SIEMENS

ACUSON Freestyle
Diagnostic Ultrasound System
User Manual

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Siemens Medical Solutions USA, Inc.

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ACUSON Freestyle
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Contents

About the User and Reference Manuals

The user and reference manuals consist of the following publications.

Publication	*Includes*
User Manual	■ Intended Audience ■ Technical description of the ultrasound system ■ Safety and care information for the system and compatible transducers ■ Descriptions of system controls ■ Procedures for system setup and examination fundamentals ■ Acoustic output data
System Reference	■ Electromagnetic Compliance Information ■ Wireless specifications, security, and quality of service information
Customer Information Note	■ Provides software release notes and updates to the User Manual

Conventions

Read and understand these conventions used in this manual.

Warnings, Cautions, and Notes	 **WARNING**: Warnings are intended to alert you to the importance of following the correct operating procedures where risk of injury to the patient or system user exists.
	 **CAUTION**: Cautions are intended to alert you to the importance of following correct operating procedures to prevent the risk of damage to the system.
	Note: Notes contain information concerning the proper use of the system and/or correct execution of a procedure.
Probe and Transducer	In accordance with ultrasound convention, these terms can be interchangeable. For the ACUSON Freestyle, in this manual: • *Probe* typically refers to the entire assembly of the handheld scanning module which includes the probe transducer, electronics, controls, and battery. • *Transducer* typically refers to the scanning array at the tip of the probe.
Key Text	There are two types of Soft Keys on the system and they are formatted differently in this manual: • Bottom Soft Keys and their menu and sub-menu items: for example, **SETUP**, **PATIENT**, **MEASURE** (formatting: bold, all caps). • Real-time Control Bar Soft Keys and their menus and sub-menu items: for example **Freeze**, **Save**, **Display** (formatting: bold, with gray bar).

ACUSON Freestyle Contents

3 Setup

4 Patient Studies

5 Scanning

6 Wireless Probes

7 Batteries

8 Connectivity

9 Artis/Freestyle Workflow

1 Introduction

A general overview of the ultrasound system and instructions on how to turn it on and off.

System Overview

The ACUSON Freestyle ultrasound system is designed for ultrasound studies. The system offers a variety of scanning modes and probes. The system probes may be operated in wireless mode, or using a Probe Adapter Cable. The system provides an intuitive and easy-to-operate user interface. It has a compact and portable design and offers DICOM archival and networking capability.

Intended Use

WARNING: The analysis of results from an ultrasound examination requires that you are trained in the interpretation of diagnostic ultrasound studies and are qualified to make clinical diagnoses.

WARNING: To avoid the risk of human injury and permanent damage to the ultrasound system, do not use the ultrasound system, transducers, or ultrasound components and accessories during magnetic resonance imaging (MRI) or in an environment with magnetic resonance (MR) equipment.

WARNING: The ultrasound system is not intended for ophthalmic use.

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

CAUTION: Ultrasound is used as an imaging aid, but may have further restrictions specific to in-vitro fertilization (IVF), chorionic villus sampling (CVS), and percutaneous umbilical cord blood sampling (PUBS) procedures. Observe local laws and regulations.

Indications for Use Statement

Product	Indications for Use Statement
ACUSON Freestyle Ultrasound System	The ACUSON Freestyle Ultrasound System is intended for diagnostic imaging or fluid flow analysis of the human body performed by an appropriately trained healthcare professional in a healthcare setting for the following clinical indications: Abdominal, Pediatric, Small Organ, Peripheral Vessel, Musculoskeletal (Conventional), Musculoskeletal Superficial.

Intended Use Environment

The ultrasound system is a mobile device intended for use in clinical environments.

Intended Users

User	*Interaction with Ultrasound Equipment*	*Expected Experience and Other Characteristics*
Sonographer	■ Acquires diagnostic views of anatomy, blood flow, and related pathology ■ Performs measurements and analysis of the acquired images ■ Prepares exam data for review and interpretation by a qualified physician	■ Ranges from novices (for example students) to advanced practitioners with certification in multiple specialties ■ Educated in anatomy, physiology, patient care, and identification of pathology in ultrasound images ■ Many sonographers have a Bachelor's degree; some have advanced degrees in related health care subjects
Physician	■ Performs ultrasound exams ■ Interprets exam data ■ Writes and assembles exam findings in a report	■ Medical doctor ■ Trained in ultrasound imaging techniques ■ Skilled in the interpreting ultrasound exam data
Radiologist	■ Performs ultrasound exams ■ Performs image-guided access and biopsy procedures ■ Interprets exam data ■ Writes and assembles exam findings in a report	■ Medical doctor ■ Expert in diagnostic imaging, including computed tomography, magnetic resonance imaging, X-ray, ultrasound, and nuclear medicine ■ Advanced training in imaging physics with typically two to six years of post-doctoral training in the field of radiology; some specialize in diagnostic ultrasound
System Administrator and Customer Service Engineer	■ Configures the ultrasound system for use in a networked environment	■ A System Administrator is an individual within your organization who is designated to set up system parameters to connect the ultrasound system or workstation to a picture archiving and communication system (PACS). ■ Customer service engineers are Siemens Healthineers representatives who configure the ultrasound system during initial installation, support troubleshooting activities, and repair the system.

Contraindications

There are no known contraindications for diagnostic ultrasound.

Transducers and Intended Applications

WARNING: The ultrasound system is not intended to be used with high-frequency surgical equipment. Use of transducers in conjunction with high-frequency surgical equipment may result in an increased risk of harm to the patient in the event of a defect in the high-frequency surgical neutral electrode connection.

Only the following transducers from Siemens Healthineers are compatible with your ultrasound system.

Transducer Name and Array Type	*Modes*	*Intended Use*	*Technical Data Frequency Range Footprint*
L8-3 Linear	B-Mode Color Doppler Amplitude Doppler	Abdominal, pediatric, small organs, peripheral vessel and vascular, and musculoskeletal.	3.0 – 8.0 MHz 38.4 x 5 mm
L13-5 Linear	B-Mode Color Doppler Amplitude Doppler	Abdominal, pediatric, small organs, peripheral vessel and vascular, and musculoskeletal.	5.0 – 13.0 MHz 25.6 x 4 mm
L17-5 Linear	B-Mode Color Doppler Amplitude Doppler	Abdominal, pediatric, small organs, peripheral vessel and vascular, and musculoskeletal.	5.0 – 17.0 MHz 25.6 x 4 mm
C5-2 Curvilinear	B-Mode Color Doppler Amplitude Doppler	Abdominal, pediatric, small organs, peripheral vessel and vascular, and musculoskeletal.	2.0 – 5.0 MHz 13.0 x 60.00 mm

Abdominal

Abdominal studies are performed to obtain images that can be used to: detect presence or absence of abdominal organ abnormalities, determine size, contour, and patency of vessels, characterize obstructions, and determine blood flow patterns and velocities.

Pediatric

Pediatric studies are performed in pediatric patients to obtain images that can be used to: detect presence or absence of organ abnormalities, detect abnormalities in superficial and bony structures, determine size, contour, and patency of vessels, and determine blood flow patterns and velocities.

Small Organs

Small Organ studies are performed to obtain images of targets such as the breast, thyroid, testicles, and lymph nodes that can be used to: detect presence or absence of organ abnormalities, determine size, contour, and patency of vessels, and determine blood flow patterns and velocities.

Peripheral Vessel (Vascular)

Peripheral vessel (vascular) studies are performed to obtain images that can be used to: detect size, contour, and vessel patency, characterize obstructions, determine blood flow patterns and velocities, and image and measure anatomic and physiologic parameters of vessels.

Musculoskeletal

Musculoskeletal studies are performed to obtain images of superficial and deeper targets such as tendons, ligaments, muscles, and bony structures that can be used to: detect presence of absence of anatomical abnormalities, and determine blood flow patterns and velocities.

WARNING: The analysis of results from an ultrasound examination requires that you are trained in the interpretation of diagnostic ultrasound studies and are qualified to make clinical diagnoses.

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

The ACUSON Freestyle ultrasound system supports the applications listed in this section.

CAUTION: In performing fetal ultrasound studies, it is important to consult consensus statements and health care organization guidelines for the use of ultrasound imaging in pregnancy. Reference: Diagnostic Ultrasound Imaging in Pregnancy. NIH Consensus Statement 1984 Feb 6-8;5(1):1-16. The ACUSON Freestyle is not indicated for Obstetric use.

WARNING: Probe sheaths cannot be relied upon to prevent contamination of the probe when used on patients with known or suspected Creutzfeld-Jakob disease (CJD). A probe exposed to central nervous system tissue from know or suspected CJD or Variant CJD should be destroyed since it may not be possible to sterilize. (See http://www.cdc.gov/ncidod/qa_cid_infection_control.htm)

CAUTION: The ACUSON Freestyle is designed to operate in the same room as X-ray equipment. However, ACUSON Freestyle probes contain sensitive electronic components not found in conventional cabled probes. Avoid leaving probes directly in the active X-ray beams.

Principles of Operation

Diagnostic ultrasound uses high-frequency (above the audible range) sound waves to produce an image of anatomical structures within the body. Electrical pulses vibrate ceramics within a transducer to transmit the sound waves into the body. Sound waves travel through body tissue at approximately 1,540 meters per second and reflect back as echoes to the transducer at each point of change in tissue density, for example, at the border of two organs in the body. These return signals provide information about the acoustic properties of the tissue. The time to receive the echo in microseconds indicates a distance into the body. Structures furthest from the transducer surface require more time to return a signal than structures closer to the transducer surface. The strength and position of each signal indicates a point of varying intensity (brightness). The distances and intensities are processed and displayed on a screen to form a two-dimensional (2D) image.

Clinical Benefits

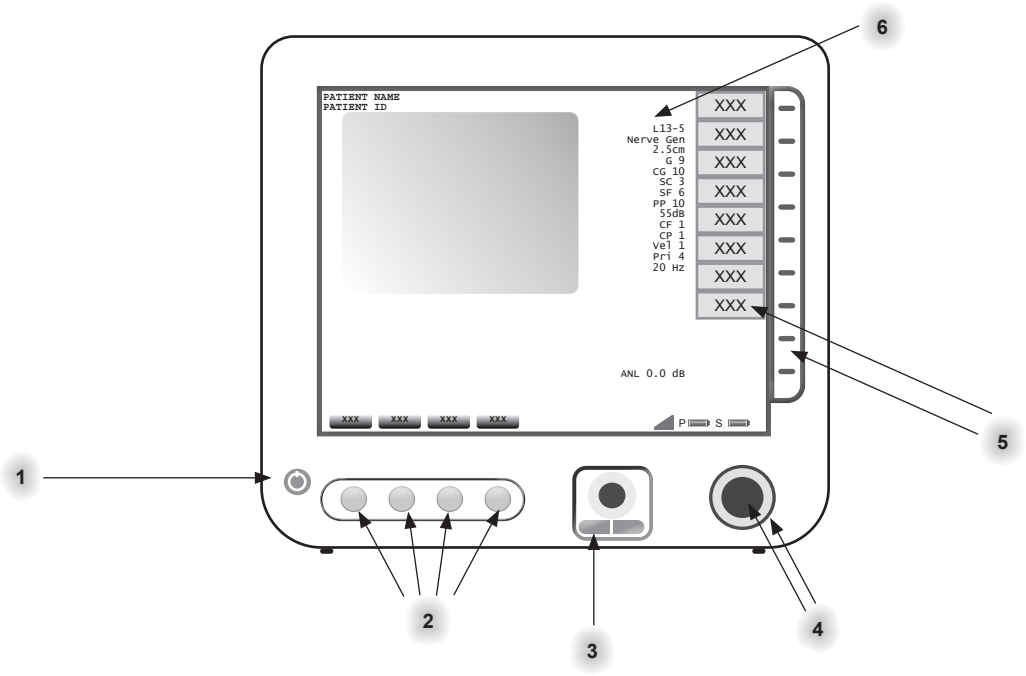
Ultrasound has a positive impact on the health of an individual as a non-ionizing diagnostic imaging tool. The device provides real-time anatomic and kinetic visualization of internal organs, tissue structures, blood flow, and Doppler-enabled hemodynamics. Ultrasound is the accepted imaging modality for the safe visualization of fetal anatomy and monitoring of fetal development.

The mobility and cost effectiveness of ultrasound increases access to patients in clinical environments. Patient benefits also include a safer examination compared to imaging modalities using ionizing radiation.

Real-time ultrasound imaging provides guidance during interventional procedures, for example, needle biopsies and fluid aspirations; in the absence of ultrasound, these procedures are conducted without visualization or with ionizing radiation.

System Console

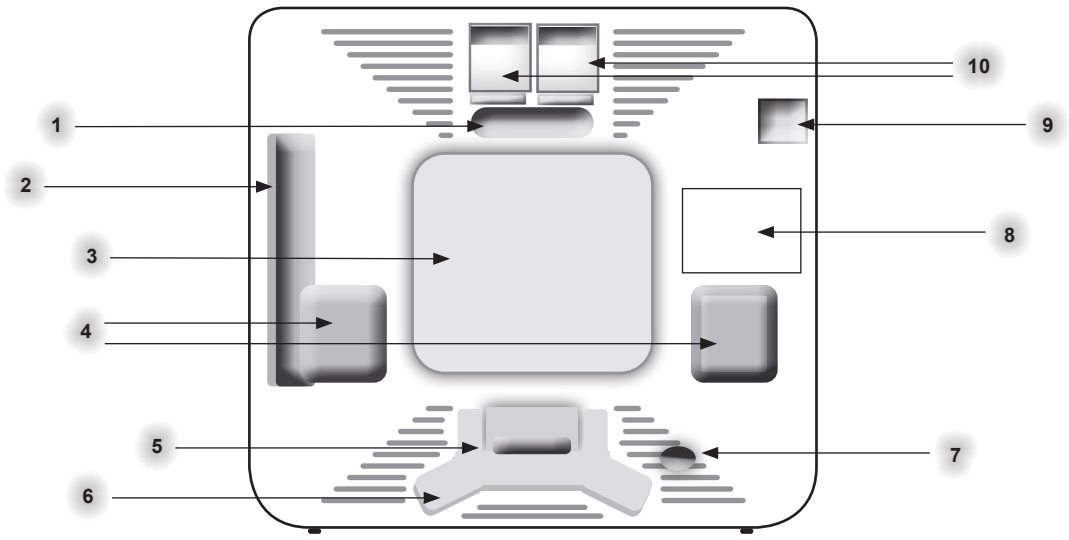
Console Front View



System Console: Front View

1. ON/OFF Button
2. Bottom Soft Keys
3. Trackball and Trackball Left and Right keys
4. Rotary knobs: press or turn the Inner Knob to activate the highlighted control.
5. Control bar Soft Keys and Control Bar Labels
6. Image Settings area

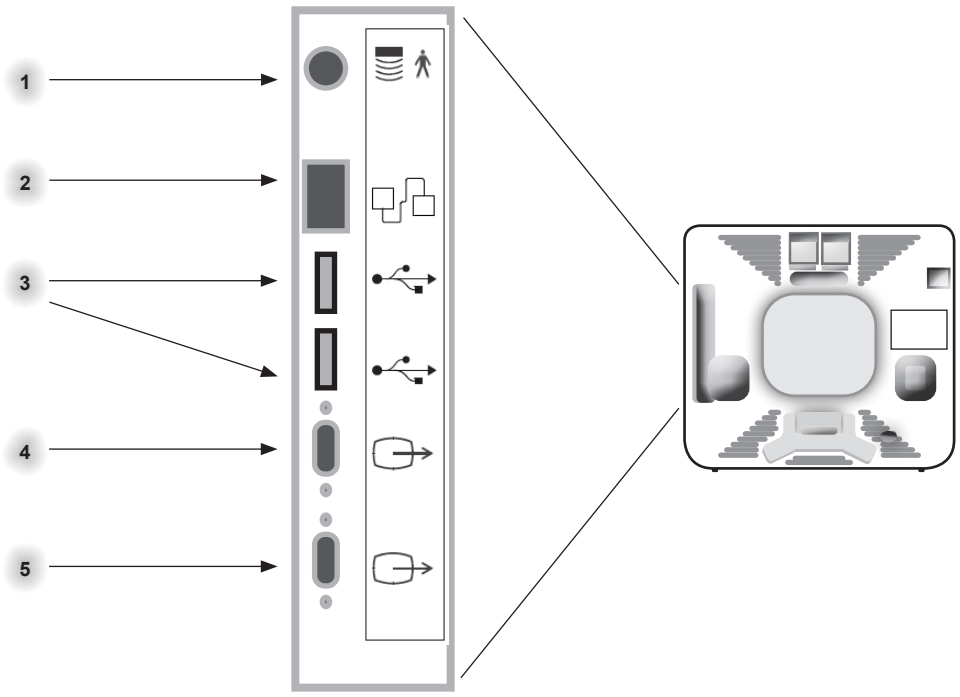
Console Rear View



System Console: Rear View

1. Hand grip
2. I/O panel
3. VESA mount locations
4. Probe holders
5. Power Cable connector
6. Tilt stand
7. *Service Use Only*
8. System label
9. External Antenna connector
10. Probe battery charge bays

Console Inputs/Outputs Panel



Inputs/Outputs Panel along right side of system console

1. Probe Adapter Cable connector
2. Network connector
3. USB ports
4. Analog Video Out (VGA)
5. Digital Video Out (DisplayPort™)

Video Out Compatibility

ACUSON Freestyle supports both Analog video out (VGA) and Digital video out (DisplayPort-DVI and DisplayPort-HDMI) connections. Both require external adapters. Please refer to the compatibility matrix below for more information.

Video Out Compatibility Matrix

VGA to VGA ✓

DisplayPort to DVI ✓

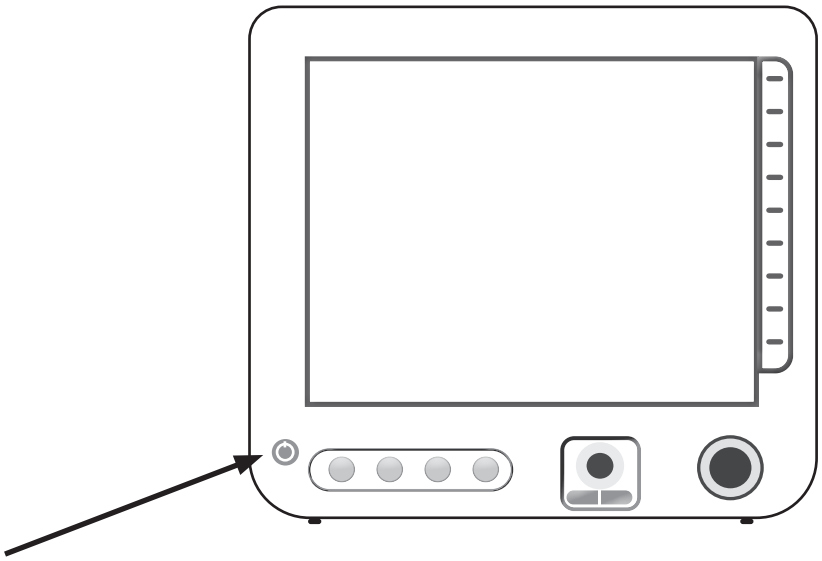
DisplayPort to HDMI ✓

DisplayPort to Display Port* ×

***** *To connect to a DisplayPort-only monitor, first adapt from DisplayPort to DVI and then convert from DVI to DisplayPort.*

Turning the System On and Off

The Power key is located in the bottom, left corner of the system console control panel.



Location of Console Power Key

Turn the System On

To turn the system on, press the **POWER** key, holding it down momentarily. You will hear a beep when power is started. The system will take a number of seconds to boot up.

NOTE: While the system is booting up, do not try to power down.

NOTE: During boot-up, the system performs a software check which may extend the boot-up time.

Turn the System Off

To power the system down, press the **POWER** key, holding it down momentarily.

If you attempt to power the system down and the momentary pressing of the **POWER** key does not shut the system off, hold the **POWER** key down continuously for five seconds to power down. If you repeatedly have problems powering down, contact your service representative.

NOTE: If the system does not boot up when it is ***not*** plugged into the AC Mains power outlet, it may be because the system battery is depleted. Plug the system into AC mains power outlet using the power cable.

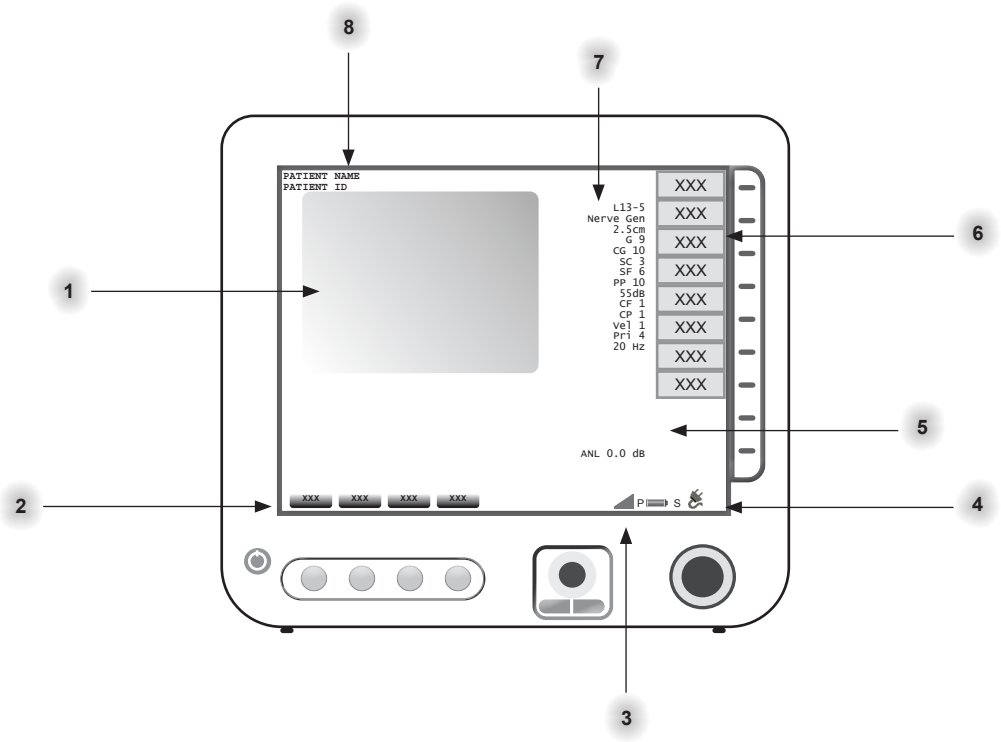
WARNING: ***Do not power down until an archival transfer is complete.*** If the system is in the process of an archival transfer operation, such as saving a patient study to a removable storage medium or over a network, powering down will terminate the transfer and result in an unsuccessful transfer.

CAUTION: ***Do not power down during a software upgrade.*** Powering down during a system software upgrade will cause the upgrade to terminate and be unsuccessful.

Imaging Screen Layout

The console displays clinical images together with important operating parameters, patient data, and control commands.

Sample Imaging Screen



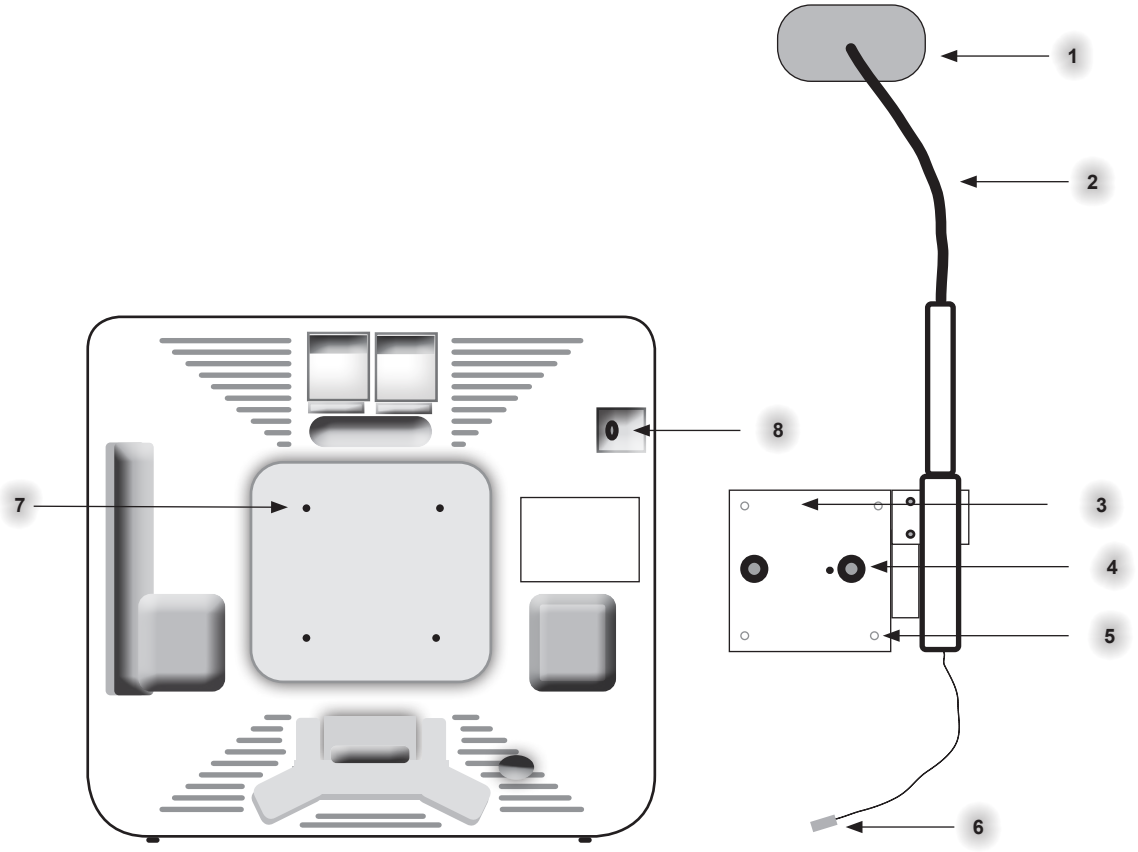
Sample ACUSON Freestyle Console Screen

1. Image area
2. Bottom Soft Keys
3. Wireless Signal Quality
4. Probe, System battery/power, Networking Status area
5. Average Noise Level
6. Control Bar Soft Keys (e.g., **Freeze**, **Save**, **Gain**, etc.); controlled by touching the bar and using the Rotary knob.
7. Image Settings area
8. Patient Name and ID

Using an External Antenna

An optional receive-only external antenna can be mounted on the ACUSON Freestyle console.

The antenna's flexible goose-neck allows you to position the antenna. Point the front of the antenna towards the probe (the front says “SIEMENS”).



External Antenna Parts and Connections

1. Antenna (back)
2. Antenna Flexible Goose-neck
3. Antenna VESA Mount plate
4. Antenna VESA Alignment pins (2)
5. Antenna Mount screw holes (4)
6. Antenna Connector plug
7. Console VESA Mount locations (4)
8. Console Connector port

Attaching the External Antenna to the ACUSON Freestyle Console

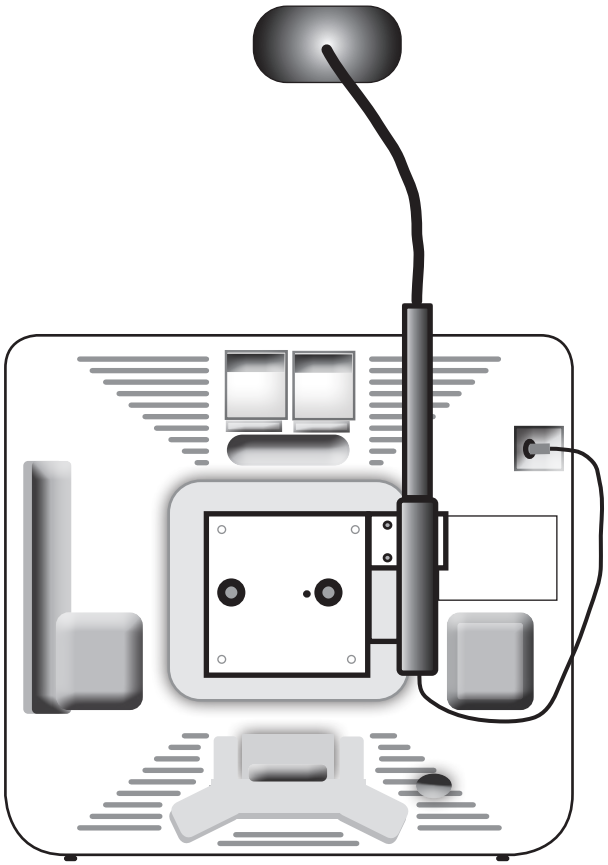
NOTE: Attaching the antenna may require two people.

NOTE: The external antenna is not compatible with the VESA Mount shipped with the rollstand. Remove the old VESA Mount before attaching the external antenna VESA Mount.

To attach the antenna to the ACUSON Freestyle console, follow these steps:

1. Make sure that the console is powered off.
2. Match the four screw holes on the Antenna VESA Mount plate to the four screw holes on the Console VESA Mount locations.
3. Using the supplied screws, attach the plate at the four corners.
4. Insert the Connector plug into the Connector port, making sure that the Connector Cable loops under the probe holder.
5. Turn on the console and look for the antenna icon ( ). When the antenna is installed and working properly the antenna icon will appear at the bottom right of the display.

The Wireless Signal Quality Meter indicates the quality of the signal; the best signal quality is six bars. See "Monitoring Wireless Signal Quality" on page 6-8 for a description of the conditions.



External Antenna Attached to ACUSON Freestyle Console

Attaching the ACUSON Freestyle Console to the Rollstand

NOTE: When using the external antenna with the ACUSON Freestyle rollstand, first attach the antenna to the ACUSON Freestyle console as described in "Attaching the External Antenna to the ACUSON Freestyle Console" on page 1-16.

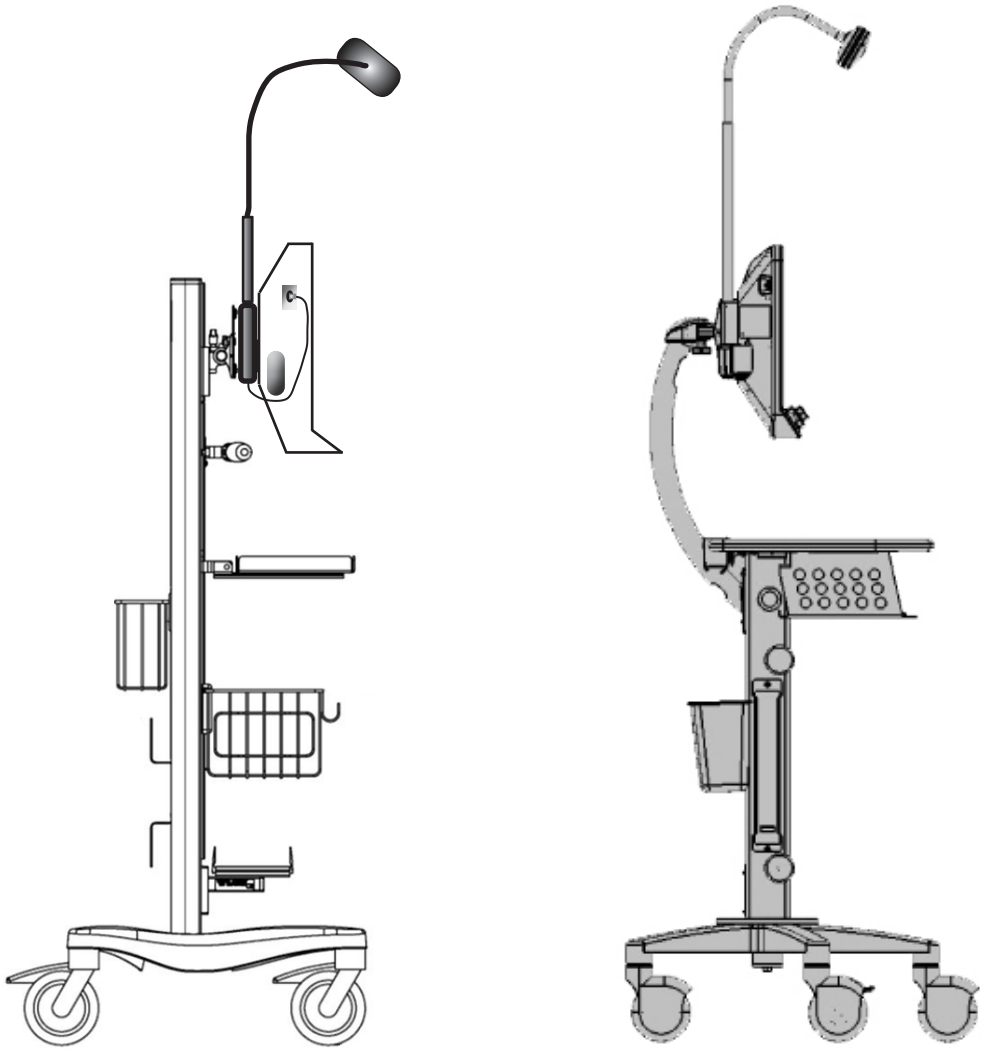
To attach the ACUSON Freestyle console to the ACUSON Freestyle rollstand, follow these steps:

1. Make sure that the console is powered off.
2. Match the two Alignment pins on the VESA Mount plate to the two Support cutouts on the rollstand Bracket.
3. Confirm that the metal Locking pin on the rollstand Bracket is securely through the hole on the external antenna VESA Mount.

   NOTE: Some styles of the rollstand do not have a metal locking pin.

4. Hand-tighten the two white Thumbscrews on the back of the rollstand Bracket to stabilize the ACUSON Freestyle console.
5. Turn on the Console and look for the antenna icon (), if equipped. When the antenna is installed properly, the antenna icon will appear at the bottom right of the display.

   NOTE: Specific version of rollstand may vary.



ACUSON Freestyle with External Antenna; Mounted on GCX Rollstand (left) and Deluxe Rollstand

2 Safety and Care

This chapter contains information regarding the safe operation of the ACUSON Freestyle Ultrasound System, including a technical description of the system. Please read and understand it prior to using the system in patient studies. Consult the System Reference section of the Manual for important information about Electromagnetic Compatibility (EMC), Wireless Security, and Wireless Quality of Service.

Operating Safety and Environment

Do not operate the ultrasound system until you fully understand the safety considerations and procedures presented in this manual.

WARNING: Failure to comply with Warnings may pose a threat to patient and/or user safety.

Siemens Healthineers recommends the use of gloves during the operation, cleaning, and care of the ultrasound system.

See also: For biohazard considerations related to the use of latex products, refer to page 2-8.

Serious Incident Reporting

If you become aware of any (potential) malfunction of our device which has resulted or could result in serious health consequences for the user, patient or any other person please inform us immediately and if legally required, inform the Competent Authority of your country.

Labels

For information regarding product labels, see the *System Reference Manual*.

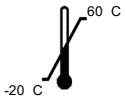
System Symbols

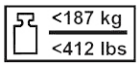
Refer to this table to identify important symbols located on the ultrasound imaging system and transducers.

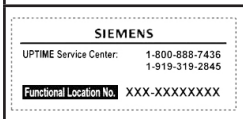
NOTE: Some symbols in this table may not be used in your system.

Symbol	*Explanation*
	Caution: Risk of electric shock.
	Operating Instructions – Mandatory Action (blue illustration)
	Consult instructions for use
	Caution (black illustration)
	General Warning (yellow and black illustration)
	Standby — ON

Symbol	*Explanation*
	USB Connection
	Ethernet 10/100BaseT
	Type B Applied Part
	The product must be properly disposed of in accordance with local, state, and regional laws and regulations. Products bearing this symbol are subject to the European Community Directive 2012/19/EU on waste electrical and electronic equipment (WEEE), amended by directive 2003/108/EC. For collection and disposal of the product, its components, or its accessories, contact your local customer service representative.
	Federal Communications Commission
	European Conformity mark Indicates the manufacturer declares the product complies with the applicable requirements in Regulation (EU) 2017/745 and other applicable European Union harmonization legislation.
	Manufacturer's declaration of product compliance with applicable EEC directives
	Safety testing classified symbol for Canada and United States of America
	Eurofins MET mark for Canada and United States of America Indicates the product complies with Underwriters Laboratories (UL) and Canadian Standards Association (CSA) safety standards. Includes the following certifications under the mark: Electrical Safety E115466
IVK	(Installierte Volumen Komponente) Identifier of selected system components or parts for product traceability
System IVK	(System Installierte Volumen Komponente) Identifies the system for product traceability
	Technical Conformity Mark for specified radio equipment in Japan

Symbol	*Explanation*
	Probe storage temperature range System storage temperature range
	Fuse. Identifies location of Fuse. **WARNING**: Risk of Fire. Replace Fuse as marked.
	Alternating Current (AC). Specifies the type of input voltage.
	Probe Adapter Cable connector
	Video Output. Connector for attaching video display monitor.
	Electrostatic sensitive devices
	Recyclable / Recoverable
	Magnetic Field. WARNING: Keep battery-end of transducer at least 3 centimeters (1.3 inches) away from implanted cardiac rhythm devices.
	Protective Earth Ground
IPX8	Protection against the effects of continuous immersion in water
	Barcode with product identification information according to the following barcode specification: GS1 DataMatrix
	Manufacturer
 **2004-06**	Date of Manufacture (YYYY-MM)
V~	AC (alternating current) voltage source

Symbol	*Explanation*
	Indicates this side up
	Do not allow to get wet
	Fragile. Handle with care.
	IEEE 802.11b/g (WiFi) connected
	Battery (charge level)
	Power Plug
	I/O; for service use only.
	Ethernet network
	Study Storage Memory Used
	Intentional transmitter of non-ionizing radiation
	Country of origin
	Caution: In the United States of America, federal law restricts this device to sale by or on the order of a physician.
	Authorized representative in the European community
	Chinese RoHS
	Weight with safe working load
	Do not lean

Symbol	*Explanation*
	Shelf Weight Restriction
	Prohibited User Servicing
	Prohibited around AP (Flammable Anesthetic) Medical Equipment
	KC Mark (Korea)
	EAC Mark (EAC Declaration of Conformity for Belarus, Russia, Uzbekistan and Kazakhstan)
	INMETRO Mark (Indicates conformity to the safety requirements of Brazil National Standards.)
	Uptime Service Center (Provides customers with a service call-in number and a Functional Location number that is used to track the location of the Ultrasound system.)
	Magnetic resonance (MR) unsafe. Prohibits the use or presence of the medical device in a magnetic resonance imaging (MRI) environment.
	Identifies the manufacturer's serial number of the medical device Includes the number adjacent to the symbol
	Identifies the manufacturer's catalog reference number of the medical device Includes the number adjacent to the symbol
	Indicates the device consists of several components that can be assembled by the manufacturer in multiple configurations
	Indicates the system (a combination of products)
	Indicates the unique device identifier (UDI)
GTIN	Global Trade Item Number
Serial SERIAL	Serial number
Model MODEL	Product model number
Origin US ORIGIN US	Manufacturer country of origin: United States of America

Biohazard Considerations

WARNING: Siemens makes every effort to manufacture safe and effective probes. You must take all necessary precautions to eliminate the possibility of exposing patients, operators, or third parties to hazardous or infectious materials. These precautions should be considered in the use of any application that may indicate the need for such care, for example, when scanning patients with open wounds.

WARNING: To eliminate the possibility of exposing patients, operators, or third parties to hazardous or infectious materials, always dispose of hazardous or infectious materials according to local, state, and regional regulations.

WARNING: Probe Sheaths: There have been reports of severe allergic reactions to medical devices containing latex (natural rubber). Health care professionals are advised to identify latex sensitive patients and to be prepared to treat allergic reactions promptly. For additional information in the U.S.A., refer to FDA Medical Alert MDA91-1.

WARNING: Ultrasound energy is transmitted more effectively through water than through tissue. When using a standoff device of any kind, for example, a water bath or gel pad, the actual mechanical and thermal indices, MI and/or TI, may be higher than indicated in the output display on the ultrasound system.

The assessment of the biological effects of diagnostic ultrasound on humans is a subject of ongoing scientific research. This ultrasound system, and all diagnostic ultrasound procedures, should be used for valid reasons, for the shortest possible period of time, and at the lowest mechanical and thermal indices necessary to produce clinically acceptable images.

According to the principles of ALARA (As Low As Reasonably Achievable), the acoustic output should be the ***lowest level required to satisfactorily perform the examination***.

The ultrasound imaging system complies with the standards of the American Institute of Ultrasound in Medicine (AIUM) and the National Electrical Manufacturers Association (NEMA), the guidelines of the United States Food and Drug Administration (FDA) and the standards of the International Electrotechnical Commission (IEC) in terms of safety and acoustic output levels. The ultrasound output levels are stated to permit the user to critically evaluate the ultrasound system settings in the event of new research findings being announced.

Acoustic Output

WARNING: Ultrasound procedures should be used for valid reasons, for the shortest period of time, and at the lowest mechanical/thermal index setting necessary to produce clinically acceptable images.

NOTE: For ultrasound systems distributed in the United States of America, refer to the Medical Ultrasound Safety ultrasound education program brochure produced by the AIUM that is shipped with the system. This document explains the interaction of ultrasound and tissue, the possibilities and mechanisms of bioeffects, and it explains the terms used to describe acoustic output.

The ultrasound energy, frequency levels, and scanning times employed by the ACUSON Freestyle have not been associated with harmful effects. Nevertheless, it is advisable to minimize the patient's exposure to ultrasound energy. This prudent use can be accomplished by following the ALARA (As Low as Reasonably Achievable) Principle, and by operating the system in a manner that reduces patient exposure to ultrasound energy. Acoustic Output tables for the ACUSON Freestyle are provided below.

The acoustic output for the ACUSON Freestyle has been measured and calculated in accordance with the "Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment" (NEMA UD2-2004), and the "Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment" (NEMA UD3-2004.)

ALARA / Prudent Use

Prudent use of ultrasound requires that patient exposure to ultrasound energy be limited to the lowest output for the shortest period of time needed to obtain acceptable diagnostic results. Techniques include:

1. Keep exams as brief as possible, consistent with diagnostic requirements.
2. Select the appropriate transducer for the patient body type and exam type in order to optimize imaging results.
3. Use overall gain or dynamic range or post processing settings, which have no effect on output, to optimize the image and obtain diagnostic results.
4. In general, as shown in the Acoustic Output Tables, Color Flow Doppler mode will have higher output levels than B-Mode (2D). Keep this in mind when scanning. New studies default to B-Mode.

Acoustic Output: Global Maximum Values

No system/transducer combination is capable of exceeding either a Thermal Index (TI) of 1.0 or a Mechanical Index (MI) of 1.0, so, in accordance with relevant standards (NEMA UD3-2004), the system does not display MI or TI. The table below, Global Maximum Values, provides the mean of the global maximum of acoustic output values. The terms are described below.

Table entries have been obtained with the same operating conditions that create the maximum value.

Uncertainties associated with the values derive from transducer and system variability, measurement variability, and engineering approximations for real-time calculations. Measurement precision and uncertainty for quantities used to calculate the values in the table are 30% for intensity and 15% for MI.

Maximum surface temperatures are in accordance with IEC 60601-2-37.

References:

Ziskin MC: “Measurement of uncertainty in ultrasonic exposimetry”, *Ultrasonic Exposimetry*, M.C. Ziskin and P.A. Lewin, eds. (CRC Press, Boca Raton, FL) pp. 409-443, 1993.

Ziskin MC: “Specification of acoustic output level and measurement uncertainty in ultrasound exposimetry,” *IEEE Transactions Ultrasonics, Ferroelectrics, and Frequency Control*, 50, 1023-34, 2003

Acoustic Terms and Definitions

Translations for language other than English.

Term	*Definition*
Acoustic Output	
Global Maximum Values	
Term	
Definition	
ISPTA.3 (Intensity, spatial-peal temporal average)	
TI (Thermal Index)	
TIC (Thermal Index Cranial)	
TIS (Thermal Index Soft Tissue)	
TIB (Thermal Index Bone)	
MI (Mechanical Index)	
IPA.3@Mimax (Intensity, pulse average at the maximum MI)	
B-Mode	
Transducer Model	
Type	
Value	
Color Doppler	

Definition of Acoustic Terms

Term	*Definition*
ISPTA.3	Intensity, spatial-peak temporal average: The value of the temporal-average intensity at the point in the acoustic field where the temporal-average intensity is a maximum, or is a local maximum within a specified region. Units: milliwatts/cm^2.
TI	Thermal Index: A quantity related to calculated or estimated temperature rise under certain defined assumptions. The thermal index is the ratio of total acoustic power to the acoustic power required to raise tissue temperature by 1º C under defined assumptions. C: Cranial. S: Soft tissue. B: Bone.
MI	Mechanical Index: The spatial-peak value of the peak rarefactional pressure, derated by 0.3 dB/cm-MHz at each point along the beam axis, divided by the square root of the center frequency.
IPA.3@MImax	Intensity, pulse average at the maximum MI: The ratio of the pulse intensity integral to the pulse duration at the maximum MI. Units W/cm^2.

Acoustic Output Global Maximum Values: B-Mode

TRACK 3 Summary (for systems with no probes having global maximum index values exceeding 1.0)

Transducer Model	*ISPTA.3*	*TI Type*	*TI Value*	*MI*	*IPA.3@MImax*
L8-3	3.58 mW/cm^2	TIC	0.09	0.76	92.7 W/cm^2
L13-5	1.15 mW/cm^2	TIS	0.02	0.33	31.74 W/cm^2
L17-5	2.43 mW/cm^2	TIS	0.02	0.43	36.89 W/cm^2
C5-2	4.53 mW/cm^2	TIC	0.15	0.76	67.21 W/cm^2

Acoustic Output Global Maximum Values: Color Doppler

TRACK 3 Summary (for systems with no probes having global maximum index values exceeding 1.0)

Transducer Model	*ISPTA.3*	*TI Type*	*TI Value*	*MI*	*IPA.3@MImax*
L8-3	33.02 mW/cm^2	TIC	0.72	0.76	132.41 W/cm^2
L13-5	54.49 mW/cm^2	TIC	0.86	0.38	86.44 W/cm^2
L17-5	40.04 mW/cm^2	TIS	0.86	0.49	111.16 W/cm^2
C5-2	19.09 mW/cm^2	TIC	0.88	0.76	75.18 W/cm^2

Accuracies

Measurement Accuracies

The ACUSON Freestyle may be used to provide measurements and calculations derived from ultrasound images. The quantified image data may be used along with other clinical information to assist a physician in making a patient diagnosis.

The sole reliance on diagnostic ultrasound data to make a clinical diagnosis is not recommended. Numerous factors related to the accuracy of ultrasound image data must be taken into account. This section describes some of these factors. Measurement accuracies are also influenced by operator experience, scanning technique, interpreting physician experience, and the technical difficulty of the patient. Many of these variables are not associated with the ACUSON Freestyle system. This limits the ability to fully specify the clinical accuracy of the measurements and calculations provided by the system.

Accuracy by Transducer Type

All transducer types have been verified for measurement accuracy in the modes appropriate to each measurement type.

Because the moderate transducer frequency range of the system, measurement accuracies for the system are not expected to vary significantly based on transducer used.

Accuracy of Primary Measurements

All reported accuracies are +/– one-half the least significant digit.

Distance

The system assumes that the speed of sound in tissue is 1540 meters per second and that this speed is homogeneous in all tissues. The diagnostic ultrasound literature states that differences in the speed of sound in the body do exist because of the differing tissue types. In *Clinical Sonography – A Practical Guide*, (2nd Edition, Roger C. Sanders, ed., Little Brown and Company 1991) the range is cited as from 1500 to 1600 meters per second. These differences would produce an inaccuracy of up to +/– 4%.

The distance measurements on the system are verified using an AIUM standard phantom with a fluid having an acoustic speed of approximately 1540 meters per second at room temperature. The accuracy of this measurement is +/– 5%. The maximum range of this measurement is 24 cm (dependent on the probe).

Area

The accuracy of the area measurement is +/– 10%.

The maximum range of this measurement is 733 cm^2 (dependent on the probe).

Potential Sources of Measurement Error During Scanning

The table below identifies potential sources of measurement error that may occur during scanning. Awareness of these sources can help you avoid errors they may cause.

Potential Source of Error	*Explanation of Error*
Patient Variability	The technical difficulty of patients in ultrasound imaging varies widely. Greater care must be taken with technically difficult patients to obtain the best images possible with the optimal transducer and system control settings.
Operator Variability	The skill, care, and experience of the person conducting the scan is one of the most critical factors in obtaining accurate measurements. Operator training should be consistent with the recommendations of the appropriate professional medical societies.
Speed of Sound	The image processing and measurement algorithms of diagnostic ultrasound assume that the speed of sound in body tissue is 1540 meters per second. Different body tissues have different sound speeds. In soft tissue there is approximately a 2% error; this may be as high as 5%, especially if fatty tissue is present in the area being measured.
Doppler Alignment	When performing Doppler scans, try to align the Doppler sample as close to parallel as possible.
Screen Pixel Resolution **WARNING**	The display screen provided in the ACUSON Freestyle system is comprised of a rectangular array of square picture elements (pixels). Measurement pixel resolution is assumed to be +/– one pixel. The maximum potential error of this resolution accuracy is 0.4% Occasionally, a pixel or a group of pixels of the display may enter a fault condition and become stuck in an on or off position. If stuck pixels occur at a place where a measurement value is displayed, it could cause the operator to misread the result. Pixels stuck in the on position may be detected by looking at the screen with a dark background. Pixels stuck in the off position will show up as dark against a bright video image. You should periodically examine your system for stuck pixels and be aware of this potential condition when reading measurements. If you believe your system has stuck pixels, contact your Service Representative.

Electrical Safety

WARNING: Explosion Hazard. Possible explosion hazard if used in the presence of flammable anesthetics.

WARNING: To avoid electric shock, use a protective earth connection to connect the ultrasound system to the AC Mains power supply. The protective earth connection ensures that the mains circuit breaker will disconnect the power supply in the event of a short circuit.

WARNING: To ensure grounding reliability, only connect the system to a hospital-grade power outlet.

WARNING: The AC Mains power connector plug for the ultrasound system is a three prong grounded plug (in the U.S.A.) and should never be adapted to any two prong (non grounded) outlet, either by modifying the plug or by using an adapter. In the U.S.A., proper grounding requires the AC Mains power connector plug to be plugged into a hospital grade power outlet.

WARNING: Risk of fire. Replace fuse as marked.

WARNING: To avoid electrical shock, never modify the ultrasound system AC Mains power connector plug, as doing so may overload your facility's power circuits. To ensure grounding reliability, connect the system only to an equivalent outlet.

WARNING: To avoid electrical shock, never use equipment or an AC Mains power cord that shows signs of wear or tampering, or that has a ground plug which has been bypassed by using an adapter.

WARNING: Equipment connected to the ultrasound system and in the patient zone must be powered from a medically isolated power source or must be a medically isolated device. Equipment powered from a non isolated source can result in chassis leakage currents exceeding safe levels. Chassis leakage current and patient leakage current created by an accessory or device connected to a non isolated outlet may add to the chassis leakage current of the ultrasound system.

WARNING: Using an extension cord or multi socket outlet setup to provide power to the ultrasound system, or to the system's peripheral devices may compromise the system grounding and cause your system to exceed leakage current limits.

WARNING: To avoid electrical shock and damage to the ultrasound system, power off and unplug the equipment from the AC Mains power outlet before cleaning and disinfecting.

WARNING: To prevent excessive leakage current from contacting the patient, do not touch a user-accessible connector on the system while touching or scanning the patient. User-accessible connectors include connectors such as the USB connectors, and any other audio, video, or data transmission connectors.

WARNING: Connecting peripheral devices to accessory outlets on the ultrasound system effectively creates a medical electrical system, resulting in a reduced level of safety.

WARNING: No modification of this equipment is allowed.

WARNING: Do not remove system covers. There are no operator serviceable parts inside. Refer servicing to qualified personnel.

WARNING: To avoid the risk of electrical shock and fire hazard, inspect the system probes and console on a regular basis for any damage to the enclosure, controls, connectors or display, and do not use if damaged. Electrical safety tests must also be performed at regular intervals as specified by local safety regulations, or as needed.

WARNING: To avoid the risk of electrical shock do not touch the probe battery recharging contacts on the system console.

CAUTION: To avoid the possibility of static shock and damage to the ultrasound system, avoid the use of aerosol spray cleaners on the monitor screens.

CAUTION: Do not use spray cleaners on the ultrasound system, as this may force cleaning fluid into the system and damage electronic components. It is also possible for the solvent fumes to build up and form flammable gases or damage internal components.

CAUTION: Do not pour any fluid onto the ultrasound system surfaces, as fluid seepage into the electrical circuitry may cause excessive leakage current or system failure.

CAUTION: To ensure proper grounding and leakage current levels, it is the policy of Siemens to have an authorized Siemens representative or Siemens approved third party perform all on board connections of documentation and storage devices to the ultrasound system.

CAUTION: To avoid the risk of electrical shock and fire hazard, inspect the system probes and console on a regular basis for any damage to the enclosure, controls, connectors or display, and do not use if damaged. Electrical safety tests must also be performed at regular intervals as specified by local safety regulations, or as needed.
EMC Note: Proximity to sources of strong electromagnetic fields, such as radio transmitter stations or similar installations may lead to interference visible on the monitor screen. However, the device has been designed and tested to withstand such interference and will not be permanently damaged.

CAUTION: Total system chassis risk current should not exceed 100 microamps.

CAUTION: Do not position the system to make it difficult to disconnect the power cable connector/plug.

CAUTION: If the probe overtemp or probe battery overtemp message appears, the system will stop imaging and the image will be frozen. **Unfreeze** will not function until the overtemp condition terminates.

Level of Protection Against Electrical Shock for Probes

According to EN 60601-1 and IEC 60601-1, the assemblies for the probes provide a “Level of Protection Against Electrical Shock” of “Type B.”

The Type B icon is located on the probe and probe connector labels

Defibrillators

WARNING: To avoid the risk of injury to the operator, remove the probe from patient contact before the application of a high-voltage defibrillation pulse.

For patient safety, be sure to use defibrillators that do not have grounded patient circuits.

Implantable Devices

WARNING: Ultrasound systems, like other medical equipment, use high-frequency electrical signals that can interfere with implantable devices such as pacemakers and implantable cardioverter-defibrillators (ICDs). If the patient has such an implantable device, you should be aware of any interference in its operation and immediately power off the ultrasound system.

WARNING: The probe battery and Probe Adapter Cable well at the back of the probe, away from the transducer end (see illustration) into which the probe battery or Probe Adapter Cable are placed, contains magnets used to secure the probe battery and Probe Adapter Cable. Keep this end of the probe at least 3 cm (1.3 inches) away from implanted cardiac rhythm devices.

Probe battery/Probe Adapter Cable well

1. Probe battery/Probe Adapter Cable well
2. Location of magnets

Possible Combinations with Other Equipment and Peripheral Equipment

WARNING: Accessory equipment connected to the analog and digital interfaces must be certified according to the respective EN and IEC standards (for example, EN 60950 and IEC 60950 for data processing equipment and EN 60601-1 and IEC 60601-1 for medical equipment). Furthermore, all configurations shall comply with the system standards EN 60601-1-1 and IEC 60601-1-1. Anyone who connects additional equipment to the signal input or signal output port configures a medical system and is therefore responsible that the system complies with the requirements of the system standards EN 60601-1-1 and IEC 60601-1-1. Siemens can only guarantee the performance and safety of the devices recommended by Siemens. If in doubt, consult the Siemens service department or your local Siemens representative.

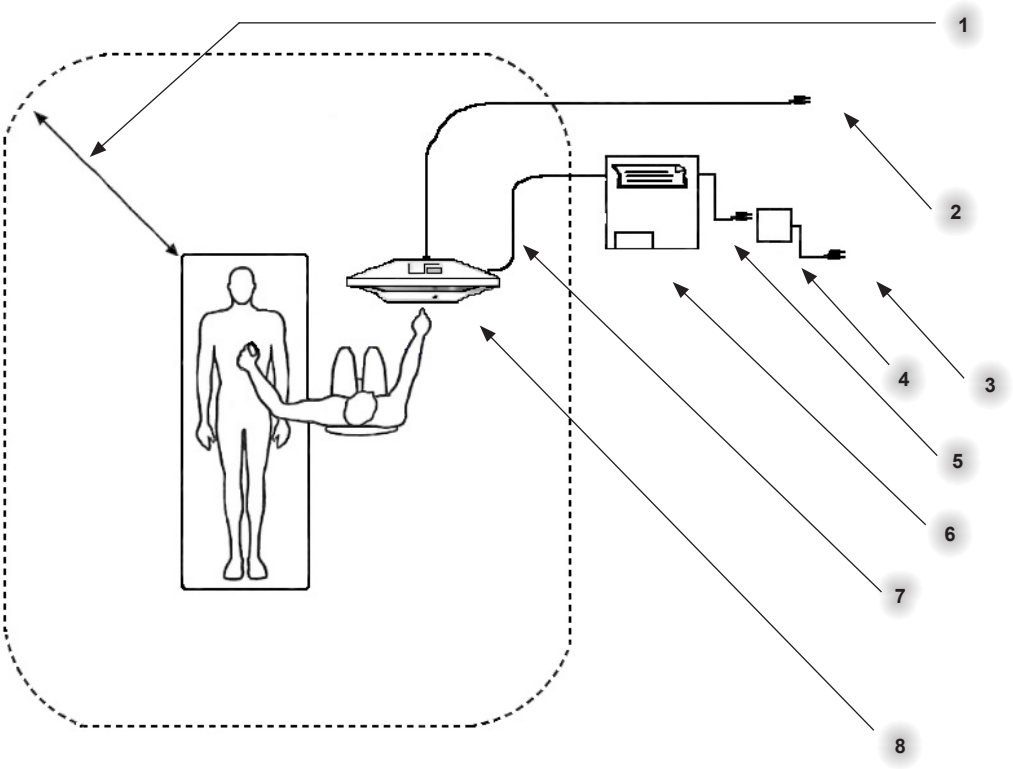
WARNING: Do not use an accessory or peripheral device, such as an external monitor within 1.5 meters (1.83 meters [6 feet] in Canada and the U.S.A.) of a patient (beyond the perimeter of the bed — examination table, treatment surface, and the like) and extending vertically 2.29 meters (7.5 feet) above the floor, unless the device receives power from an isolation transformer that meets medical safety standards.

The ultrasound system supports a maximum of two documentation or storage devices connected to the system. Siemens recommends that you power off each device whenever the system is powered off.

CAUTION: Any on-board peripheral devices must be installed by an authorized Siemens representative or by a Siemens-approved third party. Devices installed by other people will be at the user's risk and may void the system warranty.

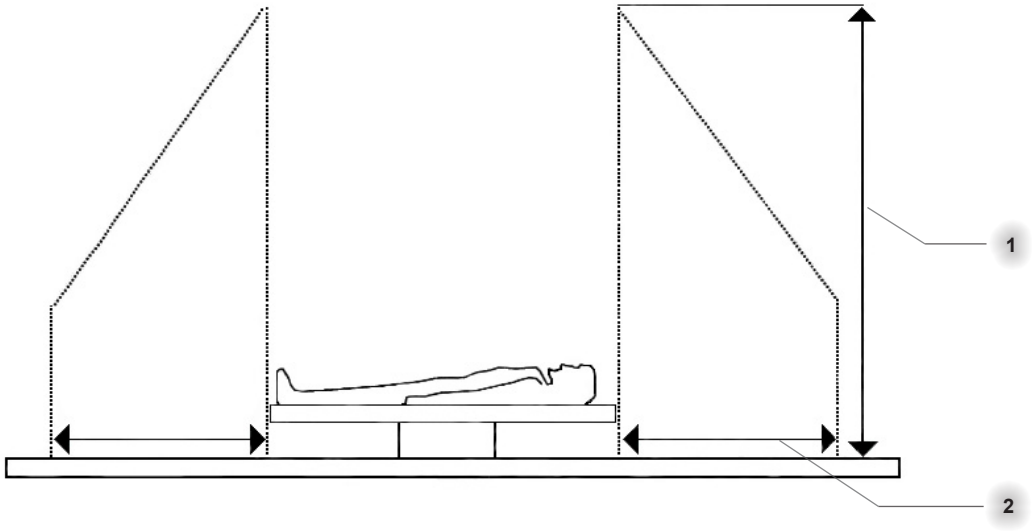
In order to fulfill EN 60601-1-1 and IEC 60601-1-1 (Medical Electrical Equipment, Part 1: General Requirements for Safety) requirements, connection of peripheral equipment to your ultrasound system much adhere to one of the following conditions:

- The peripheral equipment itself is a medical device approved according to EN 60601-1 and IEC 60601-1, or
- Non-medical peripheral equipment approved according to any other EN or IEC standard (EN XXXXX or IEC XXXXX, e.g., equipment complying with EN 60348 and IEC 60348, EN 60950 and IEC 60950, etc.) must use the following setup for connection:
  - The peripheral equipment is located at least 1.5 meters (1.83 meters [6 feet] in Canada and the U.S.A.) outside the patient environment and extending vertically 2.29 meters (7.5 feet) above the floor. A patient environment is defined as the area in which medical examination, monitoring, or treatment of the patient takes place (examination table, treatment surface, and the like).
  - The peripheral equipment is connected to a main outlet outside the patient environment but still within the same room as the ultrasound system
  - The peripheral equipment is connected to the ultrasound system using isolation adapters.



Example of a peripheral equipment connection and patient environment

1. Patient environment represented by area within the dashed line, extending exactly 1.5 meters (1.83 meters [6 feet] in Canada and in the U.S.A.) around patient and ultrasound system
2. Ultrasound system power cord
3. Medically-approved isolation transformer power cord
4. Medically-approved isolation transformer
5. Peripheral equipment power cord
6. Non-medical peripheral equipment
7. Peripheral equipment connections cable
8. Ultrasound system



Example of a peripheral equipment connection and patient environment

1. 2.29 meters
2. 1.5 meters (1.83 meters [6 feet] in Canada and the U.S.A.)

Important Information for Maintaining Data Integrity

CAUTION: To prevent corruption of data stored on inserted media, do not interrupt the exporting process. Do not delete exported patient data from the local database until the exporting process is complete and the inserted media is determined to be full (or no more exporting is planned for the inserted media).

- To prevent the loss of data that results from power failures and other system “down” occurrences, you must archive important data, such as patient records, onto a network or an external recording medium, such as a USB, or DICOM storage device.
- Loss of data is to be expected and its retrieval is not normally possible under the following conditions: loss of power to the ultrasound system, hard disk failure, CPU failure, system lockup, and other similar causes.
- Should an abnormal system shutdown occur, retrieval of data not saved to the hard disk or not archived to an external recording media is not normally possible.
- An abnormal system shutdown occurs if you do not power off the ultrasound system using the power on/off key located on the control panel. Other examples of abnormal system shutdown include:
  - Equipment malfunction
  - Loss of power
  - Accidental removal of the power cord
  - Pressing and holding the power on/off switch longer than four seconds
- Should an abnormal system shutdown occur, the system may initially require additional time to reboot or to respond to user input.

Caring for the Ultrasound System

It is the responsibility of the user to verify that the ultrasound system is safe for diagnostic operation on a daily basis. Each day, prior to using the system, perform each of the steps in the Daily Checklist.

All exterior parts of the ultrasound system, including the control panel, keyboard, system accessories, probes, and probe accessories, should be cleaned and/or disinfected as necessary or between uses. Clean each component to remove any surface particles. Disinfect components to kill vegetative organisms and viruses.

Daily Checklist

WARNING: To minimize the risk of cross contamination and infectious diseases, a sterile, non pyrogenic probe sheath must be in place during procedures requiring sterility.

WARNING: To avoid electrical shock, you must visually inspect a probe prior to use. Do not use a probe that has a cracked or punctured casing or a frayed Probe Adapter Cable.

Discoloration Exception: The use of the approved disinfectants may cause discoloration of probe housings, including the face of the probe. You can continue to use a probe if it is discolored due to the use of these specific disinfectants only.

Perform the following each day before using the ultrasound system:

- Visually inspect all probes. Do not use a probe that has a cracked or punctured casing or a frayed Probe Adapter Cable.
- Visually inspect all power cords. Do not power on the ultrasound system if a cord is frayed or split, or shows signs of wear.
- Verify that the Trackball, Rotary knobs, Soft Keys, and other controls on the control panel appear clean and free from gel or other contaminants.

Once the ultrasound system is powered on:

- Visually check the on screen displays and lighting.
- Verify that the monitor displays the current date and time.
- Verify that the probe identification and indicated frequency are correct for the active probe.

Maintenance

CAUTION: Electrical safety tests must also be performed at regular intervals as specified by local safety regulations, or as needed.

Repair

WARNING: No modification of this equipment is allowed.

For questions regarding repair or replacement of any equipment parts on your system, contact your Siemens service representative.

Siemens Authorized Care

Installers and operators must observe any statutory regulations that govern the installation, operation, inspection, and maintenance of this equipment.

Perform inspections and maintenance at the prescribed intervals to avoid worn and hazardous parts due to wear.

As manufacturers and installers of ultrasound equipment, Siemens cannot assume responsibility for the safety properties, reliability, and/or performance of the equipment, if:

- Installations, extensions, readjustments, modifications, additions, or repairs are carried out by persons not specifically authorized by Siemens.
- Components that affect the safe operation of the system are replaced by parts not authorized by Siemens.
- The electrical installation of the room where the equipment is located does not meet the power and environmental requirements stated in this manual.
- The equipment is not used in accordance with the operating instructions.
- The system is operated by personnel not adequately educated or trained.

Siemens suggests that you request any person who performs maintenance or repairs to provide you with a certificate showing:

- The nature and extent of the work performed
- Changes in rated performance
- Changes in working ranges
- Date of service
- Name of person or firm performing the service
- Signature of person performing the service

Technical documentation pertinent to the ultrasound system is available at an additional charge. However, this does not in any way constitute an authorization to conduct repairs or maintenance. Siemens refuses all responsibility whatsoever for repairs that are performed without the express written consent of the Siemens service department.

Cleaning and Disinfecting

You must take all necessary precautions to eliminate the possibility of exposing patients, operators, or third parties to hazardous or infectious materials. Use universal precautions when cleaning and disinfecting. You should treat all portions of the ultrasound system that come in contact with human blood or other body fluids as if they were known to be infectious.

All exterior parts of the ultrasound system, including the control panel, system accessories, probes, and probe accessories, should be cleaned and/or disinfected as necessary or between uses. Clean each component to remove any surface particles. Disinfect components to kill vegetative organisms and viruses.

Cleaning and Disinfecting Ultrasound System Surfaces

WARNING: To avoid electrical shock and damage to the ultrasound system, power off and unplug the equipment from the AC power outlet before cleaning and disinfecting.

WARNING: Disinfectants and cleaning methods listed are recommended by Siemens for compatibility with product materials, not for biological effectiveness. Refer to disinfectant label instructions for guidance on disinfection efficacy and appropriate clinical uses.

WARNING: Do not immerse any part of the system console in Liquid.

WARNING: Always wear protective clothing, including eye wear and gloves, when performing cleaning and disinfection.

WARNING: The use of any disinfectants other than those specified in the instructions for use may damage the ultrasound system and accessory surfaces and, as a result, may create electrical hazards for the patients and/or users.

CAUTION: To avoid the possibility of static shock and damage to the ultrasound system, avoid the use of aerosol spray cleaners on the monitor screen.

CAUTION: Do not clean the ultrasound system with chlorinated or aromatic solvents, acidic or basic solutions, isopropyl alcohol or strong cleaners such as ammoniated products, as these can damage the surface of the system. Use of unapproved cleaners or disinfectants can result in severe damage to the ultrasound system components. Use the recommended cleaning procedure.

CAUTION: Do not use spray cleaners on the ultrasound system, as this may force cleaning fluid into the system and damage electronic components. It is also possible for the solvent fumes to build up and form flammable gases or damage internal components.

CAUTION: Do not pour any fluid onto the ultrasound system surfaces, as fluid seepage into the electrical circuitry may cause excessive leakage current or system failure.

CAUTION: Do not use abrasive cloths or brushes when cleaning any part of the system. Use only soft cloths, gauze pads, or brushes. Apply solutions to the cloth, not the system.

CAUTION: To clean the lens cover of the system display monitor, use only a soft cloth lightly moistened with a mild lens or glass cleaner. Using other cleaners may damage the display and void the warranty.

The following instructions describe cleaning the surface of the ultrasound system, including the Trackball and probe holder. See also, “Approved Disinfectant Wipes for the Ultrasound System Surfaces” on page 2-27.

To	*Do This*
Clean and disinfect the surface of the ultrasound system	1. Power off the ultrasound system and unplug the power cord from the power outlet. 2. Use a clean gauze pad or lint-free cloth, lightly moistened with a mild detergent, to wipe the surface of the ultrasound system. Take particular care to clean the areas near the Trackball, Soft Keys, and Rotary knobs. Ensure these areas are free of coupling agent (gel) and any other visible residue. Ensure that cleaning solution does not seep into the control panel, or any other openings. 3. After cleaning, use a clean, lint-free cloth to dry the surface. 4. As required, use an approved disinfectant wipe to disinfect the ultrasound system and accessories. 5. Reconnect the ultrasound system power cord into the power outlet.
Clean and disinfect the holders for probes	1. Remove the holder from the ultrasound system. a. Squeeze the tab at the top of the probe holder away from the system console and pull the holder upward. 2. Clean the holder under running water, using a mild detergent, and dry with a lint free cloth. 3. As required, use an approved disinfectant wipe to disinfect the holder. 4. Reattach the holder to the ultrasound system pressing downward until the tab clicks into place.
Clean and disinfect the Trackball	**CAUTION:** Do not drop or place foreign objects inside the Trackball assembly because doing so may affect the Trackball operation and damage the ultrasound system. 1. Rotate the Trackball bezel counterclockwise and lift up to remove the Trackball bezel from the control panel. 2. Carefully remove the Trackball from the control panel. 3. Clean the bezel and Trackball with a cotton swab or lint free pad moistened with mild detergent solution. 4. Clean the inside of the Trackball assembly using a cotton swab moistened with mild detergent solution. 5. As required, use an approved disinfectant wipe to disinfect the Trackball, Trackball bezel, and Trackball assembly. 6. Allow the Trackball components to completely dry before reassembly. 7. Reinstall the Trackball and replace the Trackball bezel. a. Place the Trackball inside the Trackball assembly. b. Place the Trackball bezel over the Trackball. c. Rotate the Trackball bezel to tighten. Do not overtighten the Trackball bezel.

Approved Disinfectant Wipes for the Ultrasound System Surfaces

The following matrix provides a list of approved disinfectant wipes for use on the ultrasound system and surfaces of the listed accessories.

	Sani-Cloth®	*Sani-Cloth® Bleach Wipe**	*Sani-Cloth® HB*	*Sani-Cloth® Plus*	*Super Sani-Cloth®*	*Sani-Cloth® AF3*	*Protex® Ultra*	*Clorox Healthcare® Hydrogen Peroxide Wipe*	*Transeptic® Spray*
Ultrasound System	✓	✓	✓	✓	✓	✓	✓	✓	✓
Probe Holders	✓	✓	✓	✓	✓	✓	✓	✓	✓
Trackball Assembly	✓	✓	✓	✓	✓	✓	✓	✓	
Monitor Screen						✓	✓	✓	
Deluxe Roll Stand		✓			✓	✓		✓	

**or any bleach wipe with <1% sodium hypochlorite and no other active ingredients*

✓ = Compatible

See also: For an additional list of approved disinfectants, refer to the “Approved List of Disinfectants” on page 2-33.

Caring for Documentation and Storage Devices

For information on the care of an optional documentation or storage device, refer to the manufacturer’s operating instructions that accompanied the device.

Caring for Probes

CAUTION: Probes are sensitive instruments — irreparable damage may occur if they are dropped, knocked against other objects, cut, or punctured. Do not attempt to repair or alter any part of a probe, contact your local Siemens representative.

CAUTION: To avoid cable damage, do not roll the ultrasound system over Probe Adapter Cables.

CAUTION: To avoid damage to the probe, do not use probe sheaths containing an oil based coating or petroleum or mineral oil based ultrasound coupling agents. Use only a water based ultrasound coupling agent.

CAUTION: Follow all instructions provided by manufacturers of sterile goods (probe sheaths) to ensure proper handling, storage, and cycling of all sterile goods.

CAUTION: Take extreme care when handling or storing probes. They must not be dropped, jarred, or knocked against other objects. Do not allow probes to come into contact with any sharp edged or pointed object.

WARNING: Verify that the probe battery pack and either the probe battery receptacle or the System charging bays are free of any liquid, gels, or contaminants before inserting the battery. Inserting a battery into the probe or charger bays when liquid, gel, or contaminants are present could cause harm to the probe and/or system.

Protective Case

Due to the mechanical sensitivity of probes, Siemens recommends that you always use the probe case when you ship a probe or transport it from one place of examination to another. The case is specially designed to protect the sensitive parts of the probe. Be sure that all parts of the probe are properly placed inside the case before you close the lid.

Storage

Store probes in a clean and dry environment. Extreme temperatures or humidity may damage a probe.

Repair

Do not attempt to repair or alter any part of the probe. Contact your service representative at Siemens immediately if a probe appears to be damaged or malfunctions in any way.

Cleaning and Disinfecting Probes

WARNING: Before cleaning and disinfecting, you must read and understand the cleaning and disinfecting topic, including the warnings and cautions for cleaning and disinfecting ultrasound system surfaces provided in this chapter.

WARNING: Follow the instructions in this chapter, and your institution's procedures to avoid risk of infection.

NOTE: An accepted method of infection control for critical use is high-level disinfection and the use of a sterile gel and a sterile probe cover. (See US FDA Guidance document, "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers" dated September 9, 2008 at www.fda.gov/downloads.) Use only sterile, legally marketed probe sheaths for semi-critical or critical applications.

WARNING: Do not attempt to sterilize a transducer using steam, autoclaving, ultraviolet, gamma radiation, dry heat, ethylene oxide, or other methods.

WARNING: Unless explicitly stated otherwise, ACUSON Freestyle transducers are not indicated or intended for endo-scanning uses.

WARNING: Always wear protective clothing, including eye wear and gloves, when performing cleaning and disinfection.

WARNING: Clean the probe modules by hand. Do not use an ultrasonic cleaner or automatic washer.

WARNING: Inspect transducers for signs of wear or damage prior to use and prior to cleaning, disinfection, or sterilization. Do not process a probe that exhibits signs of wear or damage, such as cracks or fractures in the enclosure.

CAUTION: The ACUSON Freestyle is designed to operate in the same room as X-ray equipment. However, ACUSON Freestyle probes contain sensitive electronic components not found in conventional cabled probes. Avoid leaving probes directly in the active X-ray beams.

WARNING: To avoid electrical shock and damage to the system, power down and disconnect the probe prior to cleaning or disinfecting.

WARNING: To avoid electrical shock and damage to the system, remove the probe battery or the Probe Adapter Cable from the probe prior to cleaning or disinfecting.

WARNING: Disinfectants and cleaning methods listed are recommended by Siemens for compatibility with product materials, not for biological effectiveness. Refer to disinfectant label instructions for guidance on disinfection efficacy and appropriate clinical uses.

CAUTION: Before applying any other methods that might be recommended by manufacturers of sterilization equipment, please contact your Siemens representative.

CAUTION: To avoid damage to the probe, do not immerse or allow the Probe Adapter Cable or connector of a probe to become wet.

CAUTION: The probes have been designed and tested to be able to withstand high level disinfection as recommended by the manufacturers of approved disinfectant products. Carefully follow the disinfectant manufacturer's instructions. Do not immerse for more than one hour.

CAUTION: Do not use abrasive cleaning agents, organic solvents such as benzene, isopropyl alcohol, or phenol based substances, or cleaning agents containing organic solvents to clean or disinfect probes. These substances can damage the probes.

CAUTION: Prior to cleaning or disinfecting a probe, you must remove the probe battery and disconnect the Probe Adapter Cable and remove the probe from the ultrasound system. To prevent the probe cleaners or disinfectants from contacting and damaging the ultrasound system surfaces, do not clean the probe on or near the ultrasound system. Approved probe cleaners and disinfectants are not approved for use on the ultrasound system surfaces. Unintended contact with approved probe cleaners and disinfectants can result severe damage to the ultrasound system components.

All probes should be cleaned and disinfected prior to their use on each patient.

Probe General Cleaning (including Low Level Disinfection):

Clean probes (including low level disinfection) after every patient use, including non-critical applications. Do not allow body fluids, such as blood, to dry on the probe.

Routine cleaning steps are as follows:

1. Immediately after completing the exam, turn the probe off and remove the battery module. Process the pieces separately.
2. Wipe the gel off the probe with a soft cloth.
3. Use a soft brush, sponge, or gauze pad lightly moistened in an enzymatic detergent(in accordance with the manufacturer's instructions) to remove all gel, particulate matter, or bodily fluids from all components and surfaces. Carefully clean any crevices, corners or seams.
4. Rinse with quality running water, and dry with a soft cloth or gauze pad.
5. Thoroughly examine and visually inspect all surfaces that have been cleaned to make sure that they are clean. If visible debris is noticed, repeat Steps 3 and 4.
6. Immediately rinse the probe thoroughly with sterile water, then pat dry with a clean soft cloth or gauze pad.

CAUTION: Do not run the Probe Adapter Cable under water. Instead wipe with a lightly moistened sponge or gauze pad.

Probe High Level Disinfection

Preparation

Follow the Cleaning instructions above prior to high-level probe disinfection.

High-Level Disinfection

Soak the probe using a compatible disinfectant (listed below), following the manufacturer's instructions and specifications.

CAUTION: When disinfecting probes, only immerse in approved disinfectants and follow manufacturer's instructions. Do not immerse Probe Adapter Cable.

CAUTION: Strictly follow the instructions of the disinfectant manufacturer, and limit the time probes are soaked to the minimum time recommended by the disinfectant manufacturer. Follow the disinfectant manufacturer's instructions for rinsing and drying after disinfection.

CAUTION: Do not use strong solvents such as acetone, Freon, and other industrial cleaners on transducers.

Liquid Immersion

The IPX8 specification for water immersion is a depth of 1 meter for one hour. Do not immerse probe while mated to battery or Probe Adapter Cable. The probe and battery pack can separately be fully immersed in water and approved disinfectants following the disinfectants manufacturer's instructions. Do not immerse the Probe Adapter Cable; wipe it with a cloth. Do not continuously immerse the entire probe or battery pack.

Approved List of Disinfectants

The following matrix tables provide a list of approved disinfectants for all probes and batteries.

> **NOTE:** The approved disinfectants may discolor probe housings, including the face of the probe. There is no associated degradation of imaging performance or probe reliability.

Compatible Disinfectants for the System Console and Probe are listed below. Use of disinfectants not listed may cause damage to the system and void the warranty.

Tested Cleaner & Disinfectant	Probes							
	L8-3 (Part Number 11001401)	L8-3 (Part Number 11004317)	L13-5 (Part Number 11001402)	L13-5 (Part Number 11004329)	L17-5 (Part Number 11003880)	L17-5 (Part Number 11004318)	C5-2 (Part Number 11001403)	C5-2 (Part Number 11003875)
Sani-Cloth® Bleach Wipe	✓	✓	✓	✓	✓	✓	✓	✓
Super Sani-Cloth®	✓	✓	✓	✓	✓	✓	✓	✓
Sani-Cloth® AF3	✓	✓	✓	✓	✓	✓	✓	✓
Protex® Ultra Disinfectant Wipes	✓	✓	✓	✓	✓	✓	✓	✓
Clorox Healthcare® Hydrogen Peroxide Cleaner Disinfectant Wipe	✓	✓	✓	✓	✓	✓	✓	—
Clorox Healthcare® Bleach Germicide Cleaner	✓	✓	✓	✓	✓	✓	✓	✓
Enzol®	✓	✓	✓	✓	✓	✓	✓	✓

Tested Cleaner & Disinfectant	Battery (Part Number 11001411)		
	< Serial Number 199999	> Serial Number 200000	> Serial Number 300000
Sani-Cloth® Bleach Wipe	N/A	✓	✓
Super Sani-Cloth®	N/A	✓	✓
Sani-Cloth® AF3	N/A	✓	✓
Protex® Ultra Disinfectant Wipes	N/A	✓	✓
Clorox Healthcare® Hydrogen Peroxide Cleaner Disinfectant Wipe	N/A	✓	✓
Clorox Healthcare® Bleach Germicide Cleaner	N/A	✓	✓
Enzol®	N/A	✓	✓

* N/A = Not Applicable

Caring for Probe Accessories

Instructions are provided for the accessories.

Probe Sheaths

WARNING: There have been reports of severe allergic reactions to medical devices containing latex (natural rubber). Health care professionals are advised to identify latex sensitive patients and to be prepared to treat allergic reactions promptly. For additional information in the U.S.A., refer to FDA Medical Alert MDA91 1. In the United States of America, for a single copy of a reference list on latex sensitivity write to LATEX, FDA, HFZ-220, Rockville, MD 20857.

WARNING: To minimize the risk of cross contamination and infectious diseases, a sterile, non pyrogenic probe sheath must be in place during procedures requiring sterility.

WARNING: Only a sterile probe sheath provides the sterile barrier required for surgical procedures. To ensure sterility of a procedure, always place a sterile sheath on a probe, as probes cannot be sterilized using hot steam, cold gas, or Ethylene Oxide (EO) methods.

CAUTION: Siemens recommends that you follow all instructions provided by manufacturers of sterile goods (probe sheaths) to ensure proper handling, storage, and cycling of all sterile goods.

Using a disposable probe sheath on a probe reduces the possibility of cross contamination. Always use a protective probe sheath when scanning an open wound or an area where the skin is not intact.

Storage

WARNING: Before use, examine sterile goods, such as sheaths, for any material flaws. Some packaging may list an expiration date. Any product showing flaws, or whose expiration date has passed, should not be used.

CAUTION: Do not store probe sheaths in direct sunlight, as ultraviolet damage can result.

Latex products have a limited shelf life, and should be stored in a cool, dry, dark place with an ambient temperature between -5°C and +40°C and up to 80% relative humidity at +40°C.

Recommended Use of the Probe Sheaths

Siemens makes every effort to manufacture safe and effective probes. You must take all necessary precautions to eliminate the possibility of exposing patients, operators, or third parties to hazardous or infectious materials. These precautions should be considered in the use of any application that may indicate the need for such care, for example, when scanning patients with open wounds.

Probe sheaths are single use items used to ensure proper acoustic coupling and provide a prophylactic barrier for the intended ultrasound application. Sheaths are available for all probes. Use only market cleared probe sheaths.

Application

WARNING: After placing the sheath over the probe, visually inspect the sheath to ensure there are no defects. Do not use the sheath if it has any holes or tears.

WARNING: Carefully follow the labeling instructions provided with the probe sheath.

Disposal

While wearing protective gloves, remove the probe sheath from the probe and dispose of it according to local, state, and regional regulations for biohazardous waste.

Purchasing Probe Sheaths

CIV-Flex™ Covers (CIVCO Product Number 610-1212) are manufactured by CIVCO Medical Solutions and can be purchased by contacting the Customer Care Representative at your local Siemens office. Go to https://www.healthcare.siemens.com to locate your local Siemens office. The Siemens part number is 11003358.

Battery Safety

The ACUSON Freestyle contains rechargeable lithium ion batteries in the System Console. These batteries are not accessible by the operator and may only be replaced or serviced by a qualified service technician.

The ACUSON Freestyle probe also utilizes a rechargeable lithium ion battery. This is enclosed in the removable battery pack.

To prevent the probe battery from bursting, igniting, or emitting fumes and causing personal injury or equipment damage, observe the following precautions.

WARNING: Use only batteries supplied by Siemens Medical Solutions USA, Inc. with the system and probe.

WARNING: Do not disassemble or alter the battery pack or remove the casing of the pack.

WARNING: The battery contains safety circuitry and features. Do not disassemble or alter the battery.

WARNING: Charge batteries only when the ambient temperature is between 0º and 40º C (32º and 104º F).

WARNING: Do not short-circuit the battery by directly connecting the positive and negative terminals with metal objects.

WARNING: Do not heat the battery or discard it in a fire.

WARNING: Do not use a defective battery or a battery that appears to be malfunctioning or not holding a charge. Replace such batteries.

WARNING: Do not expose the battery to temperatures over 60º C (140º F). Keep it away from fire and other heat sources.

WARNING: Do not leave the battery in direct sunlight.

WARNING: Do not pierce the battery with a sharp object, hit it, or step on it.

WARNING: Do not use a damaged battery, or a battery pack with cracks or damage to the casing.

WARNING: Do not solder a battery

WARNING: The polarity of the battery terminals is fixed and cannot be switched or reversed.

WARNING: Do not force the battery into its compartment in the probe.

WARNING: Do not connect the battery to an electrical power outlet.

WARNING: Do not continue to recharge a battery if it does not recharge properly after two successive six hour charging cycles.

WARNING: If the battery leaks or emits an odor, remove it from all possible flammable sources.

WARNING: Do not attempt to recharge non-rechargeable batteries, such as the batteries included on printed circuit boards. Recycle non-rechargeable batteries according to local, state, and regional regulations.

CAUTION: Remove the battery from the probe if the probe is not likely to be used for an extended period. Prior to storage charge or discharge the battery to approximately 50% of capacity.

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

CAUTION: Do not immerse the battery in liquid if it is damaged or the housing is cracked.

CAUTION: Do not immerse the battery in any liquid not listed in this “Safety and Care” chapter and do not submerge a battery beyond the time periods specified in the instructions for recommended disinfectants.

CAUTION: If the battery emits an odor or heat, is deformed or discolored, or in any way appears abnormal, immediately remove it from use.

CAUTION: Do not put the battery into a microwave oven or pressurized container.

CAUTION: Store the battery between –20º C to 60º C (–4º F to 140º F).

CAUTION: Use only Siemens-supplied batteries and charging devices.

Good Ergonomic Practices

WARNING: The operation of an ultrasound system may to linked to musculoskeletal disorders (MSDs).

In ultrasound imaging, ergonomics may be defined as the physical interaction between the operator, the system, and the transducer, in the course of conducting exams. It is important for the operator of the system to practice good ergonomic techniques to reduce the risk of injury. This chapter is intended to provide guidelines to help you work more comfortably in order to possibly reduce the risk of musculoskeletal disorders.

When using an ultrasound system, as with many similar physical activities, you may experience occasional discomfort in your hands, fingers, arms, shoulders, eyes, neck, back, or other parts of your body. If you experience symptoms such as constant or recurring discomfort, pain, throbbing, aching, tingling, numbness, burning sensation, or stiffness, you should promptly consult a qualified health professional. These may be symptoms of MSD. MSDs can be painful and may result in potentially disabling injuries to the nerves, muscles, tendons, joints, or other parts of the body. Examples of MSDs include carpal tunnel syndrome and tendonitis.

Steps you can take to guard against discomfort while scanning, or the risk of MSD are described here. It is also recommended that you consult the guidelines of professional medical societies concerned with ultrasound.

Interrupt Scanning

Interrupt scanning frequently, using breaks to rest and give soft tissue a chance to recuperate from the strained positions and repetitive movements of examinations.

While scanning, avoid maintaining the same body position for extended periods of time, by moving and varying head, neck, body, arm, and leg positions.

Positioning

Avoid bending or stooping.

Adjust the position of the ACUSON Freestyle such that viewing or reaching the controls does not require strained or awkward body positions.

Whenever possible, use an adjustable chair with good back support, and adjust chair height to promote good body posture. If possible, adjust the height of the patient bed to optimize body posture.

Maintain a comfortable and balanced body position with minimal stress on your joints, minimizing bending and twisting.

Keep elbows close to your side and relax your shoulders in a level position.

Hand and Wrist

Do not grasp the transducer with excessive force; hold it as lightly as possible.

Minimize the amount of pressure applied when pressing the transducer against the patient.

Avoid or minimize bending your wrist.

Exercise and Stretching

Targeted exercises and stretching may help avoid the risk of MSDs. Consult with a qualified health professional to define a program suited to your needs and practices.

Moving the System

The ultrasound system is a mobile unit. Before moving the system to another location, you must prepare for the move by powering off and securing the system.

Unplug the power cord plug from the wall outlet. Pull on the plug, not the cord. Disconnect the Ethernet cables from the ultrasound system.

Secure components such as the power cord, probes, and gel.

WARNING: When operating and transporting the ultrasound system using the ACUSON Freestyle Rollstand, insure that the rollstand is configured according to the specifications provided in this manual. Failure to do so can cause the system to tip over and create a risk for injury to the user or patient and damage to the system.

WARNING: Do not tip the system in any direction more than 10 degrees. This action can cause the system to tip over and create a risk for injury to the user or patient and damage to the system.

WARNING: Preparations before moving the system are important to minimize potential damage to sensitive components and to avoid safety hazards. Review the moving instructions before moving the system.

WARNING: Do not park or leave the ultrasound system unattended on a slope. Even when the brakes are engaged, the system may slide down a ramp.

WARNING: When using the system in a tabletop use, pull out the tilt stand on the rear of the unit to position it securely. Make sure the stand is placed securely on an even surface where the system will not be accidentally pushed.

CAUTION: When moving the ultrasound system, protect if from environmental changes including : moisture, winds, dirt and dust, and extreme heat or cold exposure.

CAUTION: Avoid moving the ultrasound system on outside surfaces with loose dirt, contaminants, or standing liquids.

CAUTION: Care should be taken to minimize shock and vibration of the ultrasound system. Avoid uneven surfaces that contain an abrupt height change or jarring surface irregularities.

CAUTION: After the move, make sure the ultrasound system has proper ventilation during operation. Do not position the system against walls or hard surfaces that would impede free ventilation around the system.

CAUTION: Do not allow linens, bedding, and/or hanging curtain partitions to block the ultrasound system’s ventilation.

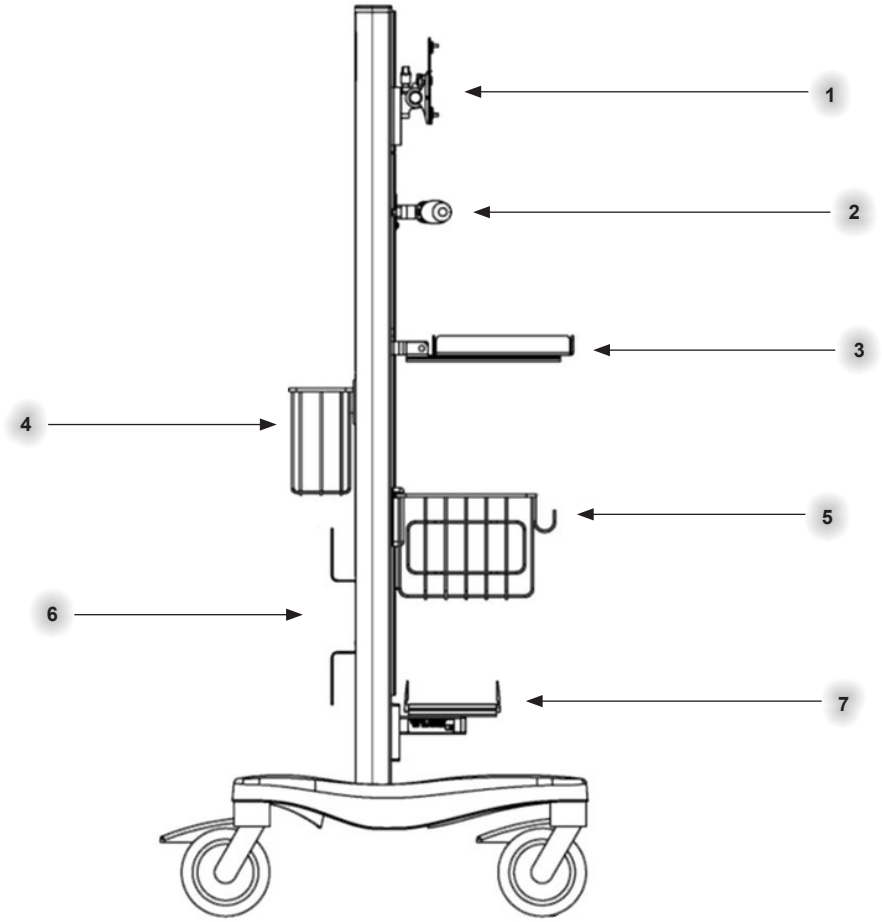
CAUTION: When moving the ultrasound system over longer distances, or shipping it, place it in the protective shipping case provided by Siemens and pack it according to the instructions.

CAUTION: When moving the ultrasound system over longer distances, remove probe batteries from the probes.

ACUSON Freestyle Rollstand Configuration

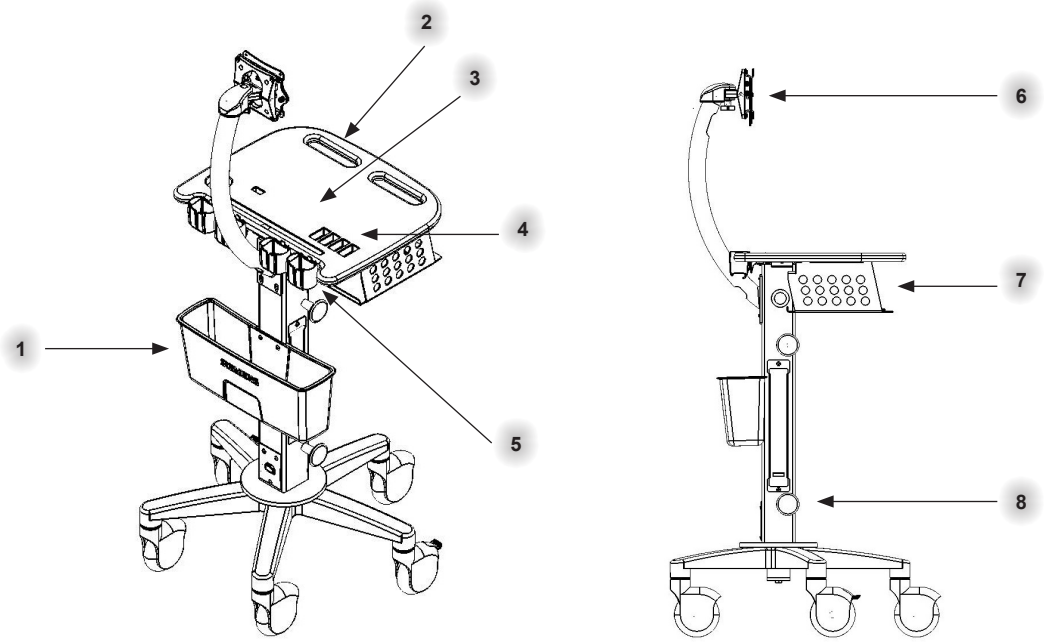
WARNING: When operating and transporting the ultrasound system using the ACUSON Freestyle Rollstand, insure that the rollstand is configured according to the specifications provided in this manual. Failure to do so can cause the system to tip over and create a risk for injury to the user or patient and damage to the system.

NOTE: Specific version of rollstand may vary.



GCX Rollstand Configuration

1. Quick Release Adaptor Plate: the top of the plate should be placed no higher than 48 in/122 cm. Do not place anything other than the ACUSON Freestyle, probe batteries, and probes on this mount.
2. Handle: the top of the Handle should be placed no higher than 40 in/101 cm from the floor.
3. Keyboard Shelf: should be placed no higher than 33 in/84 cm from the floor.
4. Rear Storage Basket: the top of the basket should be placed no higher than 30 in/76 cm from the floor. Weight limit 4 lbs/1.8 kg.
5. Front Storage Basket: top of basket should be placed no higher than 24 in/61 cm from the floor. Weight limit 4 lbs/1.8 kg.
6. Cable Wrap: should be placed no higher than 22 in/56 cm.
7. Video Printer Shelf: the shelf should be placed no higher than 12 in/30 cm from the floor. Weight limit 6 lbs/2.7 kg. Secure printer with straps.



Deluxe Rollstand Configuration

1. Rear Storage Basket
2. Built-in handles
3. Keyboard tray
4. ACUSON Freestyle Probe Battery storage
5. ACUSON Freestyle Probe storage
6. ACUSON Freestyle system mount with tilt and swivel
7. Video Printer Shelf (optional equipment)
8. Cable Wrap

System Upgrades

Performing System Software Upgrades

When performing system software upgrades, carefully follow the installation instructions that accompany the software.

CAUTION: Back up or archive any patient studies that may be stored on the system prior to performing a software upgrade.

CAUTION: Do not terminate power during a software upgrade or otherwise interrupt a software upgrade. This may cause the system not to operate and may require system servicing. When conducting a software upgrade, operate the system on AC Mains power outlet and make sure the system battery is fully charged.

Consult your service representative or help desk contact with any questions you may have regarding software upgrades.

Green Performance Management: Environmental Protection

Product Recycling and Disposal

Dispose of this product according to local, state, and regional regulations.

Batteries and electrical and electronic equipment can contain hazardous substances. If released, the hazardous substances can harm people and the environment.

Siemens provides disassembly instructions to treatment facilities for the safe and proper removal and recycling of electrical and electronic components in this product. For more information, contact your local Siemens representative.

To the extent required by local laws and regulations, Siemens has programs for the return of used products. For more information, contact your local Siemens representative.

Recycling Batteries

WARNING: Never dispose of batteries by burning or by flushing into any waste water system, for example, a lavatory. Compromising the structural integrity of a battery can result in leakage or explosion and the potential for personal injury.

WARNING: Do not throw batteries into the trash. Collect and recycle used batteries separate from other waste.

The system does not contain alkaline batteries. Printed circuit boards may contain lithium batteries. If the system clock no longer keeps time, it could be time to replace the battery. Contact your local Siemens representative.

Recycle batteries according to local, state, and regional regulations. Use a battery collection program available in your country to recycle batteries.

To the extent required by local laws and regulations, Siemens will collect and recycle batteries for this product at no charge. Contact your local Siemens representative for battery shipment instructions.

Disposing of the Packaging Materials

Dispose of or recycle the packaging materials according to local, state, and regional regulations.

To the extent required by local laws and regulations, Siemens will collect and dispose of packaging materials for this product. For more information, contact your local Siemens representative.

Disposing of Components and Accessories

WARNING: Observe local, state, and regional regulations for the disposal of the ultrasound system components and accessories.

Energy Efficient Usage: Energy Conservation

For improved energy conservation when the system is not in use, power off the system. Keep the system plugged into the power outlet.

For maximum energy conservation when the system is in storage, power off and unplug the system from the AC Mains power outlet.

NOTE: Unplugging the system from the AC mains power outlet can shorten the life of the system circuit board batteries.

Technical Description

This Section provides a summary of important information regarding the specifications and safe operation of the ACUSON Freestyle Ultrasound System. Read this entire User's Manual for important information on the safe installation and operation of the ACUSON Freestyle system, in particular, the Safety chapter.

Upon request, Siemens Medical Solutions USA, Inc. will make available circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist service personnel to repair those parts of the system which are designated by Siemens Medical Solutions USA, Inc. as repairable by non-Siemens personnel.

ACUSON Freestyle Ultrasound System Technical Description

Manufacturer	Siemens Medical Solutions USA, Inc. 22010 S.E. 51st Street Issaquah, WA 98029 USA
Electrical Power Requirements	Input Voltage : 100 – 240 V Frequency : 50/60 Hz Current : 1.5 – 0.7 A Fuse Rating: T 3.0 A L 250 V Fuse Type: 5 x 20 mm
Classifications	The ACUSON Freestyle is classified under IEC60601-1, as: 1. Class I protection against electrical shock. When probe and/or console are operated from battery power, Class is Internally Powered Equipment. 2. For continuous mode of operation 3. Equipment not suitable for use in the presence of flammable anesthetic mixture with air or oxygen or nitrous oxide. 4. System: Ordinary equipment without protection against ingress of water. 5. Probe: IPX8 6. Probe : Applied part Type B.
Environmental Requirements	Indoor Use Only
	Operating: Temperature: 10º C to 40º C (50º F to 104º F) Humidity (Relative Humidity): 10% to 75% Pressure: 700 hPa to 1060 hPa (20.7 inHg to 31.3 inHg)
	Transportation and Storage: Temperature: –20º C to 60º C (–4º F to 140º F) Humidity (Relative Humidity): 10% to 90%, Non-condensing Pressure: 500 hPa to 1060 hPa (14.8 inHg to 31.3 inHg)
Physical Specifications	Dimensions: Console: 158 mm L x 373 mm W x 335 H Probe: 153 mm L x 65 mm W x 34 mm H
	Weight: 10.5 pounds (System and one probe with probe battery)
Batteries	Probe battery reorder numbers: 11002745 (11001411 Quantity of 1) 11002304 (11001411 Quantity of 2)
	Battery Performance *(Figures approximate and will vary with operating conditions)* Charge Time (empty to full): Probe battery = 2 hours / System battery = 5 hours Run Time (full to empty): Probe battery = 1.5 hours / System battery = 1 hour Number of charge cycles before charge capacity reduced to < 70% of original capacity: Probe battery = 500 / System battery = 300
Regarding the Radio Equipment Directive (RED) 2014/53/EU	Herewith we declare that the radio equipment in question belongs to Class I and has been instructed so that it can be operated in at least one Member State without infringing applicable requirements on the use of radio spectrum. Frequency Band: 7420 – 8033 MHz Maximum Radio-Frequency Power: 0.000951 mW (E.I.R.P.) Frequency Band / Power: IEEE 802.11b/g/n Frequency Band / Power: Bluetooth® (v 2.0)

3 Setup

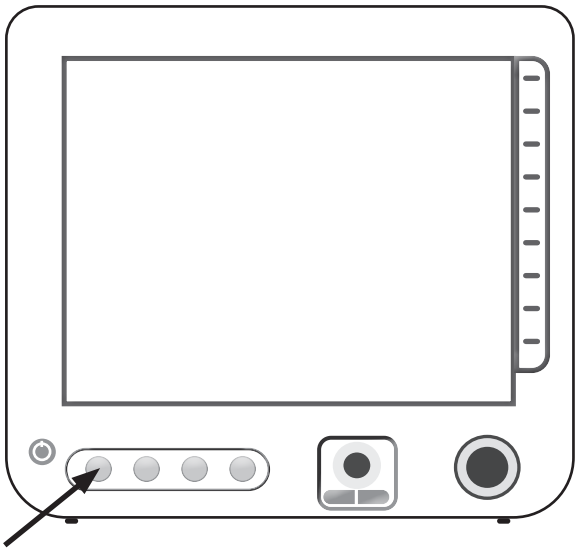
This section describes the functions of the Setup Menu that is used to specify system settings.

System Setup and Controls

This section explains how to setup the system. The Setup Menu includes patient data entry functions, patient study lists, system settings, and more.

Overview of the Setup Menu

To display the list of Setup options, press the **SETUP** Soft Key.



Location of **SETUP** *Soft Key*

Setup Menu

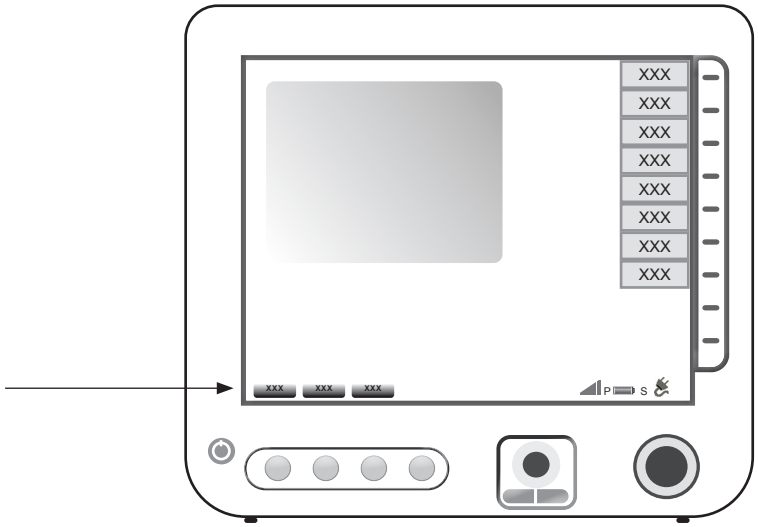
Option	*Description*
STUDY LIST	Displays the list of completed studies. For more information about the study list, see the “Patient Studies” chapter.
SYSTEM	System-related information (including: Software Release and License information, Subsystem details, and a list of installed options) and the System menu options: Display, Probes, Admin, Helpdesk, Exams, and DICOM. For more information, see “System Menus” on page 3-6.
NETWORK	Information and interface for establishing wired Ethernet or wireless connections with the system. For more information, see “Network Options” on page 3-16.
LOGOUT	Logout the current user and restrict access to Patient Health Information. For more information, see User Menu on page 3-14.

Each menu is described on the following pages.

How to Select Items from the Setup Menu

There are several ways to select an item from the **SETUP** menu:

- Turn the large, outer Rotary knob to highlight an item, then press or turn the small, inner Rotary knob.
- Use the Trackball which controls a pointer to highlight an option, and then touch the left Trackball key to activate it.
- Use a compatible USB mouse for these controls (plug the mouse into one of the USB ports on the I/O Panel; for more information see “Console Inputs/Outputs Panel” on page 1-5).



Setup Menu; there are several ways to select items from the menus

Basic Setup Screen Information

This information is displayed on all the System screens:

Option	*Description*
Serial Number	The serial number for this ACUSON Freestyle system.
Date and Time [Located at the top of the screen to the right of the serial number]	• Adjust the date: Click on the Date field and select the day from the displayed calendar. To save changes, click **OK**; to discard changes, click **Cancel**. • Adjust the time: Click on the up/down arrows to set the time. Check the AM/PM checkbox to display time in 12-hour AM or PM mode; leave the box unchecked for a 24-hour clock. The system is designed to automatically adjust the date for leap years. To save changes, click **OK**; to discard changes, click **Cancel**. **WARNING:** The ACUSON Freestyle does not automatically adjust for changes to and from daylight savings time. If and when your locality changes the clocks to begin or end daylight savings time, you will need to manually adjust the system time. **NOTE:** Be sure to check the time and date displayed on the system when you begin patient studies to make sure they are correct.
Batteries	Battery Status (e.g., Charging, AC), Charge Levels (a percentage), and Cycles (battery performance) for the system (console), left and right charger bays, and the active probe. Battery performance figures are approximate and will vary with operating conditions. Number of charge cycles before charge capacity reduced to < 70% of original capacity: Probe battery = 500 / System battery = 300

System Menus

Use either the outer rotary knob or the Control Bar Soft Keys to display the page for each of the System menus.

System Menus

Option	*Description*
SYSTEM	System-related information, including: Software Release and License information, Subsystem details, and a list of installed options.
DISPLAY	Console display information, including: user selected keys and image controls.
PROBES	Control and specify all activities related to probes including a list of the most recently used probes by *Name* (type of probe), *Serial Number* and date *Last Used*.
ADMIN	Settings include setting print and measurement options and patient anonymity settings.
HELPDESK	Access service-related information, log files, and utilities. Enter contact information for your local Service support representatives.
EXAMS	The ACUSON Freestyle comes pre-loaded with a variety of factory exam types (e.g., cardiac, vascular). Use these options to create custom User Exams with the parameters and settings that you specify. Note that a “u” preface identifies an Exam type as being user-defined.
DICOM	Information and interface for establishing and managing DICOM connections.
USER	Configure Admin, User, and Service accounts to control access to the ACUSON Freestyle.

Installed Options

Displays the individual feature licenses currently installed.

System Soft Keys

SCAN Activates the real-time imaging screen.

NETWORK Access Network menus for Adding, Editing, or Deleting Network connections.

Display Menu

Use the options on the Display menu to specify console display settings and manage image controls.

NOTE: The image control settings must be activated before saving an image or clip.

Options

Display Menu Options

Option	*Description*
Hide Image Settings after…	When enabled, hides the image settings after a selected amount of time following a controls change. Set the time by using the drop-down menu.
Enable Sleep Mode after...	When enabled, allows the console to go into a power saving “sleep” mode when inactive for a specified time. Set the inactive time by selecting a time from the drop-down menu.
Enable Menu Time-outs	When enabled, allows you to adjust the amount of time pop-up menus stay up before automatically disappearing after inactivity. Use the drop-down menu to set a faster or slower time.
Use international keyboard	Adds special characters to the on-screen keyboard.
Activate Scroll when freezing	Activates the Scroll key when image is frozen.
Save/Print Customization	Use the drop-down menu to select the desired function of **Save**: Save, Print, or Save and Print. *Save* stores a digital image to the system hard drive to be sent to PACS. *Print* prints a paper picture using an optional attached thermal printer. *Save and Print* saves a digital image and prints a paper picture using an optional attached thermal printer.
User Selected Keys	Define shortcut keys that will appear in the Real-time Control bar. Two B-Mode and two Color shortcuts can be defined. Use the drop-down menus to specify the key functions. The Tools list can be used to access functions that are not specified for these user-selected keys.
Image Size	Use the drop-down box to select the image size.
Cine Playback	Use the slider bar to set the length of time of multi-frame cine loops played back in real-time scroll memory.
Capture Quality	Use the slider bar to set the quality of JPEG-captured images. – For higher quality images, move the slider bar to the right. – For lower quality images, move the slider bar to the left.
Brightness	Move the slider bar to adjust the brightness of the monitor.

<table>
<tr><th>Option</th><th>Description</th></tr>
<tr><td>Video Out</td><td>Select the appropriate ACUSON Freestyle Video Out option for the corresponding Artis Large Display LUT selection:
<table>
<tr><th colspan="2" rowspan="2"></th><th colspan="2">Freestyle Video Out Selection</th></tr>
<tr><th>Freestyle VGA Video out with Siemens supplied VGA-to-DVI converter</th><th>Freestyle Digital Video Out (DisplayPort™)</th></tr>
<tr><td rowspan="5">Siemens Artis Large Display LUT Selection</td><td>Artis with a DICOM LUT of 0.45 cd/sqm Luminance Minimum</td><td>SIEMENS LD</td><td>DICOM GSDF</td></tr>
<tr><td>Artis with a DICOM LUT of 0.28 cd/sqm Luminance Minimum</td><td>SIEMENS LD NATURAL</td><td>DICOM GSDF 1.3</td></tr>
<tr><td>Artis with DICOM 0 Ambient</td><td>SIEMENS LD</td><td>DICOM GSDF</td></tr>
<tr><td>Artis with DICOM 0.5 Ambient</td><td>SIEMENS LD NATURAL</td><td>DICOM GSDF 0.5</td></tr>
<tr><td>Artis with DICOM 1.3 Ambient</td><td>SIEMENS LD NATURAL</td><td>DICOM GSDF 1.3</td></tr>
<tr><td colspan="3">NOTE: For all other DICOM-compliant displays, use the DICOM GSDF setting and digital video out for optimal results.</td></tr>
</table>
Use the SHOW TEST PATTERN button to display a full screen test pattern. Touch any control (system or probe) to deactivate the test pattern and display the most recent screen.</td></tr>
<tr><td>Language</td><td>Select a language for the screen display using the drop-down list. When a different language is selected, a dialog box opens to let you know that the system will restart.</td></tr>
</table>

Display Soft Keys

SCAN Activates the real-time imaging screen.

NETWORK Access Network menus for Adding, Editing, or Deleting Network connections.

Probes Menu

Use the *Probes* page to manage probe controls and view a list of the most recently used probes by *Name* (type of probe), *Serial Number* and date *Last Used*.

Options

Probes Menu Options

Option	*Description*
Enable Probe Keys Lock	When enabled, the probe keys will come up in a locked state during scanning. This prevents control changes due to unintended hits of the keys. The console will display a lock icon (a padlock) in the lower right corner of the system console. To unlock the keys: move your finger along the probe slider the length of the slider up and then down OR press the probe's plus key, then the minus key, then the plus key (or the reverse: minus, plus, minus keys). Once unlocked, after a period of inactivity, the probe controls will lock again. When enabled, select an option from the drop-down menu. The time refers to the amount of inactivity time before the probe keys will lock. When the "Always" option is selected, the probe keys will not function until the featured is turned off or is set to one of the numeric options.
Enable Probe Middle Keys	When enabled, assigns an operation to the probe middle keys. Select an option from the drop-down menu.
Enable Probe Localization Alerts	When selected, additional levels of localization are available. Select an option from the drop-down menu: Off, Low+, Medium, Medium+, High, High+. For more information see, "Finding/Locating Wireless Probes" on page 6-12.
Enable Automatic Freeze	When enabled, allows the system to freeze during real-time scanning when imaging is inactive.
Restrict wireless operation to checked probes	When enabled, restricts a console to connecting only with specified probes. Facilities with more than one ACUSON Freestyle system may wish to restrict the operation of a probe to a single system. To activate the feature, place a checkmark in the checkbox, and then use the trackball to place a checkmark next to the probe name(s) and serial number(s). **NOTE:** Effective use of this feature is achieved when ALL consoles restrict probe operation. **NOTE:** A warning will appear when attempting to connect an unauthorized probe to a restricted system. **NOTE:** When the "Restrict wireless operation to checked probes" checkbox is selected and a restricted probe serial number is listed, the probe will not automatically connect during future connection attempts and the user must approve the warning message that appears at every connection attempt. To enable future automatic connections, the user must manually place a checkmark in the row pertaining to the probe.

Probes Soft Keys

SCAN Activates the real-time imaging screen.

IDENTIFY Locates the active probe. If a probe is currently turned on and wirelessly connected to the system, pressing the **IDENTIFY** Soft Key causes the probe to emit an audible notification. This can be useful when trying to locate a probe. To stop the probe from beeping, press the **IDENTIFY** Soft Key a second time. For the Identify function to operate, the probe must be: powered on, linked to the system, and within range of the Bluetooth radio.

CONNECT Connects a probe to the console. Highlight the probe and touch the **CONNECT** Soft Key. Note that the probe must be turned on and within a three meter range of the console, or plugged into the console using the probe Probe Adapter Cable.

DISCONNECT Terminates the connection to the active probe.

For a description of the routine method of connecting probes, see the Scanning and Wireless Probe Operation chapters of this Manual.

Admin Menu

Use the options on the Admin menu to manage print, measurement, and anonymity controls.

Options

Admin Menu Options

Option	*Description*
Enable Small Print Size	When enabled, the attached compatible USB printer will reduce the size of the printed image.
Enable Freestyle Mobile Link	When enabled, the system can be used with Mobile Link. For more information, see “Freestyle Mobile Link Settings” on page 8-8. **NOTE:** The Freestyle Mobile Link App and the ACUSON Freestyle must be connected on the same network for proper functionality. Make sure to use a secure network to protect unencrypted patient information. **NOTE:** NOTE For optimal security, ensure that the Freestyle Mobile Link is disabled when not in use. **NOTE:** When Enable Freestyle Mobile Link is selected, the following dialog box opens on the ACUSON Freestyle: “Freestyle Mobile link relies on Wi-Fi encryption for security. It should be used with secure networks only.” **NOTE:** When using the Mobile Link app and a connection from a mobile device is made, the following dialog box opens on the ACUSON Freestyle: “A Mobile Link connection has been established from a mobile device. To allow the connection, press the OK button. To close the connection, press the Close button.”
Enable Clip Storage	When enabled, allows “clips” to be saved. Use the drop-down menu to set the length, in seconds, of the saved clips. Clips of 10 seconds or longer will use a reduced Capture Quality setting.
Enable Automatic Study Management	When enabled, the ACUSON Freestyle manages the Study List by automatically deleting patient studies on an as-needed basis. When the Study List reaches 80% of capacity, studies eligible for deletion will be removed from the Study List, starting with the oldest to newest, until the patient study database reaches 70% of capacity or no more eligible studies exist. For a study to be eligible for automatic deletion, it must be more than 5 days old and must either contain no image data or have been successfully archived. **NOTE:** Enabling the Automatic Study Management feature without understanding its functionality may result in the unintended loss of data.
Enable Artis Patient Synchronization	When enabled, the ACUSON Freestyle will pull the patient information from the Artis system and create an active study. For more details, see Chapter 9, “Artis/Freestyle Workflow”.
Area Measurement	Select the method to use for area measurements: point-to-point or continuous trace.
Study Anonymity	When enabled, removes patient information from images saved as either JPEG or DICOM. Make the scan anonymous by excluding either the Patient ID (Identification), the Patient Name, or both. ***Default setting***: the anonymizing features are turned off; Patient Name and ID are displayed on saved images. **NOTE:** These settings do not remove the Patient Name and ID from the DICOM data stored with the study. **NOTE:** This setting ***must be enabled before*** saving an image or clip. Patient data cannot be removed from saved images.
Shutdown when AC Power is Lost	When enabled, the ACUSON Freestyle will automatically power down approximately 60 seconds after AC power is removed. To prevent the ACUSON Freestyle from automatically powering down, select Cancel shutdown, use battery. No loss of data will occur as a result of automatic power down.

Admin Soft Keys

SCAN Activates the real-time imaging screen.

NETWORK Access Network menus for Adding, Editing, or Deleting Network connections.

Helpdesk Menu

Use the options on the Helpdesk menu to access service information and utilities.

Options

Helpdesk Menu Options

Option	*Description*
Service Information	Displays service information. Use **Save**, **Clear**, and **Cancel** to manage information in the window. An external keyboard is required to enter text into the Service Information window.
System Update	For software installation and updates.
Export Log Files	Sends system log files to a compatible USB drive.
Study Utilities	Includes options to: – Initiate **Study Database Check** to repopulate the study list, based on studies stored on the internal drive – Delete the export queue When the Study Utilities window opens, select a radio button and then select **OK** to complete the action or **Cancel** to close the window without completing the action.
Service Utilities	When the Service Utilities window opens, select an item from the drop-down menu: – Restore to Factory Defaults: deletes all DICOM settings, user exams, worklist data and network information; *does not* delete saved studies. – Export User Settings: exports system configuration files to a USB memory stick for a system backup. – Import User Settings: imports system configurations files from a USB memory stick to restore system configurations to a previous state. – Probe Recovery: performs an update to a probe that does not chime when connected to the system via the Probe Adapter Cable. – Format Internal Storage: performs a memory format and reloads the most recently installed software version. **NOTE:** Formatting the internal storage will erase all patient data, user settings, audit logs, user exam types, user id information, text annotations, network configurations and systems configuration. – Option License: enter a new, system-specific License Key to enable additional features.

Helpdesk Soft Keys

SCAN Activates the real-time imaging screen.

NETWORK Access Network menus for Adding, Editing, or Deleting Network connections.

Exams Menu

The ACUSON Freestyle comes pre-loaded with a variety of factory exam types (e.g., cardiac, vascular). Use the options on the Exams menu to create custom User Exams with the parameters and settings that you specify. Note that a “u” preface identifies an Exam type as being user-defined.

This screen lists the pre-loaded factory exam types and user-created exams (the name preceded by “u”).

Use the Trackball and the plus and minus boxes to open and close the exam sub-menus and select specific exams.

Highlight a specific exam type (e.g., Small Parts, Thyroid) to see the probe settings. Click through the probe tabs to see the specific settings for each type of probe.

For detailed instructions about Exam Types, see “Factory Exam Types” on page 4-7 and “User-Defined Exam Types” on page 4-8.

Exams Soft Keys

SCAN Activates the real-time imaging screen.

DELETE Deletes selected User Exams from the system.

RENAME Edit the name of a User Exam; names are limited to nine characters.

ACTIVATE Makes the highlighted Exam the active Exam Type.

DICOM Menu

Use the options on the DICOM menu to manage DICOM connections.

Options

DICOM Menu Options

Option	*Description*
DICOM	Displays a list of the DICOM connections and server information for each.
Freestyle AE Title	Sets the DICOM ***AE Title*** (the name the system provides to the DICOM server). Click the keyboard icon next to the option and type the name. To save changes, click OK; to close without saving, click Cancel.
Freestyle DICOM Port	Sets the DICOM port number. Click the keyboard icon next to the option and enter the number. To save changes, click OK; to close without saving, click Cancel.

DICOM Soft Keys

SCAN Activates the real-time imaging screen.

NEW Add a new network connection.

DELETE Delete the selected network connection.

EDIT Edit or configure a network connection.

For detailed instructions about DICOM settings and configuration, see the Connectivity chapter and the DICOM Conformance Statement. DICOM conformance statements for ultrasound products are available at www.siemens.com/dicom.

User Menu

The security package on the ACUSON Freestyle ultrasound system protects patient information from unauthorized access by requiring user logins (a user-specific account and password) to access the ultrasound system. It is the responsibility of the ultrasound system administrator at your facility to observe local security policies and implement security settings and policies for the ultrasound system.

Having users log on and off prevents unauthorized access to patient information, as a User ID and Password are required to gain access to the system.

The ultrasound system administrator assigns permissions for each user account. To understand the permissions assigned to your user account, or if you do not have a User ID and case-sensitive Password, contact your ultrasound system administrator.

> **NOTE:** For more information, see Protecting Patient Health Information on page 4-3.

User Soft Keys

New Creates an Administrator Account. Fill in all fields with the specified login information. If desired, select checkbox for Password never expires or Force password change at next login. Once an Administrator account is created, the Administrator can create additional Administrator accounts, User Accounts, and Service Accounts.

> **NOTE:** Once an Administrator Account has been created, only those with a valid Administrator account can create and edit user accounts.

Edit Modify user login information.

Policy Edit user account and auto-logout requirements.

Service Access Button Restricted to authorized Service Personnel.

Emergency Use

When User Logins are enabled, a valid User ID and Password are required; however, in an Emergency, you can select Emergency User. This will allow use of the ACUSON Freestyle but access to the Study List will be restricted.

Network Options

The **Network** page includes information and the interface for establishing wired Ethernet or wireless connections with the system.

Network Options

Option	*Description*
WiFi Setup	Select or define wireless network settings. For more information, see “Wireless Network Setup” on page 8-4. **NOTE:** WiFi operation can only be enabled when the Wireless Networking option is installed.
Ethernet Setup	Enter Ethernet setup information. For more information, see “Ethernet Setup” on page 8-3.
Ping	Test network connections.
Freestyle Mobile Link	Settings for using the ACUSON Freestyle with a Mobile App. For more information, see “Freestyle Mobile Link Settings” on page 8-8.

Network Soft Keys

SCAN Activates the real-time imaging screen.

SYSTEM Displays the System menu.

For detailed instructions about Connectivity settings and configuration, see the Connectivity chapter of this Manual

4 Patient Studies

This section describes how to create patient records and view, manage, and export patient studies.

Protecting Patient Health Information

Storing patient data on the ACUSON Freestyle only temporarily, and then archiving the data to your institution's secured archival systems can enhance protection of your patient's Protected Health Information (PHI).

WARNING: Protected Health Information (PHI) such as patient records, is subject to privacy protection (such as is described in the US Health Insurance Accountability and Portability Act and the European Union Data Protection Directive, 95/46/EC.) Health care providers have a responsibility to protect PHI.

WARNING: Be aware that even a highly secured wireless network can be vulnerable to unauthorized access.

NOTE: To help protect patient health information, do not grant user access above the minimum necessary user access level.

NOTE: The Freestyle Mobile Link App and the ACUSON Freestyle must be connected on the same network for proper functionality. Make sure to use a secure network to protect unencrypted patient information.

NOTE: For optimal security, ensure that the Freestyle Mobile Link is disabled when not in use. For more information, see Enable Freestyle Mobile Link in the "Admin Menu" on page 3-11.

Removing Patient Information from Images

The **Study Anonymity** option allows you to remove patient information from images saved as either JPEG or DICOM. Make the scan anonymous by excluding either the Patient ID (Identification), the Patient Name, or both. ***Default setting***: the anonymizing features are turned off; Patient Name and ID are displayed on saved images. For more information, see "Admin Menu" on page 3-11.

NOTE: These settings do not remove the Patient Name and ID from the DICOM data stored with the study.

NOTE: This setting must be enabled before saving an image or clip. Patient data cannot be removed from saved images.

About Patient Studies

Only one patient study can be active at a time.

A patient study remains open until you:

- close the current study,
- create a new study, or
- reboot the system.

To reactivate a closed study, select **SETUP / STUDY LIST**, highlight the desired study then select **EDIT**. Select **Open** and **OK** to confirm.

The most recent Institution entry in the Patient Study page is retained in memory. The Institution name is displayed on the imaging screen.

Patient Study Fields

To display the Patient Study fields press the **PATIENT** Soft Key. When entering data into the Patient Study field, the **[OK]** key confirms an entry. The study information includes the fields described in the following table.

Patient Study Information Fields

Option(s)	*Description*
Last Name, First Name, Middle Name	Patient name information. Note that the patient's name can be removed from saved image scans using the anonymity settings. For more information, see **Study Anonymity** on the "Admin Menu" on page 3-11.
Patient ID	A unique patient ID number. **NOTE:** If you do not enter a Patient ID the system will generate one based on time and date.
Birth Date	To enter data, use the number keys.
Gender	Select either Male or Female.
Exam	Select an Exam Type from the drop-down list.
Height, Weight	To enter data, use the number keys. To display values using the metric system, click the **Metric** checkbox.
Accession	Type text into the field.
Diagnosis	Type text into the field.
Institution	Select from the drop-down menu. The Institution name is displayed on the real-time imaging screen.
Physician	Select from the drop-down menu.
Operator	Select from the drop-down menu.
Comments	Enter any additional information or comments.

NOTE: Patient Name and ID fields are limited to 64 characters. If the field is too long to be completely displayed on the real-time scanning screen, the entry will be shortened in the display and followed by three dots.

NOTE: The system stores up to eight of the most recently used Institution, Physician, and Operator entries.

When using an external USB keyboard, *quickly pressing* the following key combinations allows you to enter special characters:

Press this key...	*then press this key*	*Resulting character*
‘ *(apostrophe)*	a, c, e, i, n, o, u, y, z	á, ć, é, í, ń, ó, ú, ý, ź
“ *(quotation mark)*	a, e, i, o, u, y	ä, ë, ï, ö, ü, ÿ
` *(accent grave)*	a, e, i, o, u	à, è, ì, ò, ù
~ *(tilde)*	a, n, o	ã, ñ, õ
^ *(caret)*	a, e, i, o, u	â, ê, î, ô, û
= *(equals)*	a, o	æ, œ
* *(asterisk)*	a	å
- *(dash)*	a, i, o, u	ā, ī, ō, ū
# *(pound)*	c, s, z	č, š, ž
. (period)	e, z	ė, ż
, (comma)	c, e, i	ç, ę, į
/ (slash)	l, o	ł, ø

Patient Soft Keys

Patient Soft Keys

Soft Key	*Description*
SCAN	Returns to the scan screen.
CANCEL	Closes the record without saving unconfirmed entries.
CLEAR	Lets you start over by clearing information from all the fields.
WORKLIST	Displayed if Worklist is configured for this system. For more information see, “Worklist Query” on page 4-6.

Creating New Patient Studies

To enter Patient information:

1. Press the **PATIENT** Soft Key to display the New Patient screen.
2. Use the Trackball to place the cursor in each entry field, then press the left Trackball key to open the on-screen keyboard. You can also place the cursor over the keyboard symbol to the right of the entry box and press the left Trackball key to bring up the on-screen keyboard. You can also use an external USB-compatible keyboard.
3. Save the new patient record, by selecting **[OK]**.
4. To then go directly to the real-time imaging screen select *Scan* from the **SETUP** Soft Key menu.

NOTE: If you start scanning a patient and save images without entering a patient name or ID, the system will automatically create a Study file for that patient study. The patient name will be listed as UNKNOWN, a machine-generated ID number will be created, and the date and time of the study will be recorded. This information will become a part of the image screen saved with the images. During or after the study, it is possible to modify the patient information that appears in the Patient Study Archive.

NOTE: If a patient already has a study stored in the system, you will still need to enter new patient information at the time of a new study; the system does not provide patient folders with multiple studies.

NOTE: If the on-screen keyboard does not automatically activate as expected and you have a USB mouse or a wireless USB mouse connected, disconnect the USB mouse or use the pointer to select the on-screen typewriter symbol [] to activate the on-screen keyboard.

For detailed information about using the optional Artis Patient Synchronization feature, see Chapter 9, “Artis/Freestyle Workflow”.

When User Accounts are Enabled

If User Accounts are enabled, all users are required to log in to the ACUSON Freestyle prior to use.

> **NOTE:** In an Emergency, select **Emergency User**. This will allow use of the ACUSON Freestyle but access to the Study List will be restricted.

Using Patient Information from a DICOM Server

If your system has the Worklist option and is configured and connected to a DICOM server you can obtain existing patient information (for more information, see “Overview of Connectivity” on page 8-3).

Worklist Query

This option provides a shortcut to entering patient information as you create new patient studies by accessing your DICOM Worklist Server (where patient information can be stored).

You can query the Worklist server using a variety of search terms or conditions, such as patient name or exam date (Today, Tomorrow, or Last 3 days). If the query returns a patient for whom you want to create a study, highlight the patient name in the response list, and select **Create Study** for this Patient. The data will be entered into the system and the study will be activated for that patient.

To query the Worklist select **PATIENT** / **WORKLIST**.

Study Exam Types

There are two kinds of study Exam types:

- Factory/Standard exam types
- User-created exam types

You can change the Exam Type during scanning using the **Exams** key in the real-time control window.

You can also specify which Factory/Standard Exam Types are available during scanning:

1. Select **SETUP** / **SYSTEM** / **EXAMS**.
2. Click the [+] box to display the lists of Exam types; to hide the lists, click the [–] box.
3. Use the checkboxes to select the desired Exam types.

Factory Exam Types

The factory Exam Types provide real-time parameter presets optimized for specific types of exams (for information about creating user-defined exam types see page 4-8). These standard exam types can help optimize imaging settings with minimal effort. Factory Exam Types are shown in the following table listed in alphabetical order. On the system they are displayed in the most-recently-used order.

Exam Types are organized in the following groups: Abdominal, General, Musculoskeletal, Nerve, Small Parts, and Vascular.

Factory Exam Types

Screen Display	*Description*
Abd Deep	Abdominal Deep
Abd Gen	Abdominal General
Abd Vasc	Abdominal Vascular
Abd Renal	Abdominal Renal
General	General
MSK Deep	Musculoskeletal Deep
MSK Elbow	Musculoskeletal Elbow
MSK Foot/An	Musculoskeletal Foot/Ankle
MSK Gen	Musculoskeletal General
MSK Hand/Wr	Musculoskeletal Hand/Wrist
MSK Hip	Musculoskeletal Hip
MSK Knee	Musculoskeletal Knee
MSK Shouldr	Musculoskeletal Shoulder
MSK Spine	MSK Spine
MSK Sup	Musculoskeletal Superficial
MSK Tendon	Musculoskeletal Tendon
Nerve Deep	Nerve Deep
Nerve Gen	Nerve General
Nerve Spine	Nerve Spine
Nerve Sup	Nerve Superficial
SP Breast	Small Parts Breast
SP Deep	Small Parts Deep
SP Gen	Small Parts General
SP Sup	Small Parts Superficial
SP Thyroid	Small Parts Thyroid
V Arterial	Vascular Arterial
V Carotid	Vascular Carotid
V Gen	Vascular General
V Vn Diff	Vascular Venous Difficult
V Vn LwExtr	Vascular Venous Lower Extremity
V Vn Sup	Vascular Venous Superficial
V Vn UpExtr	Vascular Venous Upper Extremity

User-Defined Exam Types

User defined Exam Types are preceded by “u”. You can create up to 64 different user exams.

The User Exam page displays the list of User Exams that have been created, including the real-time settings by Probe type.

Display the list of User Exams that have been created on the User Exams page:

1. Press the **SETUP** Soft Key.
2. Select the **SYSTEM** option.
3. Select **EXAMS**.

You can display real-time settings by Probe type and create your own Exam Type with the system settings you prefer.

User Exam Soft Keys:

- **DELETE**: deletes User Exams from the system.
- **RENAME**: allows you to edit the name of the User Exam; names are limited to nine characters.
- **ACTIVATE**: makes the highlighted Exam the active Exam Type.

Creating a new User Exam Type

1. During real-time scanning, select one of the pre-loaded factory Exam Types — not a User Exam Type; User Exams are prefaced with the letter “u” (for example, “u Vascular1”).
2. Change the system real-time control settings, such as Depth and Gain, that you prefer for the exam type you are creating.
3. When you have specified the settings you want, touch the **Exams** Control Bar Key, then select **Save Exam**. The settings will be saved with the name “u Exam” followed by a number. You can then rename the Exam in the **SETUP** / **SYSTEM** / **EXAMS** page.

   NOTE: If you are unable to create new User Exams, you may have exceeded the number of User Exams the system allows. The system stores a total of 64 User Exams. Delete unused User Exams so new ones can be created.

Updating a User-Defined Exam with New Settings

1. During real-time scanning, use the **Exams** Control Bar Key to activate the User Exam you want to update.
2. Change any of the control settings (e.g., Gain, Depth).
3. Select **Save Exam**.

For information about saving images to a Patient Study, see the Scanning Chapter.

The Study List

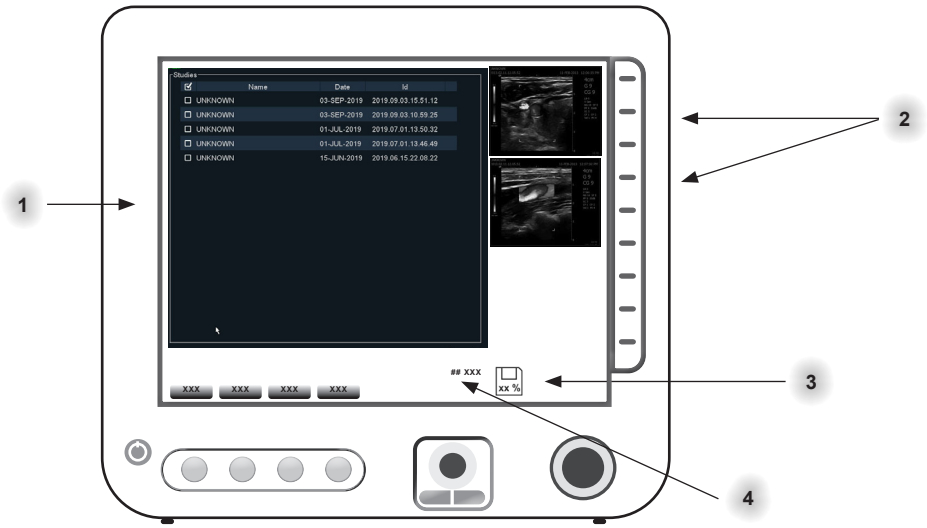
The Study List includes all the patient study files that have been created and stored on the system. You can view studies from this list and send them (using the Export function) to a storage device such as a USB drive, or to a network destination such as a DICOM picture archival system (PACS).

Viewing the List of Patient Studies

To access the Study List,

1. Press the **SETUP** key.
2. Select **STUDY LIST** from the menu.

The Study List displays the studies in a tabular form, with column headers for Patient name, exam date, Patient ID, and export status. If a study has been archived (exported) to an external storage location an arrow appears next to the study. The *study storage memory used* symbol indicates the percentage of memory that has been used.



The Studies List screen

1. List of studies
2. Thumbnail images from the highlighted study
3. Study Storage Memory Used symbol
4. The number of studies in the current Study List; in this format: # Studies

Sorting the Study List

The default is to show studies sorted by their study date.

To change the sort to a different category, click on a column header.

Scrolling through the Study List

To scroll through the study list, use the outer Rotary knobs.

If a study contains saved images they are displayed as thumbnails. The inner knob highlights the images and allows you to view them full size.

To return to scrolling through the Study List, turn the inner knob so the thumbnail image is no longer highlighted.

Selecting Multiple Studies for Export or Deletion

To select multiple studies for exporting or deleting place the pointer in the space to the left of the name and press the left Trackball key. The selected studies will be marked with a checkmark (✔). To de-select, place the pointer over the checkmark and press the left Trackball key.

Selecting All Studies for Export or Deletion

To select ALL studies for exporting or deleting place the pointer over the checkmark (✔) at the top of the first column and press the left Trackball key. A checkmark (✔) appears next to ALL studies.

To permanently delete ALL studies, select **DELETE**.

To export ALL studies, select **EXPORT**.

To de-select, place the pointer over the checkmark at the top of the first column and press the left Trackball key.

Viewing Images in a Study from the Study List

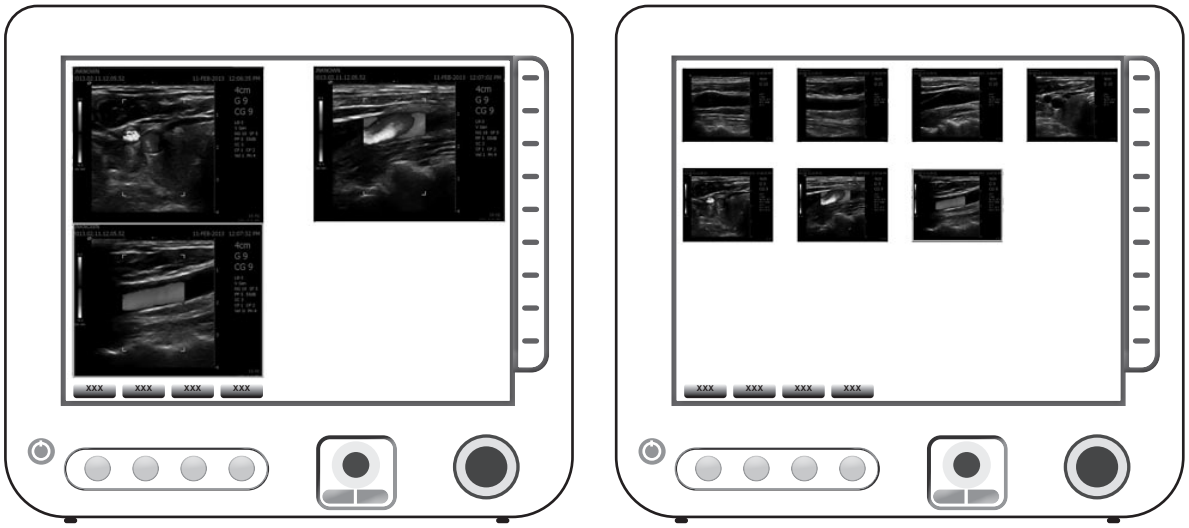
If a highlighted study has saved images, thumbnail versions of the images will be displayed at the right of the screen. To highlight an image, turn the small Rotary knob one click. To view the image in **View** mode, turn the small Rotary know a second time. To return to the Study List, select **LIST**.

Viewing Image Controls

The **VIEW** Soft Key opens all the recorded frames and clips from the active study. Studies may also be viewed by selecting them from **SETUP** / **STUDY LIST**.

When viewing study images:

- **Next** cycles through the stored frames and clips.
- **PANEL** view displays multiple images on the same screen; then use these controls:
  - **MORE** makes thumbnails smaller
  - **FEWER** makes thumbnails bigger
  - **DELETE** highlight and delete selected thumbnails
- **DELETE** removes the highlighted frames or clip from the study.



Panel views of study thumbnail images; left picture: fewer, larger thumbnails; right picture: more, smaller thumbnails

Managing Patient Studies

Exporting Patient Studies

The Export function sends selected studies to a storage medium (on a network or a compatible USB drive).

How to Export Studies

To export patient studies, follow these steps:

1. Be sure you have the desired type of export hardware connected, e.g., a USB drive or a configured DICOM network.
2. Open the study list by selecting **SETUP** / **STUDY LIST**.
3. Select a study by placing the cursor over the checkbox to the left of the study and pressing the left Trackball key to check or uncheck the box. Or, use the outer rotary knob to highlight a single study for export. Checkmark(s) will override a highlighted study. To export multiple studies at one time, check multiple boxes.
4. Press the **EXPORT** Soft Key.
5. Specify the Configure Export choices (see “Export Parameters” on page 4-13).
6. Click **[OK]** to begin the export. While the export is taking place, the Export List shows details about the study being exported and the status of the export. To terminate the export, press the **CANCEL** Soft Key.

   NOTE: Allow the status indication to complete and show no additional files to store before removing the USB drive, otherwise the export may not be successful.

   NOTE: Do not attempt to delete any studies from the Study List when an export is in progress.

   NOTE: Export Queue – Failed attempts are periodically retried. Repeated failures will be automatically deleted from the export queue. The study will not be deleted from the Study List.

The following icons indicate the status of an export:

 – Export in progress

 – Export error

When a study has been successfully exported, a curved arrow symbol () is displayed to the right of the study in the Study List.

Selecting the View Export Page button will display the current Export List.

Export Parameters

Pressing the **EXPORT** Soft Key opens the **Configure Export** list with the following fields:

- **Export Format**: choose an export format: *DICOM Network*, *DICOM Media*, *DICOM Media DSF (Decompressed Single Frame)*, or *PC Viewable*. DICOM Media and PC Viewable are used to store studies to a compatible USB external drive connected to the system. If no drive is connected, these options are not displayed.
- **Storage Destination**: for detailed information see the Connectivity chapter of this Manual.
- **Storage Commitment Destination**: for detailed information see the Connectivity chapter of this Manual

Editing Patient Studies

1. Open the study list by selecting **SETUP** / **STUDY LIST**.
2. Use the outer Rotary knob to highlight the study.
3. Press the **EDIT** Soft Key to activate the Studies page where you can edit patient information (name, birth date, etc.).

   NOTE: Patient ID cannot be edited.

Deleting Patient Studies

The Delete function removes studies from the system.

1. Open the study list by selecting **SETUP** / **STUDY LIST**.
2. Highlight a study in the Study List and press the **DELETE** Soft Key.

You will be prompted to confirm that you intend to delete the study before it is removed.

If you intend to archive a study to an external storage medium, do not delete the study prior to the archival being performed. Once a study has been deleted, it cannot be recovered from the system.

CAUTION: Confirm that an archival operation has been successful before deleting a study from the system.

5 Scanning

This section describes the real-time scanning operation.

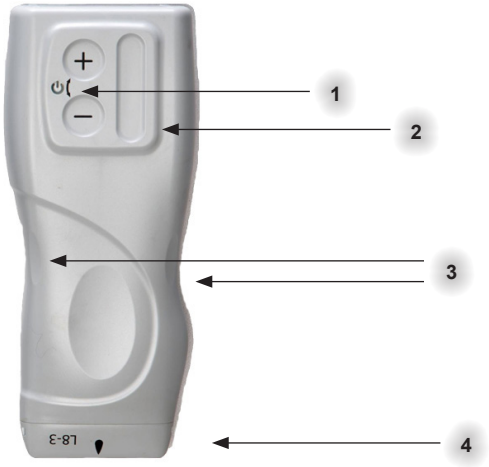
Using the Probe

About the Probe

Probe Orientation

The probe index marker is the side of the probe where the probe on/off symbol is located. This corresponds to the ACUSON “a” symbol at the top left of the image display ( ). The probe model numbers, such as “L8-3” also serve as index markers. For transducers in non-cardiac applications, the normal and default location of the on-screen index marker symbol is to the left of the image.

Overview of the Probe



Controls on the probe include a slider, plus/minus keys, middle keys

1. Index marker light
2. Circular plus/minus keys and slider bar
3. Probe *middle keys*
4. Probe nose

NOTE: In wireless mode, press the two on-probe circular *keys* continuously to turn the probe on and off (see “Wireless Probe Operation” on page 5-6).

Probe Controls

Functions in the real-time Control Bar can be adjusted or selected using the controls on the probe. These controls include the slider, the two circular buttons, and the two buttons in the middle of the probe.

The slider mimics the function of the large Rotary knob on the console, moving the selection of the active item in the real-time control knob:

- To move the highlight up the list, push upward on the slider, away from the transducer face.
- To move the highlight down, push downward on the slider, toward the transducer face.

The button towards the rear of the probe (away from the transducer) represents **Plus**, the button towards the front of the probe (towards the transducer) represents **Minus**. These mimic the functions of the inner Rotary knob on the console.

- Plus corresponds to clockwise rotation of the knob.
- Minus corresponds to counterclockwise rotation of the knob.

Locking and Unlocking the Probe

Before using the probe controls, you may have to unlock these functions on the probe if you unchecked the *Enable Probe Keys Lock* selection in the **SETUP** / **SYSTEM** / **PROBES** page.

> **NOTE:** When the probe is locked, a padlock icon is displayed on the bottom right of the console screen ().

There are two ways to unlock the probe:

- Slide the tip of your finger up and then down the slider channel in one continuous motion (do not lift your finger)
- Press the plus key, then the minus key, then the plus key (or the reverse)

Once unlocked, the controls will lock again after a period of inactivity.

Probe Shortcuts for Select Features

The two keys in the middle of the probe can be used as shortcuts for the function you select on the **PROBES** page. Tap either probe key three times to activate the function.

Connecting the Probe

There are two ways to operate the probe with the system:

- Cabled
- Wireless

Cabled Probe Operation

To operate the probe with the removable Probe Adapter Cable, plug the probe cable into the system I/O panel (see “Console Inputs/Outputs Panel” on page 1-5), and insert the probe end into the probe.

> **NOTE:** Both ends are keyed to prevent improper connection. Do not use force to connect either end of the cable.

During cabled probe operation, the probe comes up with the image frozen. Select **Unfreeze** to go to real-time scanning.

> **NOTE:** If a probe is already connected using the Probe Adapter Cable you cannot connect another probe using the wireless connection. To make a wireless probe connection, unplug the Probe Adapter Cable at the probe or system console.

Wireless Probe Operation

To operate the system probe in wireless mode, insert a charged probe battery pack into the probe.

> **NOTE:** The battery pack is keyed to prevent improper connection. Do not use force when inserting the probe battery pack.

Probe and battery; line up battery connectors with probe connectors

With the system power ON, turn the probe on by continuously pressing the two circular on-probe buttons. When power has been turned on for the probe, you will hear a beep from the probe. The system and the probe will automatically connect.

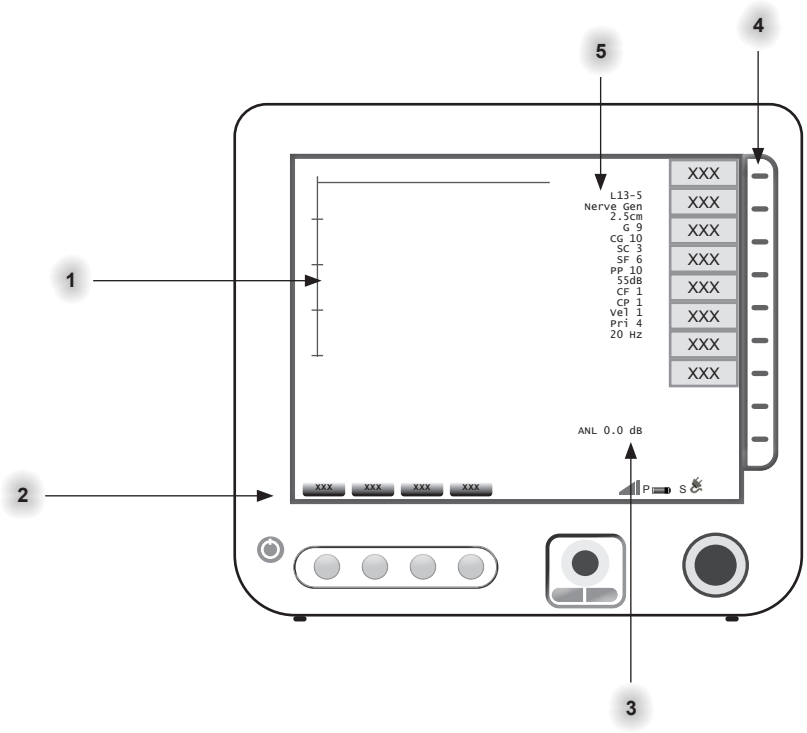
Connecting More Than One Wireless Probe

To use more than one probe in wireless mode during an exam:

1. Turn the first probe off by continuously pressing the two circular on-probe buttons, thereby disconnecting it from the console.
2. Connect to the second probe.

> **NOTE:** If a Probe is connected to the console with the Probe Adapter Cable, you will need to disconnect it to make a wireless connection to another probe. You can disconnect it either at the probe or the console end.

The Real-Time Scanning Screen



Real-time Scanning

1. Imaging Area
2. Soft Keys
3. ANL: Average Noise Level. A measure of wireless probe signal quality. See the Wireless Probe Operation chapter of the Manual for details about ANL.
4. Real-time Control Bar Soft Keys: touch the control bar to activate the Soft Key next to the bar (e.g., **Freeze**, **Save**, etc.).
5. The on-screen settings window is the area next to the image that displays the settings of controls including depth, gain, probe type, exams, etc.

Overview of the Scanning Process

Scanning is controlled using the Soft Keys, real-time Control Bar, and Rotary knobs.

Basic steps to complete a scan and save it to the Study List:

1. Press the console power button to turn the system on and allow it to boot up.
2. To enter a new Patient Name and create a new Patient Study, press the **PATIENT** Soft Key, then use the on-screen keyboard or an external keyboard to enter the patient Name, ID, etc (see “Creating New Patient Studies” on page 4-5).
3. Select an Exam Type (see “Study Exam Types” on page 4-6).
4. Press the **SCAN** Soft Key to go to scanning mode and start imaging.
5. Make sure your probe is connected (either cabled or wirelessly) and turned on. To turn a probe on for wireless operation, press the probe Plus and Minus keys continuously until you hear the probe beep.
6. Make any adjustments using the real-time Control Bar Soft Keys or Probe Controls.
7. Press the **Freeze** key to freeze an image.
8. Press **Save** to save frames or select **Unfreeze** to save clips.
9. If desired, press the **MEASURE** Soft Key to make measurements (see “Measurements” on page 5-17).
10. Press the **VIEW** Soft Key to view saved frames or clips.
11. To export studies to an external drive or system, see “Exporting Patient Studies” on page 4-12.
12. To view a list of completed studies press **SETUP** / **STUDY LIST** (see “The Study List” on page 4-9).

Real-Time Scanning Controls

The Real-time Control Bar along the right side of the screen provides Soft Keys for the functions described in the following table.

The larger, outer Rotary knob moves up or down the list, highlighting an active control. The smaller, inner Rotary knob adjusts the settings of the highlighted function. The probe controls also provide these functions. Additionally, the controls may be activated by pressing the button area next to the control on the front panel.

Real-Time Scanning Controls

Real-time Control Bar Keys	*Description*
Freeze/Unfreeze	Freezes and unfreezes the image. When the image is frozen, the light on the probe will flash on and off. When you press **Freeze** during real-time scanning, you can select **Scroll** and use the inner Rotary knob or probe keys to step frame-by-frame through the image memory. The scroll memory is the immediate sequence of frames that were produced just prior to the freeze. The **Cine** key plays the scroll memory in a repeating loop.
Save	Stores a still-frame image to the Patient Study file in internal memory. **NOTE:** During live scanning a circular symbol appears in the upper right corner of the screen for the length of time the Save or Clip is taking place. A new Save or Clip cannot be started until the Save or Clip is completed. **NOTE:** If you select Save or Clip and the system does not have any study storage memory available, the study storage memory used symbol will appear showing 100%. Delete studies to make memory available.
Clip	Stores a multi-frame image clip to the Patient Study file in internal memory. In order for clips to be stored, the **Enable Clip Storage** checkbox on the **SETUP / SYSTEM / ADMIN** page must be checked. **NOTE:** During live scanning a red circular symbol [] appears in the upper right corner of the screen for the length of time the Save or Clip is taking place. A new Save or Clip cannot be started until the current Save or Clip is completed. **NOTE:** If you select Save or Clip and the system does not have any study storage memory available, the study storage memory used symbol will appear showing 100%. Delete studies to make memory available. **NOTE:** If a Clip capture is started while the ACUSON Freestyle is changing imaging configurations such as Depth of a Mode change, only a single frame capture will be saved.
Gain	Adjusts the overall image gain. Displayed in the on-screen settings window as **G**.

Real-time Control Bar Keys	*Description*
Depth	Adjusts the scanning field of view. Scale markers in centimeters are displayed along the edge of the image. In the on-screen settings window, the bottom depth number is displayed in centimeters. Note that for linear array probes, distance markers are also shown along the top of the image and the center of the probe is marked with an arrow. When making changes to the depth setting, the displayed depth setting number turns blue until the actual image depth changes to the new setting.
View	When the imaging screen is in **Freeze** mode, the **View** button will be displayed on the side control panel. Users have the option to use the probe controls to select **View** to display the saved images of the active study. While displaying saved images in the View mode, a **Scan** button will be displayed on the side control panel. Users have the option to use the probe controls to select SCAN to exit View mode and return to the real-time imaging screen.
Color	Turns color flow mapping on and off. The region of interest is moved up or down with the **Color Box** Soft Key. Displayed in the on-screen settings window as **C Box**.
Dual	Activates dual imaging mode. The system displays one real-time image and one frozen image in a side-by-side format. To exit Dual mode, select **Dual** again. Once Dual is activated, use **Update** to alternate the live image between the left or right side of the image screen.
N Gain	Adjusts the near field gain. Displayed in the on-screen settings window as **NG**.
Tools	Activates the Tools menu for additional image adjustment.
Exams	Displays the list of factory and user-defined Exam Types. For more information, see “Selecting an Exam Type from the List of Exams” on page 5-11.

Selecting an Exam Type from the List of Exams

Pressing the **Exams** Soft Key on the Real-time Control Bar displays a list of factory Exam Types and user-defined Exam Types that you can select from. Exam types provide presets of system controls in order to simplify optimization of images for different applications and patient types. See the Setup and Patient Studies chapters for more information regarding Exam Types.

Pressing Exams displays the following buttons in the real-time control window:

Exit Exams – exits the Exam list.

Save Exam – saves the current control settings as a user-defined exam. This can be viewed and edited in the Setup/Settings/Exams page.

User-defined exams are shown with the letter “u” in front of the name.

Page – steps through multiple pages of Exam Type lists if there are more than can be displayed in the real-time control window.

Exam Types (e.g., **Vascular**, **Abdominal**) – the list of Exam Type groups are in the most-recently-used order. Selecting an Exam Type group will display the individual Exam Types available for that group.

Freezing an Image

When you press the **Freeze** Soft Key during real-time scanning, the current image freezes. Use the following Control Bar options:

Save – saves the current image.

Scroll – use the inner Rotary knob or probe keys to step frame-by-frame through the image memory. The scroll memory is the immediate sequence of frames that were produced just prior to the freeze.

Cine – plays the scroll memory in a repeating loop.

Tools – displays the Tools sub-menu (see “B-Mode Scanning” on page 5-13 and “Color Flow Tools” on page 5-15).

Text – lets you add text to an image (see “Text Functions” on page 5-19).

Close – closes the active study and if the optional Auto Send feature is configured, the study will be exported to the default PACS.

Update – alternates the live image under active control between the Left image or Right image while in Dual mode.

Scanning Soft Keys

The four Soft Keys along the bottom of the screen are controlled by the four circular buttons on the system console. They are described in the following table.

Scanning Soft Keys

Soft Key	*Description*
SETUP	Displays the Setup menu.
PATIENT	Displays the New Patient data entry page.
MEASURE	Displays the Measurement tools.
VIEW	Opens all of the recorded clips from the active study. Studies may also be viewed by selecting them from **SETUP** / **STUDY LIST**. When Viewing study images: • To cycle through the stored clips, press **Next** on the real-time Control Bar. • To display multiple thumbnail images on the same screen press the **PANEL** Soft Key. - To display a larger number of thumbnails, press **MORE**. - To display a smaller number, press **FEWER**. - To display the highlighted clip in full-screen mode, turn the inner Rotary knob or press the probe key. • To review stored clips, select **Play**; to stop the playback, select **Pause**. • To delete a clip from the study, highlight the clip then press **DELETE**. • To display the Study List, press **LIST**.

B-Mode Scanning

The default scanning mode for the system is B-Mode.

> **NOTE:** Functions listed in the Tools menu will vary depending on how the System Administration / User Selected Keys are configured.

B-Mode Tools

The real-time Control Bar Tools Soft Key displays a number of secondary-level real-time imaging-related controls. The active Tools items will vary according to the scanning mode.

Press the **Tools** button to display the Tools options. When this list is active, the Rotary knobs will control interaction with the list. Use the knobs in the same manner as is used to control the real-time control bar. The outer knob moves up and down the list and the inner knob adjusts the value or state for individual items.

B-Mode Tools Sub-Menu

B-Mode Tools Sub-Menu	*Description*
Exit Tools	Exits the **Tools** sub-menu.
PostProc	**Post Processing**. Adjusts the gray scale curves of the B-mode image. Lower values will have softer appearance, higher values will have a more “contrasty” appearance. Displayed in the on-screen settings window as **PP**.
Dyn. Range	**Image Dynamic Range**. Displayed in decibels (dB). Displayed in the on-screen settings window as numerical units followed by **dB**.
Compound	**Spatial Compounding**. Selects different levels of spatial compounding. Spatial compounding combines different scan steering angles to improve image quality. Displayed in the on-screen settings window as **SC**.
Speckle	**Speckle Filter**. Applies image filters that remove speckle or enhance edges. In general, higher values will apply more filtering for potentially smoother image appearance. Displayed in the on-screen settings window as **SF**.
L/R Reverse	**Left/Right Reverse**. This switches the orientation of the image on the screen so that the index marker symbol display is moved from the left of the image to the right of the image.
M-Line	Displays a dotted line through the middle of the image with depth markers.
Needle Visualization	Improves the display of needles during procedures. See below for details.
Wide	Widens the image of linear probes in a Trapezoidal display.
Dual	Activates dual imaging mode. The system displays one real-time image and one frozen image in a side-by-side format. To exit Dual mode, select **Dual** again. Once Dual is activated, use **Update** to alternate the live image between the left or right side of the image screen.

Needle Visualization

This setting improves the display of needles during procedures by brightening linear structures, such as needles, when they are perpendicular to steered frames activated by the user.

It adjusts the system's spatial compounding function to emphasize steering angles that may improve the display of needles. It also adjusts other image parameters, such as speckle filter, for this purpose.

If you specify Needle Visualization as one of your User Selected Keys in the System Administration settings (see **Enable Probe Middle Keys** on the "Probes Menu" on page 3-9), **Needle V** will be a dedicated key in the Real-time Control bar, and will not be listed in the Tools menu.

When the **Needle V** key is active it has six settings (the default setting is OFF). Turn the small knob or select the "+" or "-" button on the probe to pick a setting:

- ON: needle entering from the side of probe with the index marker, with steep angle.
- ON: needle entering from the side of probe with the index marker, with shallow angle.
- OFF
- ON: needle entering from opposite the side of probe with the index marker, with shallow angle.
- ON: needle entering from opposite the side of probe with the index marker, with steep angle.
- ON: needle enhancement without steering angle.

When one of the ON settings is active, a graphic overlay will appear on the image. The dotted line through the image approximates the steered angles active for that setting for brightening the display of a needle. For optimal display, the needle would be on a path that is perpendicular to this dotted line. Other linear shapes in the image that are perpendicular to this line, may also appear brighter.

Press the system console **Needle V** key to turn the most recently used Needle Visualization setting ON and OFF. If you specify Needle Visualization as the User Selected Key for the Probe middle keys, pressing either of the Probe's middle keys three times will also turn the most recently used Needle Visualization setting ON and OFF.

> **NOTE:** Needle Visualization can also be used in Color Flow mode.

Dual

This setting allows for the display of one real-time and one frozen image in a side-by-side format. **Dual** is a dedicated key in the **B-Mode Real-time** Control bar. For **Dual** to be available in Color Doppler mode, it must be chosen as either the **Color 1** or **Color 2** User Selected Keys in the System configuration settings (see User Selected Keys "Display Menu" on page 3-7).

To enable **Dual** mode, select **Dual** from the Real-time Control bar. Note that to enable Dual mode with Color Doppler, first activate **Color**, then select **Dual**. When Dual Mode is entered, the live image will move to the left side of the imaging screen. Select Freeze or Update to freeze the left image. Selecting **Update** will alternate the imaging screen under active control, as indicated by the gold "A" (). While in Dual mode, some Real-time controls will not be available. To exit Dual mode, select **Dual** again.

With both Dual images frozen, the Scroll and Clip controls will affect the active image indicated by the gold "A" (). For more information on Scroll and Clip, see page 5-11. Select **Update** to alternate the imaging screen under active control.

Color Flow Mode Scanning

Pressing **Color** on the real-time Control Bar activates color flow mapping mode. This key switches color flow on and off.

In color flow mode the real-time controls include:

C Gain – Color Gain controls the color flow overall gain.

C Box – Color Box controls the up/down position of the color flow box.

Color Flow Tools

The real-time Control Bar Tools Soft Key displays a number of secondary-level real-time imaging-related controls. The active Tools items will vary according to the scanning mode.

Press the **Tools** button to display the Tools options. When this list is active, the Rotary knobs will control interaction with the list. Use the knobs in the same manner as is used to control the real-time control bar. The outer knob moves up and down the list and the inner knob adjusts the value or state for individual items.

Color Flow Mode Tools Sub-Menu

Color Flow Mode Tools Sub-Menu	*Description*
Split	Activates two real-time images from the same acquisition in a side-by-side format, the Left image in B-Mode, the Right image in Color Doppler mode. To exit Split mode, select **Split** again.
Exit Tools	Exits the **Tools** sub-menu.
Color Map	Steps through multiple color flow maps. This selection also allows you to move from velocity mode to power mode. They are displayed in the on-screen settings window as either **Vel** (velocity maps) or **Pwr** (Amplitude Power maps). The maps are represented in the color bar next to the real-time image.
Vel Invert	**Velocity Invert**. Shifts the color map orientation from the default of red = towards the transducer, to blue = towards the transducer. When invert is selected, the color map graphic bar will invert. Displayed in the on-screen settings window as **Vel**. **WARNING:** It is important to pay careful attention to the color flow invert status of the system. The non-inverted state is red=towards the transducer, displayed at the top of the color bar and blue=away from the transducer, displayed at the bottom of the color bar.
Priority	Adjusts the arbitration that takes place between B-Mode tissue signals and Color Flow mapping signals. Higher priority settings will give greater weight to color flow signals. This can be used with weaker flows or to fill in flow near vessel borders. Displayed in the on-screen settings window as **Pri**.
C Persist	**Color Persistence**. Increases or decreases the amount of persistence applied to Color Flow signals. Higher settings will produce a smoother looking image and may help with weak flow, but may have an appearance of lower frame rates. Displayed in the on-screen settings window as **CP**.
C Filter	**Color Filter**. Adjusts the Color Flow high pass filter. Lower settings will pass through lower frequency flow signals. Displayed in the on-screen settings window as **CF**.
C Scale	**Color Scale**. Increases or decreases the Color Flow pulse repetition frequency. The scale is displayed next to the color bar in centimeters per second.

Split

This setting allows for the display of two real-time images from the same acquisition in a side-by-side format, the Left image in B-Mode, the Right image in Color Doppler mode. Split mode is available as one of the Color 1 or Color 2 User Selected Keys in the System configuration settings (see User Selected Keys on the “Display Menu” on page 3-7). If Split is not selected as the active control for Color 1 or Color 2, it will be available in the Color Doppler **Tools** menu.

To enable Split mode, first activate **Color**, then select **Split**. Select **Freeze** to freeze both images. To exit Split mode, select **Split** again. While in Split mode, some Real-time controls will not be available. While the image is frozen, Scroll and **Clip** controls will affect both images simultaneously. For more information on Scroll and Clip see page 5-11.

Measurements

Performing a Measurement

The measurements function can be performed from real-time scanning or starting with a frozen image. Up to ten individual measurements can be made on an image.

To perform measurements on an image:

1. Press the **MEASURE** Soft Key. The image will freeze and the measurement choices will appear in a menu above the key.
2. Use the Rotary knobs to make your selection, highlighting the item with the outer knob, and activating it with the inner knob.
3. When you select **DISTANCE**, a cross-hair cursor will appear on the screen. Place this at the starting point using the Trackball, then press the left Trackball button.
4. Use the Trackball to place the cursor at the endpoint, then press the left button again to complete the measurement. During the drawing, you can reverse direction using the right Trackball button to back up and delete parts of the trace. The numerical result is shown next to the drawing.
5. Press **Save** to save an image with measurements.

NOTE: You can perform measurements on images viewed from the **STUDY LIST**, but these measurements cannot be saved.

Deleting Measurements

Press **DELETE** to delete the last completed measurement.

To skip to an earlier measurement for deleting, use **Next**.

To delete all measurements, press **DELETE ALL**.

Ellipse Measurement

To perform an ellipse measurement:

1. Activate the ellipse function by selecting **ELLIPSE** from the **MEASURE** sub-menu. This brings up a cross-hair cursor you can position with the Trackball at the area of interest.
2. To display the ellipse form, press the left Trackball button. With the cursor inside the ellipse, press the left button continuously and use the Trackball to reposition the ellipse.
3. To change the size or shape of the ellipse, place the cursor well outside of the ellipse and press the left button continuously and use the Trackball to change the shape or size of the ellipse, moving the cursor to different positions around the ellipse to do so.
4. When you have finished, double-click the left Trackball button to complete the measurement.

NOTE: It is possible to perform measurements on images being viewed from the Study List, but the measurements cannot be saved in this case.

Area Measurement

To perform an area measurement:

1. Activate the Area function by selecting **AREA** from the **MEASURE** sub-menu.
2. Position the cross-hair cursor at the starting point by pressing the left Trackball button.

   NOTE: If you have selected the continuous trace method in the **SETUP** / **SYSTEM** / **ADMIN** page, use the Trackball to trace the area.

3. While drawing you can reverse direction using the right Trackball button to back up and delete parts of the trace. If you have selected the point-to-point method in the **SETUP** / **SYSTEM** / **ADMIN** page (by disabling Continuous Trace), use the Trackball to position the cursor, and the left Trackball button to set multiple points.
4. To complete the measurement, leave at least a small gap between your finishing point and the starting point, and press the left Trackball button twice. The system will complete the trace and display the result next to the trace.

   NOTE: It is possible to perform measurements on images being viewed from the Study List, but the measurements cannot be saved in this case.

Adding Text Annotations to Studies

Text labels can be added and saved to images.

To add text annotations or a pointer to an image screen:

1. Press the **Text** Soft Key.
2. Use the controls described in the Text Annotation Functions table to add text labels.
3. To exit Text mode, press the **Exit Text** Soft Key. When you save an image with text annotations, the text will be saved with the image.

NOTE: Text cannot be saved to images displayed in View mode.

NOTE: When a text annotation is newly created or selected from the list, it will be initially placed immediately below the most recently placed text annotation.

Text Functions

Text Annotation Functions

Text Function	*Description*
New	Creates a new text label. Use the on-screen keyboard or an external keyboard to type the text and add it to the list.
Exit Text	Closes the Text menu.
Clear	Clears all text labels on the current image.
Pointer	Use the pointer to select a location for the text label. Provides an arrow point to place in an area of interest. Use the Trackball to position the pointer. Use the inner Rotary knob to rotate the orientation of the arrow. Press the left Trackball button to lock the position of the annotation.
Text List	Provides a list of the text entries that have been created on the system. These are presented in most recently used order. The small Rotary knob highlights entries in the text list. When you have highlighted the desired entry, press the left Trackball button to activate the term so it can be placed in the image using the Trackball. You can also directly activate the entry by clicking on it in the list using the Trackball.
Right Mouse Key	Removes a highlighted entry from the text list.

6 Wireless Probes

This chapter contains information about operating the ACUSON Freestyle system with wireless probes.

Overview

When the system is operated in “wireless mode” the Probe Adapter Cable is not used; instead, the probe and console communicate wirelessly. To obtain successful results scanning wirelessly, follow the instructions provided here.

NOTE: Consult the Safety chapter and *System Reference Manual* for important information about wireless operation and electromagnetic compatibility issues associated with the system.

NOTE: See the Safety chapter and *System Reference Manual* for important information about the ACUSON Freestyle wireless probe specifications, electromagnetic compatibility considerations, and security features.

CAUTION: The ACUSON Freestyle is designed to operate in the same room as X-ray equipment. However, ACUSON Freestyle probes contain sensitive electronic components not found in conventional cabled probes. Avoid leaving probes directly in the active X-ray beams.

WARNING: To avoid the risk of electrical shock, do not insert the battery pack into probe or charger bays unless the battery pack, probe, or charger bays are dry and free of liquids.

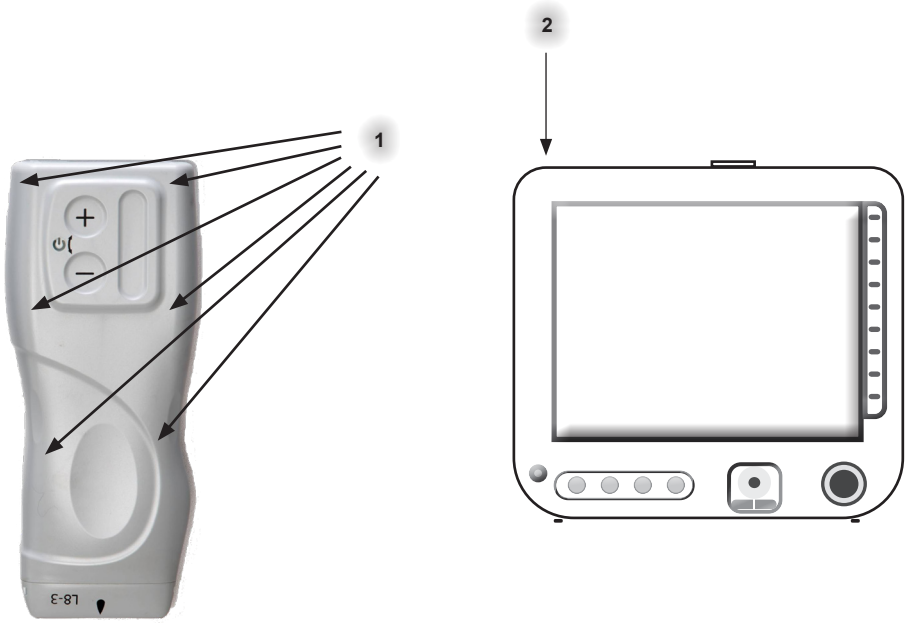
CAUTION: Verify that the probe battery pack, the probe battery receptacle, and the system charging bays are free of any liquid, gels, or contaminants before inserting the battery. Inserting the battery into the probe or charger bays when liquid, gel, or contaminants are present could cause harm to the probe and/or system.

Antenna Locations

There are multiple antennas located throughout the probe. The antennas are located around the battery well. If possible, keep your hand away from this area for optimal operation.

Additional antennas are also located in the midsection of the probe.

The system antennas are located in the upper left corners of the console. Maintain an unblocked line of sight between the probe and the console for optimal operation.



Location of Probe Antennas on Probe and Console

1. Probe antennas
2. Console antennas

Equipment Setup for Optimal Scanning

The radio frequency (RF) transmitters used in the ACUSON Freestyle to send image data from the probe to the console are designed to cover distances of no more than three (3) meters. It is important to make sure that the distance between the probe and the console does not exceed three (3) meters. Improved performance may be achieved with shorter distances.

When scanning, do not hold your hand at the back of the probe because by doing so you may cover up the primary internal antennas and disrupt the wireless communication with the console. Hold your hand towards the front of the probe.

The console and the probe should be oriented with the console facing the location of the transducer with a clear line of sight. The quality of the wireless link is weakened if the co-location of the two is too far out of plane, horizontally or vertically. The antennas in the console that communicate with the probe are located in the upper-left corner of the front of the display. Do not block these console locations; they must form a clear line of sight with the probe.

NOTE: Noise on the image, or disruptions in the wireless link, may be caused by RF generators in the vicinity. If problems occur, try relocating offending devices away from the system.

CAUTION: Operating more than one ACUSON Freestyle system in wireless probe mode in the same room where a probe is within five (5) meters of an unintended console unit, may cause interference problems on the unintended console unit. If this occurs, increase the distance from the probe to the unintended console unit until the interference disappears.

Connecting a Wireless Probe

> **NOTE:** For important information about the Wireless Signal Quality meter and the Average Noise Level index which are displayed during wireless scanning, see “Wireless Signal Quality” on page 6-7 in this chapter.

To connect a wireless probe to the system:

1. With the console unit powered on, hold the probe within three meters of the console, with a line-of-sight to the front of the console, and without obstructions between the probe and the console.
2. Turn the probe on by continuously pressing both circular buttons on the probe until you hear a beep that indicates the probe is powered on. The probe sends a signal to the console requesting the connection. The console displays this message: “Connecting to Probe” with the unique probe ID number, and sends a return signal which establishes the connection.
3. When the connection is made, the console screen displays this message: “Wireless connection established.”
4. Next, the message “Configuring System” is displayed and the console will beep. The console screen will show the probe battery symbol. You can now begin real-time scanning.

This process normally takes under three seconds to complete.

Problems Connecting

If the probe and console cannot establish a connection within ten seconds, the process is terminated and the probe is automatically powered off.

The console displays a status message: “Wireless connection timed out.”

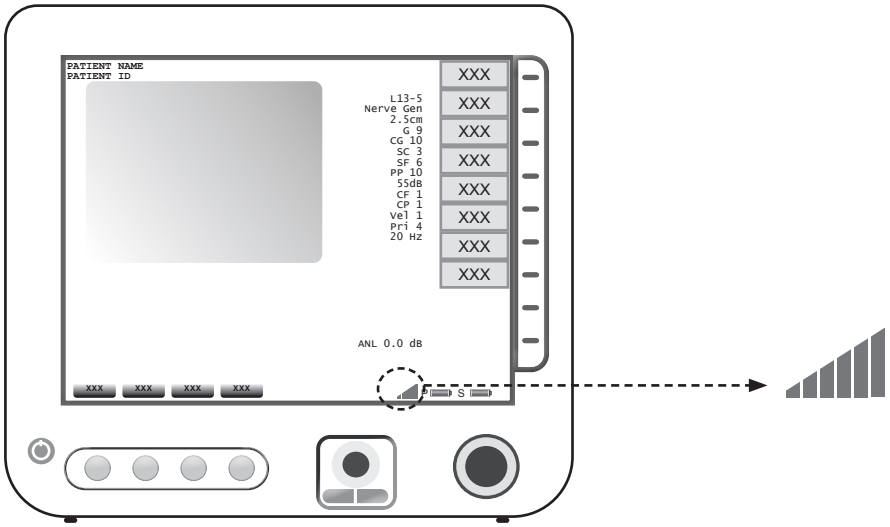
This situation can occur due to improper probe/console positioning. Check your equipment setup, then repeat the connection process by turning the probe back on again.

> **NOTE:** For proper probe/console positioning, follow the instructions described in “Equipment Setup for Optimal Scanning” on page 6-5.

Wireless Signal Quality

The ACUSON Freestyle console has a wireless signal quality meter that represents the wireless probe signal quality. Always position the probe and system to maximize the signal quality.

By staying inside the 3 meter range and maintaining a good line-of-sight between the probe and the console — without obstructing the antennas — you will be able to operate with good results.



The Wireless Signal Quality Meter indicates the wireless probe link quality; best signal quality is six bars.

The number of bars on the wireless signal quality meter has been empirically correlated to the potential for artifact to be introduced into the image because of a weak signal. This correlation has been experimentally quantified for a variety of system settings, probe types, image characteristics, and bit error levels in the wireless signal.

Use the display as a guide to maintaining a good link, following the guidelines below.

Monitoring Wireless Signal Quality

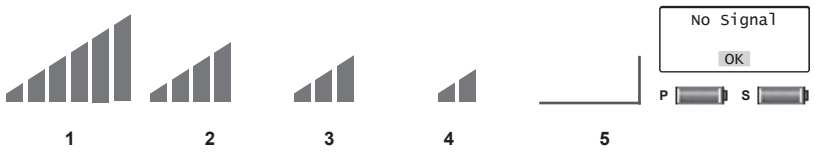
The ACUSON Freestyle has two methods of monitoring wireless signals:

- Wireless Signal Quality meter
- Average Noise Level indicator

Each is described in the following sections.

Wireless Signal Quality Meter

The signal meter has a total of six bars.



Wireless Signal Quality Meter; showing five different conditions

Number of Bars in the Wireless Signal

The number of bars in the wireless signal quality meter correlates to the potential of artifact being introduced because of a weak signal.

Always monitor the number of bars displayed in the meter. See the following table for a description of the conditions.

Wireless Signal Quality Meter Conditions

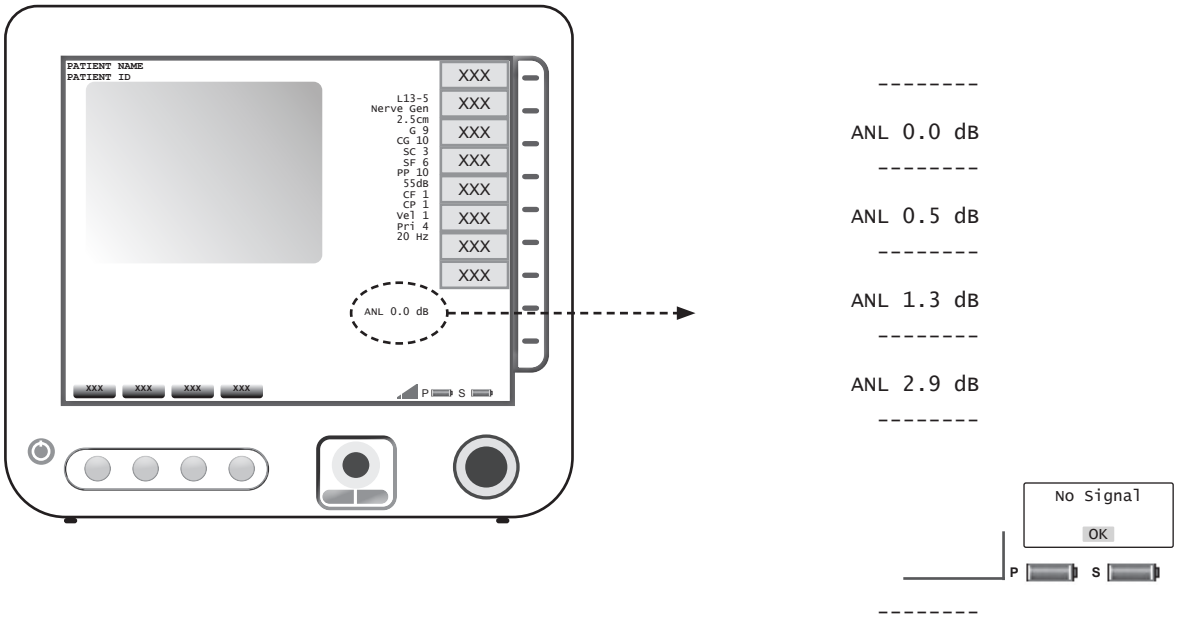
Number of Bars	*Condition Expectations*
4 to 6	The best signal quality. Expect a very reliable wireless probe performance without noise being introduced because of wireless link quality.
3	Very reliable wireless probe performance, this noise is typically imperceptible, but there is a possibility of low levels of noise (artifacts) being introduced into the image because of a compromised wireless probe link. Reorient the probe/console to within 3 meters of each other, in a line-of-sight, without obstructions between the probe and the console.
2 or 1	There is an increased possibility of noise (artifacts) being introduced to the image because of a compromised wireless probe link. These artifacts may appear as bright, streaky lines. See the image in “B-Mode Wireless Noise” on page 6-11. Reorient the probe/console to within 3 meters of each other, in a line-of-sight, without obstructions between the probe and the console.
0	The wireless signal has been lost, so the image screen is blank. A message appears on the console screen informing you of this condition. Reorient the probe/console to within 3 meters of each other, in a line-of-sight, without obstructions between the probe and the console.

Average Noise Level Indicator

An additional indicator of wireless imaging quality, called the **Average Noise Level** (ANL) has been calculated for various conditions. ANL is another tool to guide wireless scanning. It provides a measure of the potential for a compromised wireless link to introduce noise artifact into the image. ANL is displayed in real-time above the wireless signal quality meter.

ANL is displayed in dB. An ANL value of 0.0 represents the optimal setting and indicates that the signal quality is very good and free of errors that might introduce noise into the image.

Be alert to the ANL level, in accordance with the guidance below. To insure optimal wireless imaging, use the information from both the wireless signal quality meter and the ANL.



Five different Average Noise Level (ANL) conditions; last one showing “No Signal”

The wireless Average Noise Level (ANL) is displayed in real-time. Examples are provided above. Values above the 0.0 level reflect an increased possibility of noise being introduced into the image because of a compromised wireless link. The upper range is approximately 4.0 dB. For best results position the probe and system such that ANL is not above 1.0 dB.

Always monitor the noise levels on the console. See the following table for a description of the conditions.

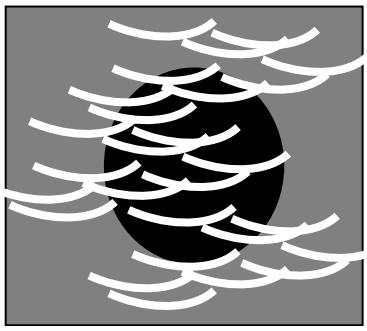
Average Noise Level Indicator Conditions

ANL decibels (dB)	*Condition Expectations*
0.0 to 0.3	Expect very reliable wireless probe performance without noise being introduced because of wireless link quality.
0.4 to 1.0	Very reliable wireless probe performance, but there is a possibility of low levels of noise being introduced into the image because of a compromised wireless probe link. This noise is typically imperceptible. Reorient the probe/console to within 3 meters of each other, in a line-of-sight, without obstructions between the probe and the console.
Signal greater than 1.0	There is an increased possibility of noise being introduced to the image because of a compromised wireless probe link. Reorient the probe/console to within 3 meters of each other, in a line-of-sight, without obstructions between the probe and the console.
No signal	The wireless signal has been lost, so the image screen is blank. A message appears on the screen informing you of this condition and the ANL display is also blank. Reorient the probe/console to within 3 meters of each other, in a line-of-sight, without obstructions between the probe and the console.

Wireless Noise Examples

B-Mode Wireless Noise

In B-Mode, if the wireless signal quality is compromised, noise may occur as shown in the simulated image below. If you experience such noise, reposition to improve the link quality.



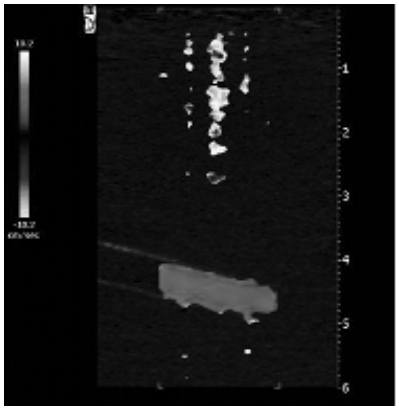
B-Mode wireless noise (simulated image)

Reasons for a Low Wireless Signal in B-Mode

- The probe is too far away from the console
- The probe is out of a line-of-sight to the console
- There is an obstruction between the probe antennas and the console antennas
- Some combination of these

Color Flow Wireless Noise

In Color Flow Doppler mode, if the wireless signal quality is compromised, excess background noise, as demonstrated in the simulated phantom flow image here may occur. If you experience such noise, reposition to improve the link quality.



Color Flow Doppler wireless noise (simulated image)

Reasons for a Low Wireless Signal in Color Flow

- The probe is too far away from the console
- The probe is out of a line-of-sight to the console
- There is an obstruction between the probe antennas and the console antennas
- Some combination of these

Finding/Locating Wireless Probes

It is very important to carefully manage the location of your wireless probes and not misplace them. Do not leave probes behind when performing mobile procedures.

The system provides multiple settings as a means of assisting in preventing the unintentional separation of the wireless probe from the console. By monitoring the strength of the Bluetooth radios and/or periods of inactivity, a series of audible and visual alerts can be used to locate and secure the probes.

NOTE: To hear the audible tone, follow these steps:
1. Connect a probe to the system by pressing the +/- buttons.
2. Select **SETUP / SYSTEM / PROBES** then press the **IDENTIFY** Soft Key.
3. Press **IDENTIFY** a second time to stop the audible tone.
4. Press **SCAN** to return to the imaging screen.

Probe Localization Features

Additional levels of localization are available to further assist in preventing the unintentional separation of the probe from the console. The additional levels of localization include the basic level described above. To enable the available options, select **SETUP / SYSTEM / PROBES**. Click the **Enable Probe Localization Alerts** checkbox and then select one of the options from the drop-down menu.

Off
Low+
Medium,
Medium+
High
High+

A detailed explanation of each setting can be found in the *Probe Localization Features* table on page 6-13.

When a dialog box is displayed, use the probe controls to select the options on the notifications dialog box and then secure the probe.

NOTE: The localization feature requires a probe to be turned on and connected wirelessly to the console, and to be in **Freeze**, that is, not live scanning. Enabling **Automatic Freeze** in the **SETUP / SYSTEM / PROBES** page will improve the function of this feature by automatically freezing the system when imaging is not active. This feature is subject to uncertainties inherent to Bluetooth radio connection quality and should not be relied on as a primary means of locating probes.

Probe Localization Features

Feature	*Off*	*Low +*	*Medium*	*Medium+*	*High*	*High+*
Auto-Freeze forced enabled					✓	✓
Probe out-of-range (low Bluetooth signal strength)						
Probe Audible Notification		✓		✓		✓
Visual Notification		✓		✓		✓
Console Audible Notification (initiated 15 seconds after Visual notification)		✓		✓		✓
Probe Link Disconnected (loss of Bluetooth connection)						
Probe Audible Notification (if battery is still in probe and charged)	✓	✓	✓	✓	✓	✓
Visual Notification	✓	✓	✓	✓	✓	✓
Console Audible Notification (initiated 15 seconds after Visual notification)					✓	✓
Probe Inactivity Auto-Freeze with Alerts						
Visual Notification (displayed when auto-freeze occurs)					✓	✓
Console Audible Notification (initiated 2 minutes after Visual notification)					✓	✓
Probe Audible Notification (initiated 1 minute after Console Audible notification)					✓	✓
Probe Inactivity of 6 Minutes after Manual Freeze						
Visual Notification (displayed 6 minutes after freeze if no activity occurs)					✓	✓
Console Audible Notification (initiated 2 minutes after Visual notification)					✓	✓
Probe Audible Notification (initiated 1 minute after Console Audible notification)					✓	✓
Study Closure						
Visual Notification	✓	✓	✓	✓	✓	✓
Turn Off Probe (press +/- keys to turn probe off)						
Console Audible Notification (probe power off sound)	✓	✓	✓	✓	✓	✓
Visual Notification			✓	✓	✓	✓
Turn Off Console (probe on)						
Probe Audible Notification	✓	✓	✓	✓	✓	✓

NOTE: Visual Notification and Console Audible Notifications stop whenever a new probe is connected.

Using Multiple Probes

Multiple probes can be used with the system, but only one probe can be *activated* at a time.

More than One Wireless Probe

To use more than one probe in wireless mode during an exam:

1. Turn the currently-connected probe off, thereby disconnecting it from the console.
2. Position the second probe and turn it on.

A Probe Connected via Probe Adapter Cable

If a Probe is connected to the console with the Probe Adapter Cable, you will need to disconnect it to make a wireless connection to another probe. Disconnect it at either the probe or the console end.

Powering Down the Probe

When you have finished scanning with the connected probe and are ready to either clean it or store it, power it down by continuously pressing both circular buttons on the probe until it beeps.

When the probe is turned off, the battery symbol will disappear from the display. Removing the battery also powers the probe down.

Before trying to scan with a new probe, be sure to power the active probe off.

> **NOTE:** During the course of a procedure, it is recommended that you leave the probe powered on so that the probe localization feature may function. See “Finding/ Locating Wireless Probes” on page 6-12 for more information.

> **NOTE:** For important information about the ACUSON Freestyle wireless probe specifications, electromagnetic compatibility considerations, and security features, see the Safety and Warnings chapter.

7 Batteries

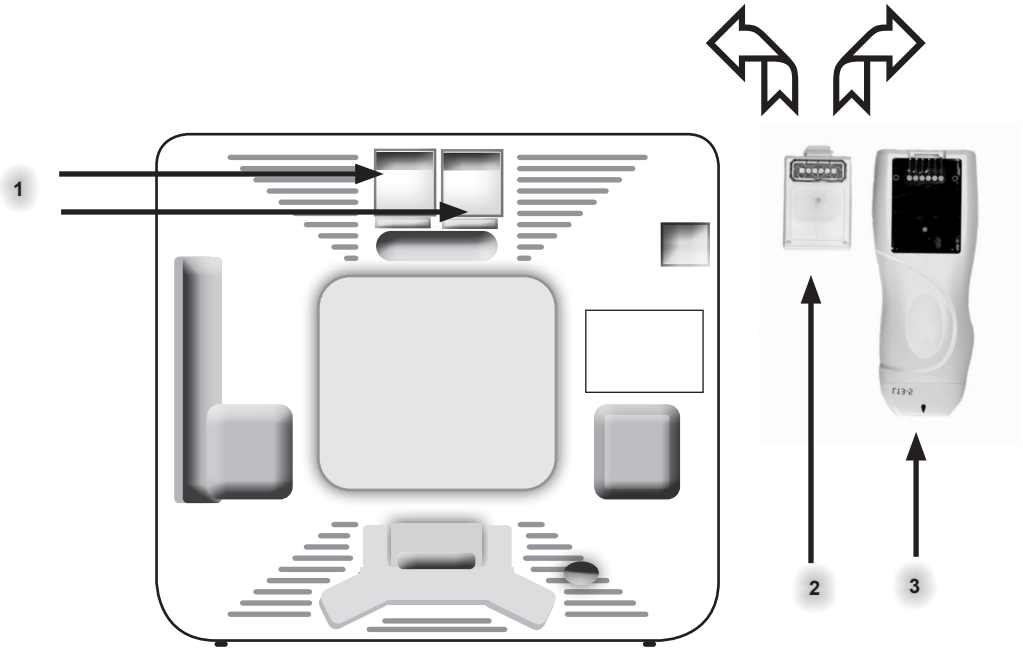
This chapter contains information regarding the battery operation of the system and wireless probes.

Overview of the Probe Battery

WARNING: Read the Safety Chapter of this manual for important information regarding safe operation of the ACUSON Freestyle batteries.

WARNING: To avoid the risk of electrical shock, do not insert the battery pack into probe or charger bays unless the battery pack, probe, or charger bays are dry and free of liquids.

CAUTION: Verify that the probe battery pack, the probe battery receptacle, and the system charging bays are free of any liquid, gels, or contaminants before inserting the battery. Inserting the battery into the probe or charger bays when liquid, gel, or contaminants are present could cause harm to the probe and/or system.



The probe battery is recharged in the charging bays at the rear of the System Console; when charged, return it to the probe

1. Probe charging bays
2. Probe battery
3. Probe

Charging the Probe Battery

Successful wireless probe scanning without interruption requires a properly charged battery pack. To charge the probe batteries, use the on-board two-port charging bays built into the back of the console.

For optimal charging in the console charging ports, the console should be plugged into AC Mains power outlet. If the system is unplugged from the AC mains power outlet, the probe batteries will recharge from the batteries inside the console, provided that those batteries have sufficient charge to do so. If the console internal batteries are depleted, and the console is unplugged, the probe batteries will not recharge.

To charge the probe battery, follow these steps:

1. Remove the probe battery from the probe by placing a finger at the back of the pack in the indentation and applying forward and outward pressure on the latch. As the battery releases from its compartment, be sure to prevent it from falling to the floor.
2. Place the battery into one of the console's charging bays with the metal contacts facing inwards. To be sure that the pack is properly engaged, confirm that the light next to the bay is lit, but not flashing.

   NOTE: The probe's battery pack is "keyed" to prevent improper insertion.

   CAUTION: The battery pack is keyed to fit into the charging bay in the proper orientation. Do not use excessive force in inserting the pack into the charging bay. Make sure that you have lined it up properly when inserting.

3. Confirm the status of the probe batteries in the charging bays by checking the Battery page in the **SETUP** Menu. Even if the console has enough battery charge to charge the probe batteries, if the console battery charge is low, you should plug it into an AC Mains power outlet.

Checking the Status of Charging Batteries

Charging status can be checked in two places: the charging bay and the console screen.

When the probe batteries are properly placed in the charging bay, a small light next to each bay will light to show the status of that battery.

- A green light means the battery is fully charged.
- A steady amber light means the battery is charging.

When probe batteries are being charged in the console charging bays and the system is on, their charging status is displayed at the top of the system screen directly under the probe battery.

Five dashed lines represent the charge status, with the bright dashes representing the battery charge level. For example, four bright dashes and one dim dash mean the battery is at least 80% charged. Charge status is also displayed in the **SETUP** / **SYSTEM** page.

Inserting the Battery into the Probe

To insert a charged battery pack into a probe:

1. Place the metal contact side facing into the well on the probe with the label facing down and the metal contacts towards the back of the probe.

CAUTION: The battery pack is keyed to fit into the probe in the proper orientation. Do not use excessive force in inserting the pack into the probe. Make sure that you have lined it up properly when inserting.

CAUTION: Use only your fingers to insert and remove the battery pack from either the probe or the charging ports. Do not use tools. Use of tools may damage the battery pack

Monitoring the Battery Charge Level while Scanning

During live scanning, monitor the charge level status of the probe battery by observing the probe battery (“P”) symbol and the system console battery (“S”) on the screen.

The green portion of the battery symbol represents the estimated charge remaining. Typically, a fully-charged probe battery will provide approximately 90 minutes of scanning.

NOTE: The estimated charge remaining is an approximation, and numerous factors, such as scanning mode and battery age can affect its accuracy.

When the probe battery charge level goes below 20%, the light on the probe changes to amber.

*On-screen display of the **P**robe battery charge level (shown partially charged), **S**ystem battery charge level (shown fully charged), and the **S**ystem power plug symbol (when the system console is plugged into an AC Mains power outlet instead of running on battery power)*

Low Battery Alerts

A pop-up message on the console will alert you when the probe battery approaches approximately 20% of remaining power.

You should then take action to avoid an interruption to the exam:

1. **Freeze** the image.
2. Turn the probe off.
3. Replace the probe battery with a fresh battery.
4. Turn the probe on and resume the exam.

Alternatively, you can begin using the probe cable connector or proceed to promptly complete the exam.

When the system battery approaches 10% the battery alert message will be repeated. Shortly, following that, the probe will automatically shut down. When the 10% remaining charge message appears, you should take action so as not to interrupt the exam.

When the system is plugged into AC Mains power, if the console batteries require recharging, and probe batteries are inserted into the onboard charging ports and also require recharging, the system will give higher priority to recharging the probe batteries.

8 Connectivity

This chapter tells you how to configure your system for connectivity, and how to operate connectivity commands.

Overview of Connectivity

The ACUSON Freestyle includes the DICOM (Digital Imaging and Communications in Medicine) networking capability. DICOM communications comply with the DICOM standard and provide links between the system and DICOM picture archival systems (PACS), modality worklist servers, and storage commitment servers.

Consult with your PACS Administrator when using the DICOM features of the ACUSON Freestyle.

> **NOTE:** Confirm compatibility between your DICOM PACS system and the ACUSON Freestyle before archiving from the ACUSON Freestyle to the PACS system.

System configuration for connectivity are usually carried out by your organization's network or PACS Administrators.

Connectivity features may be options which are not provided on every system.

Configuring the Network Settings

To configure your system for connectivity, go to **SETUP / NETWORK**. This takes you to the Network page.

Ethernet Setup

This defines the network identification of the system, using the IP address, Subnet Mask and Gateway to give the ACUSON Freestyle a unique identifier on a specific network.

Check the **Auto IP Enabled** box to enable the IP address to be assigned on startup.

Ethernet Network Configuration Fields

Network Field	*Description*
Auto IP Enabled	When checked allows the system to automatically obtain an IP Address.
IP Address	Automatically assigned or manually entered IP Address.
Subnet Mask	IP address formatting.
Gateway	Network access point.
MAC Address	The MAC (media access control) Address is a unique identifier for the system.
[OK]	Saves the settings for the network.
[Cancel]	Closes the menu without saving settings.

To edit the IP Address, Subnet Mask, or Gateway, click on the typewriter symbol next to the field.

> **NOTE:** The MAC address displayed cannot be edited.

Wireless Network Setup

> **NOTE:** The term “WiFi” is used here to represent the wireless networking standard IEEE 802.11b/g. Refer to the Safety chapter of this Manual and the *System Reference Manual* for important information about the operation of IEEE 802.11b/g on the ACUSON Freestyle.

Important: For important information about WiFi Security, refer to the *System Reference Manual*.

Use the WiFi Setup section of the Network page to configuring the ACUSON Freestyle to connect to a wireless network (go to **SETUP** / **NETWORK**).

To turn wireless networking on and off, use the **Enable WiFi** checkbox. When wireless networking is enabled, the system will automatically search for and connect to configured wireless networks in range, according to their order in the list.

> **NOTE:** Follow your institution’s guidelines for wireless networking security, and consult with your IT administrator when configuring the system for WiFi connectivity. Even secured WiFi networks may be the subject of unauthorized access.

The system can be configured to store multiple wireless network configurations.

Working with Multiple WiFi Networks

If multiple WiFi networks have been set up, use the options described in “Configuring the WiFi Network” on page 8-5 to manage them.

- **Move Up**: moves a network up in the list.
- **Move Down**: moves a network down in the list.
- **Release**: disconnects a connected WiFi network.
- **Connect**: manually connects to the selected WiFi network.
- **Edit**: modify the settings for a WiFi network.
- **Add**: initiates a search for wireless networks.
- **Remove**: deletes a network from the list.

Detecting WiFi Networks

Use the following options to detect WiFi networks:

- To detect and display WiFi networks, select **Add**.
- To repeat the search, select **Refresh Network List**.
- To manually enter a WiFi network settings, select **Manual Entry**.
- To open the **WiFi Network Settings** menu, double-click on a detected WiFi network. Use this option to configure the network.

Configuring the WiFi Network

WiFi Network Configuration Fields

Network Field	*Description*
Network Name	Unique name to identify the network in the Network List.
Network Type	Select either Infrastructure or Adhoc. • ***Infrastructure*** uses central access points such as routers for communication. • ***Adhoc*** allows wireless devices to communicate in a peer-to-peer fashion.
Security	Use the drop-down menu to select the security method used by the WiFi network. See the Safety chapter of this Manual for information about 802.11 b/g security. Use the data entry fields in the security box to enter security data. To import Enterprise WiFi Certificate data, select **IMPORT CERTIFICATE**. Copy the certificate to a USB drive, then plug the USB drive into the ACUSON Freestyle. Select the certificate file name and press **OK** to import the certificate.
Auto IP Enabled	When checked allows the system to automatically obtain an IP Address.
IP Address	Automatically assigned or manually entered IP Address
Subnet Mask	IP address formatting.
Gateway	Network access point.
[OK]	Saves the settings for the network.
[Cancel]	Closes the menu without saving settings.

Configuring the DICOM Setup

To access the DICOM setup screen, select **SETUP** / **SYSTEM** / **DICOM**.

Types of DICOM Devices

DICOM Field	*Description*
PACS	Configures the ACUSON Freestyle to link to a DICOM-compliant Picture Archival and Communications System (PACS).
Storage Commitment (Commit)	When on, supported by your PACS system and, configured on the ultrasound system, confirms that a study has been received and stored by the target device. It can take up to several minutes for the Storage Commitment Server to respond to a storage commitment request. During that time, any other transfers that have been lined up will continue. If a Storage Commitment Server is designated as a default server, a Storage Commitment operation will begin once the study has been transferred to the PACS.
Worklist	When supported by your PACS system and configured on the ultrasound system, manages the ACUSON Freestyle's communication with a DICOM Worklist Server to download patient information.
MPPS	When supported by your facility and configured on the ultrasound system, MPPS (Modality Performed Procedure Step) allows communication about the status of the study. If the study was opened from the Modality Worklist and MPPS is configured, when the study is closed, the user must select either **STUDY COMPLETED** or **STUDY DISCONTINUED** to export the study.
System	Sets the DICOM ***AE Title*** (the name the system provides to the DICOM server) and the port to use. The default AE Title is FREESTYLEN, where *N* is the ACUSON Freestyle serial number. The AE Title cannot contain the less than (<), greater than (>), period (.), or ampersand (&) characters. The default port number is 104.

DICOM Setup Menu Soft Keys

DICOM Soft Keys

Soft Key	*Description*
SCAN	Returns to the Scan screen.
NEW	Select to open the DICOM Device window. To add a new connection, fill in the fields and click **OK** (to cancel without saving changes, click the **X** to close the window). See "Configuring a DICOM Connection" on page 8-7 for a description of the fields.
DELETE	Highlight a connection and then select **DELETE** to delete the connection.
EDIT	Highlight a connection and then select **EDIT** to open the DICOM Device window. Make any changes. To save changes, select **OK**; to cancel without saving, click the **X** to close the window.

Configuring a DICOM Connection

To configure a DICOM connection,

1. Go to **SETUP** / **SYSTEM** / **DICOM**.
2. Select **NEW** Soft Key.
3. Enter the DICOM storage server information as described in the following table.
4. Click the **TEST** button to test the connection.
5. Click **OK** to save the DICOM connection.

DICOM Device Window Fields

DICOM Storage Server Field	*Description*
Alias	A name you create to identify the DICOM server. Limited to 16 characters.
IP Address	The IP (Internet Protocol) address for the server. See your System Administrator to determine your IP Address.
AE Title	Identifies the server application that receives the images from the ACUSON Freestyle. The alphanumeric characters entered in this field must exactly match (including case) the *Application Entity* name assigned to the server application. Limited to 16 characters. The AE Title cannot contain the less than (<), greater than (>), period (.), or ampersand (&) characters.
Port Number	The remote port on the server that is to receive the connection request and the patient studies. The default setting is 104.
Type	Specify the type of device as described in the Types of DICOM Devices table.
Set as default	To set a default DICOM device, place a check mark in the **Set as default** box in the DICOM Device window. In the DICOM listing, the default device will appear at the top of the list with a check mark. Only one default setting is permitted for each DICOM device type. Only one DICOM device for each function (Storage, Storage Commitment, Modality Worklist, and Modality Performed Procedure Step) can be designated as the default device. If no PACS is set as the default device, the Auto Send feature will be disabled. **NOTE:** To change the default DICOM device, place a checkmark in the last column of the DICOM device list. **NOTE:** The Default Device setting is required for the Auto Send and Artis Patient Synchronization features. For more information, see Auto Send (below) and “Artis Patient Synchronization” on page 9-4.
OK	To save changes, click **OK**.
Test	Used to test the connection once you have entered the configuration data. You can test using either Ping or C-Echo (DICOM Verify). Ping tests the connection across the network; C-Echo additionally tests that the DICOM server is active. For security reasons, some network and network servers are set up not to respond to Ping or C-Echo commands. Check with your IT department or PACS Administrator to determine how your network handles these functions. Note that the **TEST** button is displayed when you add or edit a network connection.
Auto Send	Auto Send, when enabled, allows the Freestyle to automatically send stored images and cine clips to a connected PACS systems when the exam is closed. To enable the Auto Send feature, a default PACS device must be selected on the DICOM setup page by placing a check mark in the last column of the DICOM device list. The default device may also be selected by highlighting the device and selecting **EDIT**, and then placing a check mark in the **Set as default** checkbox. If no PACS device is set as the default device, the Auto Send feature will be disabled.

Freestyle Mobile Link App

NOTE: The Freestyle Mobile Link App and the ACUSON Freestyle must be connected on the same network for proper functionality. Make sure to use a secure network to protect unencrypted patient information.

NOTE: For optimal security, ensure that the Freestyle Mobile Link is disabled when not in use. For more information, see **Enable Freestyle Mobile Link** in the "Admin Menu" on page 3-11.

NOTE: Images displayed using the App are for informational purposes only and are not intended for diagnostic use.

For instructions on using the Mobile Link App on a Microsoft Windows 8 mobile device, see the instructions provided with the App.

Freestyle Mobile Link Settings

Freestyle Mobile Link App Settings

Function	*Instructions*	*Additional Information*
Enable Freestyle Mobile Link	Select: **SETUP** / **SYSTEM** / **ADMIN**. Check the Enable Mobile App checkbox.	The App links using the WiFi connection. When the Mobile Link App is *Enabled*, the mobile symbol appears on the console imaging screen:  To disable the Mobile Link, uncheck the box.
Set Security PIN Code	Note that the PIN code specified here must also be entered on the Microsoft Windows mobile device in order to link to the ACUSON Freestyle. Select: **SETUP** / **NETWORK**. Go to the Mobile Link section. Select: PIN Code. Enter a four-digit PIN Code.	After entry, the PIN code is not displayed.
Confirm Port Number	The port number entered for the ACUSON Freestyle must be the same as the number entered in the App.	If the port number is changed, the ACUSON Freestyle must be restarted.
Activate New Patient Study from App	After sending patient study information from the App, select **PATIENT** / **WORKLIST**. Highlight the patient entry and select **Create Study**.	—

NOTE: When Enable Freestyle Mobile Link is selected, the following dialog box will be displayed on the ACUSON Freestyle: "Freestyle Mobile Link relies on Wi-Fi encryption for security. It should be used with secure networks only."

NOTE: When using the Mobile Link app and a connection from a mobile device is made, the following dialog box will appear on the ACUSON Freestyle: "A Mobile Link connection has been established from a mobile device. To allow the connection, press the OK button. To close the connection, press the Close button."

Privacy and Security

To insure proper protection of Protected Health Information and networking security when using the App, note the following recommendations and instructions.

- For important information about 802.11 (WiFi), refer to the Safety Chapter of this Manual and the *System Reference Manual*.
- For important information about Protected Health Information (patient privacy), refer to “Protecting Patient Health Information” on page 4-3 and the *System Reference Manual*.
- Follow your regional and institutional guidelines regarding networking security and Protected Health Information (patient privacy).
- If you do not want mobile devices to link to the ACUSON Freestyle using the Mobile Link App, uncheck (disable) the box on the **SETUP** / **SYSTEM** / **ADMIN** page.
- If a mobile device is connected through the Mobile Link App, the mobile symbol () will be displayed on the console screen.
- Protect the security of the PIN code used to allow devices to link. Change the PIN code if necessary to improve security.
- To prevent the patient name and ID from being displayed on saved images, use the Study Anonymity feature. Select **SETUP** / **SYSTEM** and check the two checkboxes to exclude Patient Name and Patient ID. Note that the Patient Name will still show up in the patient list.
- To create a fully anonymous study file, follow these steps: create a new patient study but do not enter a patient name or ID. When you select Save, to save the images, the system will automatically assign the name “UNKNOWN” and a date- and time-based ID.

9 Artis/Freestyle Workflow

This chapter describes using an external monitor and external antenna and the probe's remote controls to access the ACUSON Freestyle.

Overview of Setup

The optional Artis/Freestyle workflow allows you to access the ACUSON Freestyle from the patient table using the remote probe controls. The ACUSON Freestyle is optimized for use with various Siemens Artis systems. Refer to Chapters 1-8 in this User Manual and the *System Reference Manual* for complete operating instructions. Read ALL instructions before operating the ACUSON Freestyle ultrasound with an Artis system.

An example of an Artis Large Display; front (left picture) and back (right picture). Configurations may vary.

1. ACUSON Freestyle External Receive-only Antenna (front view)
2. ACUSON Freestyle External Receive-only Antenna (back view)
3. ACUSON Freestyle Console

Artis Patient Synchronization

Artis Patient Synchronization is an optional workflow enhancement that enables the Freestyle ultrasound system to communicate with an Artis angiography system to share patient information. Artis Patient Synchronization utilizes the Freestyle Modality Worklist feature to automatically create a new ultrasound study when a new exam is started on the Artis system. When the exam is closed on the Artis system, the ACUSON Freestyle will automatically close the ultrasound study and send any saved images to PACS through a direct connection to the hospital DICOM network, if configured.

How to Setup Artis Patient Synchronization

1. Power on the Freestyle console.
2. Navigate to the **SETUP / SYSTEM** window. Verify that the ACUSON Freestyle has the Artis Patient Synchronization option installed.
3. Navigate to the **SETUP / SYSTEM / DICOM** window. Create a new Worklist device. Enter in the following information:
   a. - AE Title: AE_WORKLISTSCP
   b. - Port: 3000
   c. - Alias: ArtisMWL
   d. - IP Address: (Artis technician will need to log into the Artis to find this information)
   e. - Type: Artis Worklist
   f. - Click the checkbox to Set as Default.
4. Create a new PACS device (obtain the following required information from the PACS Administrator):
   a. - Alias
   b. - IP Address
   c. - AE Title
   d. - Port
   e. - Type: PACS
   f. - Click the checkbox to **Set as Default**. (This will enable the Auto Send feature)
5. Navigate to the **Admin** window. Select Enable Artis Patient Synchronization.
6. Go to **SETUP / SYSTEM / DISPLAY** and select the appropriate VIDEO OUT option for your monitor. For additional information, review the description of the VIDEO OUT option (see “Video Out” on page 3-8).

NOTE: If Artis Patient Synchronization is enabled, ultrasound studies will be automatically created and closed based on the information received from the Artis angiography system. Do not manually create a new ultrasound exam or close an open ultrasound exam.

NOTE: Mobile use of the ACUSON Freestyle will require changing/adding a Modality Worklist server.

Conducting an Ultrasound Procedure with Artis/Freestyle Workflow

NOTE: If the ultrasound studies will be exported to a PACS, the ACUSON Freestyle must be configured to communicate with the PACS and a default server must be selected. For important information regarding connectivity, see the “Connectivity” chapter in this Manual.

NOTE: Monitor the probe battery for the power level and change the battery when necessary. For important information about the probe and console batteries, see the “Batteries” chapter in this Manual.

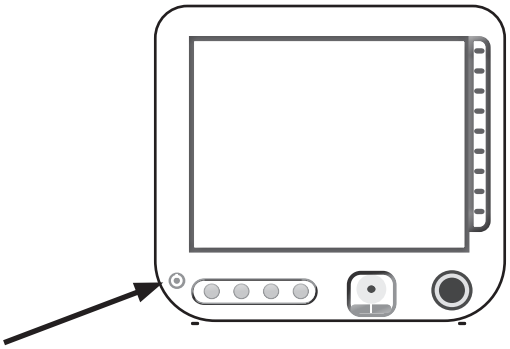
P 

***P** (Probe battery charge level icon) (shows a partially charged battery); appears at bottom right of display*

To conduct a scan using Artis/Freestyle workflow, follow these steps:

1. Power on the ACUSON Freestyle console.

For a complete introduction and overview of the ACUSON Freestyle, see the “Introduction” chapter in this Manual.



2. With the console unit powered on, hold the probe within three meters of the external antenna, with a line-of-sight to the front of the external antenna, and without obstructions between the probe and the external antenna.

   NOTE: Mobile use of the ACUSON Freestyle may require changing/adding a Modality Worklist server.

   Artis Patient Synchronization is a workflow enhancement that enables the Freestyle ultrasound system to communicate with an Artis angiography system to share patient information. When enabled, the ACUSON Freestyle automatically creates a new ultrasound study when a new exam is started on the Artis system. When the exam is closed on the Artis system, the ACUSON Freestyle will automatically close the ultrasound study and send any saved images to PACS, if configured.

   NOTE: If Artis Patient Synchronization is enabled, ultrasound studies will be automatically created and closed based on the information received from the Artis angiography system. Do not manually create a new ultrasound exam or close an open ultrasound exam.

3. Turn the probe on by continuously pressing both circular buttons on the probe until you hear an initial tone that indicates the probe is powered on.
   – When the connection is made, the console screen displays this message: “Wireless connection established.”
   – Next, the message “Configuring System” is displayed and the console will beep. The console screen will show the probe battery symbol. You can now begin real-time scanning.

   This process normally takes under three seconds to complete.

Probe Controls

1. Circular plus/minus keys
2. Index marker light
3. Slider bar
4. Probe middle keys
5. Front (or “face”) of probe

Controls on the probe can be used to select and adjust functions on the real-time Control Bar.

Use the probe's **slider** to select image parameters. To move the highlight bar up the list, push upward on the slider, away from the transducer face; to move the highlight bar down, push downward on the slider, toward the transducer face.

Use the probe's **+/-** buttons to adjust the settings of the highlighted option (e.g., to step frame-by-frame through an image sequence). **Plus** corresponds to clockwise rotation of the inner Rotary knob; **minus** corresponds to counterclockwise rotation of the inner Rotary knob.

For important information about the probe operation and scanning, see the "Scanning" and "Wireless Probes" chapters in this Manual.

CAUTION: The ACUSON Freestyle is designed to operate in the same room as X-ray equipment. However, ACUSON Freestyle probes contain sensitive electronic components not found in conventional cabled probes. Avoid leaving probes directly in the active X-ray beams.

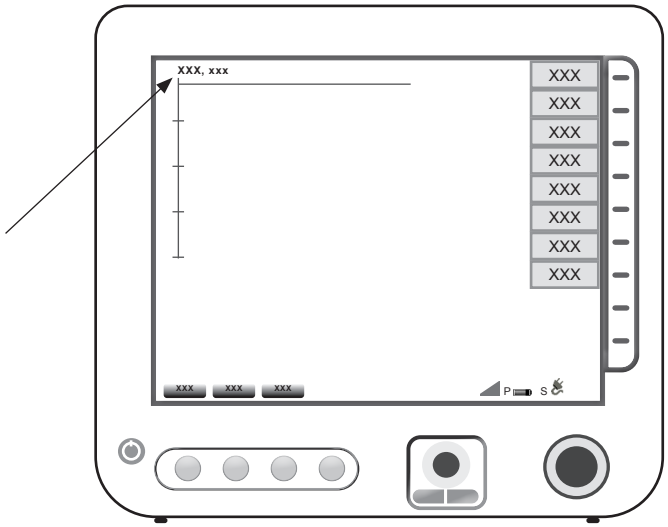
WARNING: To avoid the risk of electrical shock, do not insert the battery pack into probe or charger bays unless the battery pack, probe, or charger bays are dry and free of liquids.

CAUTION: Verify that the probe battery pack, the probe battery receptacle, and the system charging bays are free of any liquid, gels, or contaminants before inserting the battery. Inserting the battery into the probe or charger bays when liquid, gel, or contaminants are present could cause harm to the probe and/or system.

4. When new patient registration data is entered on the Artis system, the ACUSON Freestyle will automatically pull the patient registration data within 60 seconds and create an ultrasound study. Turning on the ACUSON Freestyle Probe will also initiate patient registration data synchronization.

   NOTE: Confirm the correct patient registration data appears on the Artis system before turning on the ACUSON Freestyle probe.

WARNING: Verify that the patient information is correct after auto-registration. Do not attempt to manually enter or edit patient information on the Freestyle when Artis Patient Synchronization is enabled. For information about manual entry of patient information, see “Patient Study Fields” on page 4-4.



Location of the PATIENT Registration information

5. Use the probe controls to select **Freeze**/**Unfreeze**, **Save** the scan, or change **Depth**, **Gain**, and other image parameters.

For important information about using the probe, see the “Scanning” chapter in this Manual.

Shutdown When AC Power is Lost

To automatically power down the ACUSON Freestyle approximately 60 seconds after AC power is removed (for example, when the Artis is powered down), enable the Shutdown when AC Power is Lost option. To prevent the ACUSON Freestyle from automatically powering down, set the Cancel shutdown, use battery option. No loss of data will occur as a result of automatic power down. For more information, see “Shutdown when AC Power is Lost” on page 3-11.