode and Freeze mode • Battery status • Biopsy Guide Line and Zone • Configurable user-interface with anatomy specific presets

Table 6-4: System Parameters

System Setup • Factory default application data • Languages setup for UI: English, German, French, Italian, Spanish, Portuguese, Simplified Chinese, Swedish, Norwegian, Danish, Finnish, Greek, Russian, Dutch, Japanese • Languages for Manuals: English, French, Spanish, German, Italian, Portuguese, Japanese, Chinese, Czech, Danish, Dutch, Estonian, Finnish, Greek, Hungarian, Latvian, Lithuanian, Norwegian, Polish, Russian, Slovakian, Swedish, Korean	• Operation Error Message Display • Patient Name Format: Last, First • System Boot Up: <16 sec • Probe Loading: <3 sec

Table 6-5: Imaging Processing and Presentation

Image Archive/Connectivity • Image Browser: Previewing of previous archived images as well as current stored patient images • Image Management (removable media) — Delete Selected Image — Review in Full Image Area • One Print (Recording) UI Keys to approved printer • Live Scan Save: Configure save button to save an image during live scanning — Archiving Format: JPEG, MPEG4/ H.264 • 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 and Search/Create Patient Window — Column header sorting from Image Review Screen by name, date, ID — Automatic generation of patient ID — Search by ID, First Name and Last Name • DICOM — DICOM store — Worklist query — Multi-frame DICOM • Network Quicksave	Software Intensive Ultrasound Imaging Platform • Digital Beamformer —Displayed Imaging Depth: Minimun Depth of Field is 0.5cm (probe dependent); Maximum Depth of Field is 30cm (probe dependent). • Continuous Dynamic Receive Focus/Aperture • Multi-Frequency/Wideband Technology CINE Memory/Image Memory • 250MB Standard CINE Memory (120 sec of recording at most) • CINE Review: frame-by-frame and loop replay • Live Scan Save: Configure save button to save an image during live scanning

Table 6-6: Scanning Parameters

B-Mode • Acoustic Output • Thermal Index: TI • Gain • Frequency • CrossXBeam • Gray Map • Focus Position • Reverse • Harmonics: defined by the preset • Depth: 0.5-30cm, defined by the preset, probe dependent • TGC • ATO level • Dynamic Range • Compression • Rejection • Frame Average • SRI HD • Edge Enhance • FOV M-Mode • Gain • Depth: 0.5-30cm, defined by the preset, probe dependent • Speed • Layout • Gray Map • Compression • Edge Enhance Needle Recognition Mode • Needle Direction • Beam Angle • Needle Gain	Color Flow Mode • ROI Position • ROI Size • Gain • Scale • Depth: 0.5-30cm, defined by the preset, probe dependent • Threshold • Sample Volume • Frame Average • Frequency • Steer • Acoustic Output • Wall Filter • Focus Position • Color Map • Compression • Invert • Quantification: the amount of blood flow within ROI PDI-Mode • ROI Position • ROI Size • Gain • Scale • Depth: 0.5-30cm, defined by the preset, probe dependent • Threshold • Sample Volume • Frame Average • Frequency • Steer • Acoustic Output • Wall Filter • Focus Position • Color Map • Compression • Quantification: the amount of blood flow within ROI

Table 6-7: Measurements and Calculations

General Measurements	Obstetrics Measurements/Calculations
• Distance • Area • Volume • Angle • Open Trace • Heart Rate/Time OB Worksheet • 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 Graphical Trending, Quad views, Ultrasound and gestational age	• Abdominal Circumference (AC) • Amniotic Fluid Index (AFI) • 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) • Occipito frontal 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, Abdominal (GYN & Urology), Pediatric, Small Organ (breast, testes, thyroid), Neonatal Cephalic, Conventional Musculoskeletal, Superficial Musculoskeletal, Thoracic/Pleural, Intraoperative (abdominal, thoracic and peripheral), Ophthalmic, Tissue Biopsy/Fluid Drainage, Vascular Access, Nonvascular • FOV (max): 38.4mm • B-mode Imaging Frequency: 8.0-13.0 MHz • CFM Imaging Frequency: 5.0-6.67 MHz • Steered Angle: +/-20 • Biopsy Guide Available: Multi-angle, Transverse bracket, Infinite biopsy kit 3S-SC Wide Band Phased Array Probe • Applications: Fetal/OB, Abdominal (GYN & Urology), Pediatric, Neonatal Cephalic, Adult Cephalic, Cardiac (adult & pediatric), Conventional Musculoskeletal, Thoracic/Pleural, Intraoperative (abdominal, thoracic and peripheral), Ophthalmic, Tissue Biopsy/Fluid Drainage • FOV (max): 60°-90° • B-mode Imaging Frequency: 2.0-3.4 MHz • CFM Imaging Frequency: 1.82-3.08 MHz • Biopsy Guide Available: Multi-angle 4C-SC: Wide Band Phased Array Convex Probe • Applications: Fetal/OB, Abdominal (GYN & Urology), Pediatric, Conventional Musculoskeletal, Thoracic/Pleural, Intraoperative (abdominal, thoracic and peripheral), Tissue Biopsy/Fluid Drainage, Nonvascular • Convex Radius: 60 mmR • FOV (max): 35°-55°, application dependent • B-mode Imaging Frequency: 2.5-5.0 MHz • CFM Imaging Frequency: 2.22-3.08 MHz • Biopsy Guide Available: Multi-angle	L8-18i-SC: Wide Band Linear Probe • Applications: Peripheral Vascular, Abdominal (GYN & Urology), Pediatric, Small Organ (breast, testes, thyroid), Neonatal Cephalic, Conventional Musculoskeletal, Superficial Musculoskeletal, Thoracic/Pleural, Intraoperative (abdominal, thoracic and peripheral), Tissue Biopsy/Fluid Drainage, Vascular Access, Nonvascular • FOV (max): 25.2mm • B-mode Imaging Frequency: 9.0-16.0 MHz • CFM Imaging Frequency: 5.0-8.7 MHz • Steered Angle: +/-20 E8CS-SC: Wide Band Phased Array Convex Probe • Applications: Fetal/OB, Abdominal (GYN & Urology), Transvaginal, Tissue Biopsy/Fluid Drainage • Convex Radius: 8.7 mmR • FOV: 145° • B-mode Imaging Frequency: 5.0-9.0 MHz • CFM Imaging Frequency: 4.0-5.0 MHz • Biopsy Guide Available: Multi-angle 10C-SC: Wide Band Phased Array Convex Probe • Applications: Abdominal (GYN & Urology), Pediatric, Small Organ (breast, testes, thyroid), Neonatal Cephalic, Superficial Musculoskeletal, Thoracic/Pleural, Intraoperative (abdominal, thoracic and peripheral), Ophthalmic • Convex Radius: 10.0 mmR • FOV: 75°-102° • B-mode Imaging Frequency: 6.0-10.0 MHz • CFM Imaging Frequency: 4.0-5.0 MHz

Table 6-9: Inputs and Outputs

• 3 USB interface on Docking Station/Cart • 1 USB interface on console • 1 SD interface on console • Docking Connector	• Wireless LAN 802.11 b/g/n by wireless card • Wired LAN 10/100/1000 BaseT • HDMI interface on Docking Station/Cart: resolution 1280x1024@60Hz

Clinical Measurement Accuracy

Basic Measurements

The following information is intended to provide guidance to the operator in determining the amount of variation or measurement error that should be considered when performing clinical measurements with this equipment. Measurement 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 operators 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%	
Time		Timeline Display	±5%	M mode

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	7	5.00	35
	M	63	7	5.00	35
	H	110	7	5.00	35
3S-SC	L	15	15.5	2.20	34.1
	M	63	15.5	2.20	34.1
	H	110	15.5	2.20	34.1
4C-SC	L	15	16.2	2.20	35.64
	M	63	16.2	2.20	35.64
	H	110	16.2	2.20	35.64
L8-18i-SC	L	15	4.00	6.67	26.68
	M	63	4.00	6.67	26.68
	H	110	4.00	6.67	26.68
E8CS-SC	L	15	7	4.00	28
	M	63	7	4.00	28
	H	110	7	4.00	28
10C-SC	L	15	7.5	4.00	30
	M	63	7.4	4.00	29.6
	H	110	7.4	4.00	29.6

Anti-Virus Software Note

Venue 50 Security

At GE we're committed to providing technologies to help you excel every day. The Venue 50 Ultrasound system is designed with you, your specialty and your patients in mind offering extraordinary image quality, easy workflow and expert tools to help you provide the best patient care.

Since the Venue 50 is integrated into your data network, GE wants to ensure that you are comfortable with the proactive measures we are taking to secure the product. Below are some activities and measures that we have performed and implemented to help secure the Venue 50.

1. Only communication ports that are needed for the Venue 50 to operate are enabled. All other operating system communication ports are disabled.
2. Ports remaining opened are:
   - Port 104 is used for DICOM communication only.
   - Ports 137, 138, 139 and 445 are used for QuickSave communication only.
   - Port 2501 is used for Gateway only.

   All operating system services that are not used by the system application software are disabled to help ensure that the source of security vulnerabilities is minimized.
3. The operating system is locked down to prevent an operator from loading software, opening email, or using a web browser and introducing viruses or Trojan horses to the system.
4. The "auto run" feature is disabled on the system. For instance, when a SD card or USB memory stick that has a program that runs automatically is inserted, the system will not open or run the program.
5. Our Engineering team performs a security scan on the Venue 50 system using the same tools that major organizations and hospital IT organizations use to check for vulnerabilities on their networks. Failures that are detected during this test process are corrected as expediently as possible and are deployed to our installed base customers.

Venue 50 Security (continued)

We have worked diligently to develop a combination of the safety measures above and the native security advantage of Venue 50 to provide a degree of safety against Viruses, Worms, Trojan Horses, etc., especially for a system used in a professional hospital grade networking environment that also typically features its own sufficient safety measures.

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

- Customized OS of Venue 50 is natively immune to most viruses. Only few viruses can run on Venue 50 system.
- Every Virus scanner is constantly active in the background. Due to the software-intensive operating system of the Ultrasound scanner, all computing resources are required for normal operation of this device. Anti-Virus software activities would have a negative impact on the system performance.
- The operating software of a medical Ultrasound system is part of an FDA-cleared medical device that requires a specific release process. Any update of the Anti-Virus software would mean a change of the system software. Such change would require an extensive release and validation process to help ensure that the Anti-Virus update does not have any impact on the system software performance and stability.

System Care and Maintenance

Overview

Refer to Chapter 10 of the Venue 50 Service Manual for any additional maintenance guidance.

The operator must ensure that safety inspections are performed at least every 12 months according to the requirements of the patient safety standard IEC 60601-1. Refer to the Service manual, Chapter 10.

Only trained persons are allowed to perform the safety inspections mentioned above.

Technical descriptions are available on request.

To ensure that the unit constantly operates at maximum efficiency we recommend that the following procedures be observed as part of the customer's internal routine maintenance program.

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:

- Console
- Docking Station/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 cleaning and sterilization

To clean the monitor face:

Use the protective bag to wipe monitor face gently.

Or

Wipe the LCD monitor 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)
- Alcohol (concentration no more than 75%)

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. Disconnect the footswitch from the Venue 50.
2. Moisten a soft, non-abrasive folded cloth with a mild, general purpose, non-abrasive soap and water solution.

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

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

Docking Station/Cart

To clean the Docking Station/Cart:

Use a soft, folded cloth with lukewarm water. Gently wipe the top, front, back, and both sides of the Docking Station/Cart. 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)
- Alcohol (concentration no more than 75%)

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.

Quality Assurance

Introduction

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

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

The frequency of Quality Assurance Evaluations should be based on operator'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 6-13 for more information.*

Typical Tests to Perform

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

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

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

The phantom shown is shown as a representative example of a phantom. You can select from any number of phantoms available on the market.

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 operator 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 operator'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.

The RMI 403GS phantom is shown in the illustration below as a representative example of a phantom.

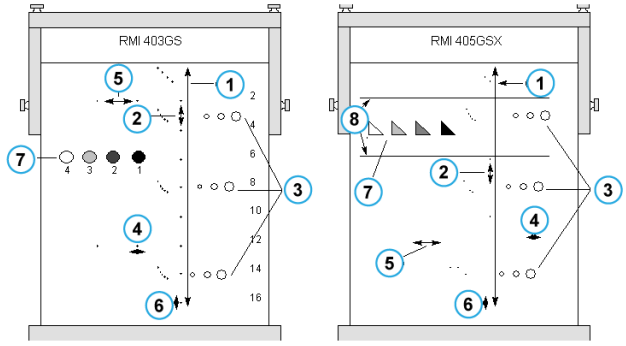


Figure 6-1. Phantoms

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

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

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

Test Procedures

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

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

Axial distance measurements

Description

Axial measurements are the distance measurements obtained along the sound beam. See Figure 6-1 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 6-1 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 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 6-1 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 6-1 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 6-1 for more information.

Penetration can be affected by the system's:

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

Benefit

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

Method

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

Procedure

To measure penetration:

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

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

Functional resolution

Description

Functional resolution is an imaging system's ability to detect and display the size, shape, and depth of an anechoic structure, as opposed to a pin target. See Figure 6-1 for more information.

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

Benefit

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

Procedure

To measure functional resolution:

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

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

Contrast resolution

Description

Contrast resolution is the ability of an imaging system to detect and display the shape and echogenic characteristics of a structure. See Figure 6-1 for more information.

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

Benefit

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

Method

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

Procedure

To measure contrast resolution:

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

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

Gray Scale photography

Description

Poor photography will cause loss of low level echoes and the lack of contrast between large amplitude echoes. See Figure 6-1 for more information.

Benefit

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

Procedure

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

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

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

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

Setting up a Record Keeping System

Preparation

The following is needed:

- Quality Assurance binder
- Hard copy or electronic file of images
- Quality Assurance checklists
- Display the following information while testing quality assurance:
  - Acoustic Output
  - Gain
  - Depth
  - Probe
  - 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: Ultrasound Quality Assurance Checklist (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 50.

Supplies/Accessories

CAUTION

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

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

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

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

Peripherals

Table 6-14: Peripherals and Accessories

Accessory	Unit
Sony Digital Graphic Printer (UP-D897)	Each
SDHC Card (Kingston 8GB SDHC Class 10 Flash Card V)	Each
SD Card Reader (Transcend Compact Card Reader TS-RDP5K)	Each
USB Memory Stick (SanDisk Cruzer Micro 4GB Flash Drive)	Each
Edimax Wireless Adapter EW-7711UTn	Each
Barcode Reader (Honeywell Corded Area-Imaging Scanner Xenon 1900)	Each
Footswitch (Steute MKF 2 1S/1S-MED HID GP26)	Each

Console

Table 6-15: Console Accessories

Accessory	Units
Battery Pack model (NZBP32)	Each
3-probe Port	Each
Docking Station	Each
Docking Cart	Each

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
10C-SC	Each
3S-SC biospy kit	Each
12L-SC biospy kit	Each
4C-SC biospy kit	Each
E8CS-SC biospy kit	Each

Gel

Table 6-17: Gel

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

Contact Information

Contacting GE Ultrasound

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

INTERNET

http://www.gehealthcare.com

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

Clinical Questions

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

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

Service Questions

For service in the United States, call GE CARES.

TEL: (1) 800-437-1171

In other locations, contact your local Service Representative.

Information Requests

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

TEL: (1) 800-643-6439

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

Placing an Order

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

TEL: (1) 800-558-5102

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

Contacting GE Ultrasound (continued)

AMERICAS

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

BRAZIL
GE Healthcare do Brasil Comércio e Serviços para Equipamentos Médico- Hospitalares Ltda
Av. Das Nações Unidas, 8501
3º andar parte - Pinheiros
São Paulo SP – CEP: 05425-070
C.N.P.J.: 02.029.372/0001-40
TEL: 3067-8010 FAX: (011) 3067-8280

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

LATIN & SOUTH AMERICA
Ultrasound Service Engineering
9900 Innovation Drive
Wauwatosa, WI 53226
TEL: (1) 262-524-5300
Customer Answer Center TEL: (1) 262-524-5698

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

USA
Ultrasound Service Engineering
9900 Innovation Drive
Wauwatosa, WI 53226
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ASIA

ASIA PACIFIC JAPAN
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4-7-127, Asahigaoka
Hinoshi, Tokyo
191-8503, Japan
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AUSTRALIA
Building 4B, 21 South St
Rydalmere NSW 2116
Australia
TEL: 1300 722 229

CHINA
GE Healthcare - Asia
No. 1, Yongchang North Road
Beijing Economic & Technology Development Area
Beijing 100176, China
TEL: (8610) 5806 8888 FAX: (8610) 6787 1162

INDIA
Wipro GE Healthcare Pvt Ltd
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Bangalore, 560067
TEL: +(91) 1-800-425-8025

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343, Hakdong-ro, Gangnam-gu
Seoul 135-820, Korea
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Auckland 1010
New Zealand
TEL: 0800 434 325

SINGAPORE
ASEAN
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HarbourFront Center
Singapore 099253
TEL: +65 6291 8528

Contacting GE Ultrasound (continued)

EUROPE

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

AUSTRIA
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A-1120 Vienna
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GE Medical Systems Ultrasound
Eagle Building
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1831 DIEGEM
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CZECH REPUBLIC
GE Medical Systems Ultrasound
Vyskocilova 1422/1a
140 28 Praha

DENMARK
GE Medical Systems Ultrasound
Park Alle 295, 2605 Brøndby
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ESTONIA & FINLAND
GE Medical Systems
Kuortaneenkatu 2, 000510 Helsinki
P.O.Box 330, 00031 GE Finland
TEL: (+358) 10 39 48 220 FAX: (+358) 10 39 48 221

FRANCE
GE Medical Systems Ultrasound
and Primary Care Diagnostics
F-78457 Velizy
General Imaging TEL: (+33) 13 449 52 43
Cardiology TEL: (+33) 13 449 52 31
FAX: (+33) 13 44 95 202

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42655 Solingen
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Athens 15125 Hellas
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HUNGARY
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Budaors 2040 Hungary
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GE Healthcare
Victoria Business Park
9, Westbank Road, Belfast BT3 9JL.
TEL: (+44) 28 90229900

REPUBLIC OF IRELAND
GE Healthcare
Unit F4, Centrepoint Business Park
Oak Drive, Dublin 22
TEL: (+353) 1 4605500

ITALY
GE Medical Systems Italia spa
Via Galeno, 36, 20126 Milano
TEL: (+39) 02 2600 1111 FAX: (+39) 02 2600 1599

LUXEMBORG
See Belgium.

NETHERLANDS
GE Healthcare
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NORWAY

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GE Medical Systems Ultrasound
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P.O. Box 141, 3191 Horten
TEL: (+47) 33 02 11 16

POLAND

GE Medical Systems Polska
Sp. z o.o., ul. Woloska 9
02-583 Warszawa, Poland
TEL: (+48) 22 330 83 00 FAX: (+48) 22 330 83 83

PORTUGAL

General Electric Portuguesa
SA. Avenida do Forte, n° 4
Fraccao F, 2795-502 Carnaxide
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UNITED KINGDOM	GE Medical Systems Ultrasound TEL: (+44) 1707 263570 71 Great North Road FAX: (+44) 1707 260065 Hatfield, Hertfordshire, AL9 5EN

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