SIEMENS

ACUSON Freestyle System Reference Manual

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Siemens Medical Solutions, USA, Inc.

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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 ■ Open Source Software Statement
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.

Intended Audience

The intended audience for the user and reference manuals includes the following users.

User	*Interaction with Ultrasound Equipment*	*Expected Experience and Other Characteristics*
Sonographer or Nurse	■ Acquires diagnostic views of anatomy, blood flow, and related pathology ■ Performs measurements and analysis of the acquired images ■ Performs ultrasound-guided procedures ■ 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 ■ Expert in ultrasound guided procedures ■ Many sonographers and nurses have a Bachelor's degree in related health care subjects
Physician	■ Acquires diagnostic views of anatomy, blood flow, and related pathology ■ Performs measurements and analysis of the acquired images ■ Performs ultrasound-guided procedures ■ Writes and assembles exam findings in a report	■ Medical doctor ■ Expert in diagnostic imaging, including computed tomography (CT), magnetic resonance imaging (MRI), X-ray, ultrasound, and nuclear medicine ■ Skilled in the interpretation of ultrasound exam data ■ Expert in ultrasound-guided procedures
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 representatives who configure the ultrasound system or workstation during software installation and support troubleshooting activities

Safety – Electromagnetic Compatibility

Electromagnetic Interference

The ACUSON Freestyle has been tested and found to comply with the electromagnetic compatibility (EMC) limits for medical devices provided in IEC 60601-1-2:2007. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

Compliance with the test limits of the standard does not guarantee that a particular installation will be free from electromagnetic interference. This equipment generates, uses, and can radiate radio frequency energy. Medical electrical equipment requires special precaution regarding EMC and must be installed and operated in accordance with manufacturer instructions. Use only accessories specified here.

WARNING: Operating the ultrasound system in close proximity to other equipment can cause reciprocal interference. You should observe and ensure normal operation of the ultrasound system and other equipment. Use of accessories other than those specified here may result in increased electromagnetic emissions or decreased electromagnetic immunity of the ACUSON Freestyle.

It is possible that high levels of radiated or conducted RF communications equipment or other strong RF sources in the vicinity could result in a performance disruption of the ACUSON Freestyle. Evidence of disruption might include, among other behaviors, image noise, interruption of wireless links, or image freezing. Such interference may be caused by equipment that also meets the 60601-1-2:2007 standard.

There is no guarantee that interference will not occur in a particular installation. If a problem occurs you can try to correct it by one or more of the following measures:

- Reorient or relocate interfering equipment.
- Turn nearby equipment on and off to isolate disruptive sources.
- Increase the distance between equipment.
- Connect the equipment to an outlet on a circuit different from that to which the other device or devices are connected.
- Switch between wireless and wired ACUSON Freestyle probe operation to see if this affects the disruption.
- Educate staff regarding the recognition and handling of potential electromagnetic interference (EMI) problems.
- Switch between battery-operated and AC operated power of the Main Unit to determine if this affects disruption.
- Eliminate or reduce EMI with technical solutions (such as shielding).
- Purchase medical devices that comply with IEC 60601-1-2 EMC standards.
- Use only recommended accessories or peripherals.
- Consult the manufacturer of the other device, or your service representative.

Electrosurgical Devices

Electrosurgical devices are designed to introduce RF electromagnetic fields or currents into patients. The overlap of the frequencies used by these devices and ultrasound imaging systems creates a susceptibility to interference on the part of the ultrasound system. During electrosurgical device operation the ultrasound image should be expected to experience severe interference that may make the image unusable. This interference typically will be sufficiently severe that it is obvious to the user that the image is unusable. This interference stops as soon as the electrosurgical device is turned off.

Electrostatic Discharge

Electrostatic discharge (ESD), or static shock, is a naturally occurring phenomenon. ESD is common in conditions of low humidity, which can be caused by heating or air conditioning. Static shock is a discharge of the electrical energy from a charged body to a lesser or non-charged body. Equipment that complies with the IEC 60601-1-2 standard is designed to withstand ESD, but the degree of discharge can be significant enough to cause interruption or damage to a device. The following precautions can help reduce ESD:

- Use anti-static spray on carpets or linoleum flooring.
- Use anti-static mats.

Restrictions for Use

If RF interference is detected, then the physician must determine if an artifact caused by the interference will negatively impact image quality and the subsequent diagnosis.

Immunity Level Test Results

Immunity is defined in the standard as the ability of a system to perform without degradation in the presence of electromagnetic disturbance. The EMC standards require manufacturers of patient-coupled equipment to specify immunity levels for their systems. The standards recognize that ultrasound equipment is designed to receive and amplify low-level signals in the same bandwidth as the interference. Therefore, it is reasonable to expect image noise during electromagnetic disturbance.

> **EMC Note:** Operating the ultrasound system in close proximity to sources of strong electromagnetic fields, such as radio transmitter stations or similar installations, as well as portable and mobile RF 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.

When comparing immunity levels of different ultrasound systems, recognize that although the EMC standard does define the test methodology, it does not specify the criteria to assess degradation. Degradation assessment may vary by manufacturer.

A qualitative assessment of degradation in image quality is subjective. Noting when the first sign of an artifact is seen in the image minimizes the issue of subjectivity and also provides for stringent test results.

The results of emissions testing and immunity testing are provided in the accompanying tables. The standards used in testing are also provided in the tables. Testing was performed on a typical ultrasound system configuration.

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 any signal input or signal output ports 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 listed in your system's operating instructions. If in doubt, contact your local Siemens representative.

WARNING: You must only use the transducers, accessories, cables, and replacement parts for internal components specified by Siemens to reduce the risk of increased RF (radio frequency) emissions or decreased immunity of the ultrasound system.

Manufacturer's EMC Declaration

The tables below specify the intended use environment and EMC compliance levels of the ACUSON Freestyle. For optimal performance, ensure that the system is used in the environment described here.

TABLE 1: *Guidance and Manufacturer's Declaration: Electromagnetic Emissions for the ACUSON Freestyle*

NOTE: The ACUSON Freestyle system is intended for use in the electromagnetic environment specified below. The customer or the user of the ACUSON Freestyle system should assure that it is used in such an environment.

Emissions Test	*Compliance*	*Electromagnetic Environment – Guidance*
RF emissions CISPR 11	Group 1	The ACUSON Freestyle uses RF energy for it internal function. Therefore, its unintentional RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The ACUSON Freestyle is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network which supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

TABLE 2: *Guidance and Manufacturer's Declaration: Electromagnetic Immunity for the ACUSON Freestyle System, Independent of Transducer Type*

NOTE: The ACUSON Freestyle system is intended for use in the electromagnetic environment specified below. The customer or the user of the ACUSON Freestyle system should assure that it is used in such an environment.

Immunity Test	*IEC 60601-1-2 Test Level*	*Compliance Level*	*Electromagnetic Environment – Guidance*
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	AC Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+1 kV line(s) to line(s) ±1 kV line(s) to earth	+1 kV differential mode ±1 kV common mode	AC Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle	System may shut down and the mains circuit breaker could be switched to the off position (O = OFF).	Ensure the mains circuit breaker is in the on position (I = ON) and then use the power on sequence to reboot the system. Mains power quality should be that of a typical commercial or hospital environment. If the user of the ACUSON Freestyle system requires continued operation during power mains interruptions, it is recommended that the ACUSON Freestyle system be powered from an uninterruptible power supply or a battery.
	40% U_T (60% dip in U_T) for 5 cycles	40% U_T (60% dip in U_T) for 5 cycles	AC Mains power quality should be that of a typical commercial or hospital environment. If the user of the ACUSON Freestyle system requires continued operation during AC power Mains interruptions, it is recommended that the ACUSON Freestyle system be powered from an uninterruptible power supply or a battery.
	<70% U_T (30% dip in U_T) for 25 cycles	70% U_T (30% dip in U_T) for 25 cycles	
	<5% U_T (>95% dip in U_T) for 5 sec	System goes to normal power down condition	For extended mains power outages without the use of an uninterruptible power supply or a battery, the system will shut down normally. Use the power on sequence to reboot the system.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: U_T is the AC Mains power voltage prior to application of the test level.

Electromagnetic Immunity

TABLE 4: *Guidance and Manufacturer's Declaration: Electromagnetic Immunity for ACUSON Freestyle System*

NOTE: The ACUSON Freestyle system is intended for use in the electromagnetic environment specified below. The customer or the user of the ACUSON Freestyle system should assure that it is used in such an environment.

Immunity Test	*IEC 60601-1-2 Test Level*	*Compliance Level*	*Electromagnetic Environment – Guidance*
			Portable and mobile RF communications equipment should be used no closer to any part of the ACUSON Freestyle system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance (*d*):
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	V_1 = 3 Vrms 150 kHz to 1.0 MHz 5.1 MHz to 80 MHz V_1 = 0.02 Vrms 1.0 MHz to 5.1 MHz	$d = [\frac{3.5}{V_1}] \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	E_1 = 3 V/m 80 MHz to 2.5 GHz	$d = [\frac{3.5}{E_1}] \sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}] \sqrt{P}$ 800 MHz to 2.5 GHz where ***P*** is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and ***d*** is the recommended separation distance in meters (m). V_1 and E_1 = Compliance Level Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:  (Intentional transmitter of non-ionizing radiation symbol)

NOTE: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ACUSON Freestyle system is used exceeds the applicable RF compliance level above, the ACUSON Freestyle system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as changing transducers or transducer operating frequency, or re-orienting or relocating the ACUSON Freestyle system.

b Over the frequency range of 150 kHz to 80 MHz, field strengths should be less than the compliance level (V_1).

TABLE 5: *Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the ACUSON Freestyle System*

NOTE: The ACUSON Freestyle system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ACUSON Freestyle system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ultrasound system as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W (watts)	*Separation Distance According to Frequency of Transmitter m (meters)*		
	2.582 MHz to 5.898 MHz **35.361 MHz to 37.912 MHz** $d = [\frac{3.5}{V_1}] \sqrt{P}$	**80 MHz to 800 MHz** $d = [\frac{3.5}{E_1}] \sqrt{P}$	**800 MHz to 2.5 GHz** $d = [\frac{7}{E_1}] \sqrt{P}$
0.01	0.12	0.11	0.23
0.1	0.37	0.36	0.73
1	1.17	1.16	2.33
10	3.69	3.68	7.37
100	11.66	11.66	23.33
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

Interference from Leaking Microwave Ovens

Avoiding Interference from Leaking Microwave Ovens

Faulty microwave ovens can leak RF energy at levels that have been associated with interference to wireless devices operating at or around the same 2.4 GHz frequency as the leaking microwave. Leaking is typically associated with older ovens, or ovens with damage to the door hinges, latch, or seals. Interference caused by a leaking microwave can disrupt the throughput of 802.11 or Bluetooth data, or cause a disconnection in the link. Because the ACUSON Freestyle employs 802.11 and Bluetooth radios that operate in the 2.4 GHz band, testing has been conducted to verify that the ACUSON Freestyle will operate reliably in the presence of a leaking microwave. Even though this testing has demonstrated reliable operation in the presence of a leaking microwave, it is important for you to be aware of the potential for this type of interference and to take additional steps to minimize the risk of interference.

Steps for Avoiding Interference from Leaking Microwave Ovens

- Do not place microwave ovens in the same vicinity as the ACUSON Freestyle. If placement of a microwave in the vicinity of the ACUSON Freestyle cannot be avoided, maintain a minimal separation distance of at least 3 meters.
- Do not operate a microwave oven in the vicinity of the ACUSON Freestyle at the same time the ACUSON Freestyle is in use.
- Do not operate a microwave oven if the door does not close firmly or is bent, warped, or otherwise damaged.
- Never operate a microwave oven if you have reason to believe it will continue to operate with the door open.
- If you suspect that a microwave oven is leaking RF energy, replace it with a newer model. At a minimum, you should consult with your Biomedical Engineering Department about evaluating the suspect microwave using a professional service and calibrated testing equipment.
- Further information is available at: http://www.fda.gov/radiation-emittingproducts/resourcesforyouradiationemittingproducts/consumers/ucm142616.htm#8

Interference from RFID Devices

The application of radio frequency identification (RFID) devices is growing. This technology is increasingly found in the healthcare environment for uses such as security, and the location and tracking of medications, patients, assets and equipment.

RFID devices operate at a number of frequencies, from as low as 125 KHz to over 6 GHz. As this technology has expanded, there are studies and reports of RFID devices interfering with medical equipment as well as with implantable pacemakers and cardioverter defibrillators.

The table below lists different types of RFID systems. Active tags refer to RFID tags which provide their own internal power for transmission. Passive tags rely on electromagnetic transmissions from the reader to power their transmission back to the reader.

TABLE 6: *RFID Types*

Type/Frequency	*Maximum Read Range/ Typical Tag Type*	*Typical Healthcare Use*
Low Frequency: 125 – 135 KHz	1 meter (passive)	Access control
High Frequency: 13.56 MHz	1 meter (passive)	Smart cards, access control, medication tracking
High Frequency: 433 MHz	100 meters (active)	Asset, staff, patient, location
Ultra-High Frequency: 902 – 928 MHz	3 meters (passive)	Asset, staff, patient, location
Microwave: 2.45 GHz	3 meters (passive) 60 meters (active)	Asset, staff, patient, location
Ultra-Wideband: 3.1 – 10.6 GHz	60 meters (active)	Asset, staff, patient, location

Avoiding Interference from RFID Devices

The ACUSON Freestyle has been tested for immunity to RFID devices, including each of the types listed above. The results of this testing have demonstrated reliable immunity of the ACUSON Freestyle to interference from a variety of RFID transmitters. Even though this testing has demonstrated reliable operation in the presence of RFID transmitters, it is important for you to be aware of the potential for this type of interference and to take additional steps to minimize the risk of interference. The increasing number and variety of RFID devices being introduced means that situations may arise where there is a risk of an RFID transmitter interfering with the operation of the ACUSON Freestyle. This potential interference is not restricted to wireless operation, but may include other functions of the system.

Steps for Avoiding Interference from RFID Devices

- To the extent possible, do not place RFID devices directly in the vicinity of the ACUSON Freestyle.
- If you intend to use RFID for asset tracking of the ACUSON Freestyle, confer with your Biomedical Engineering Department and your Siemens Service Representative to ensure that the proposed RFID system does not pose compatibility issues.
- Operate RFID devices only in accordance with manufacturer's instructions, and do not operate them inside of recommended separation distances from other equipment.
- Deploy only RFID systems that have been developed and tested for use in healthcare settings.
- If there are questions about the potential for interference of an RFID device, reference 1 below (ANSI C63.18) provides a protocol for testing the compatibility of RF transmitters with medical devices.
- Consult with your Siemens Service Representative with any other questions regarding RFID and the ACUSON Freestyle.
- Further information is available at: http://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/ElectromagneticCompatibilityEMC/ucm116647.htm

RFID References

1. American National Standards Institute. *Recommended practice for an on-site ad hoc test method for estimating radiated electromagnetic immunity of medical devices to specific radio-frequency transmitters* (Standard C63.18). Piscataway, NJ: IEEE, 1997.
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3. Christe, B., Cooney, E., Maggioli, G., Doty, D., Frye, R., Short, J. Testing potential interference with RFID usage in the patient care environment. *Biomedical Instrumentation and Technology 2008*; 42: 479-484.
4. Seidman, S.J., Brockman, R., Lewis, B.M., Guag, J., Shein, M.J., Clement, W.J., Kippola, J., Digby, D., Barber, C., Huntwork, D. In vitro tests reveal sample radio frequency identification readers inducing clinically significant electromagnetic interference to implantable pacemakers and implantable cardioverter-defibrillators. *Heart Rhythm 2010*; Jan; 7(1):99-107.

Wireless Specifications

Safety – Wireless RF Transmission

NOTE: In its wireless operation, the ACUSON Freestyle intentionally radiates radio frequency (RF) signals.

This device complies with part 15 of United States FCC Rules. Operation is subject to the following two conditions:

- This device may not cause harmful interference, and
- This device must accept any interference received, including interference that may cause undesired operation.

NOTE: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commmercial environment. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his or her own expense.

This device complies with ETSI EN 302 065.

Unauthorized changes or modifications to the ACUSON Freestyle's wireless RF components may void the authority to operate the system in wireless mode.

The installer of this radio equipment must ensure that the antenna is located or pointed such that it does not emit RF field in excess of Health Canada limits for the general population; consult Safety Code 6, obtainable from Health Canada's website www.hc-sc.gc.ca/rpb.

This device complies with Industry Canada license-exempt RSS standard(s).
Operation is subject to the following two conditions:
(1) this device may not cause interference, and
(2) this device must accept any interference, including interference that may cause undesired operations of the device.

Cet appareil est conforme avec Industrie Canada exempt de licence Rss standard(s).
Son fonctionnement est soumis aux deux conditions suivantes:
(1) cet appareil ne peut causer d'interférences, et
(2) cet appareil doit accepter toute interférence, y compris des interférences qui peuvent provoquer un fonctionnement indésirable du périphérique.

Safety – Wireless RF Transmission & Receive

ACUSON Freestyle Wireless Technologies

The ACUSON Freestyle operates using several wireless technologies. The wireless probe utilizes a proprietary, unidirectional ultra-wideband radio to send image data to the system. An integrated bidirectional Bluetooth radio is used in the probe and the system to communicate control data between the probe and system. A standard 802.11b/g/n transceiver is used to provide “wireless Ethernet” (WiFi) communication to DICOM servers. Bluetooth is also used for the wireless probe tracking feature. Details on the proper operation of these wireless functions are provided in several previous chapters in this User’s Manual.

This overview is meant to supplement the details provided in the relevant chapters, which are also referenced below. Specifications and operational guidelines for ACUSON Freestyle wireless devices are summarized below.

TABLE 5: *RF and Wireless Technology Summary*

	Probe		*Main Unit (Console)*			
Function	Image Data Transmit	Control Data Communications: Probe/System	Image Data Receive	Control Data Communications: Probe/System	Probe Tracking	Wireless Ethernet
Technology	Ultra-wideband (Proprietary FCC Part 15 Subpart F & ETSI EN 302065 Compliant)	Bluetooth 2.0 Class 2	Ultra-wideband (Proprietary FCC Part 15 Subpart F & ETSI EN 302065 Compliant)	Bluetooth 2.0 Class 2	Bluetooth 2.0 Class 2	802.11 b/g/n (WiFi)
Transmit/ Receive	Transmit	Transmit/Receive	Receive	Transmit/Receive	Transmit/ Receive	Transmit/ Receive
Frequency	7.8 GHz	2.4 GHz	7.8 GHz	2.4 GHz	2.4 GHz	2.4 GHz
Range (meters)	~ 3	~ 10	~ 3 (from probe)	~ 10	~ 10	~ 38
Modulation	DBPSK	GFSK	DBPSK	GFSK	GFSK	OFDM
Bandwidth	500 MHz	1023 MHz	500 MHz	1023 MHz	1023 MHz	12.16 MHz 802.11b 16.60 MHz 802.11g 20 MHz or 40 MHz 802.11n
Effective Radiated Power	< − 41.3 dBm/ MHz (EIRP)	− 0.26 dBm	Not applicable	− 0.26 dBm	− 0.26 dBm	Reference FCC ID RYK-WUBR507N

TABLE 6: *RF and Wireless Technology: About, Use, Configuration, Setup*

	Probe Ultra-Wideband (UWB)	*Bluetooth Probe/ System Control*	*802.11 b/g/n (WiFi)*
About the Technology (see TABLE 5 for specifications)	Ultra-wideband is a very low power, broadband, wireless technology capable of high data rates over short distances.	Bluetooth is a standardized, open wireless protocol for exchanging data over short distances.	IEEE 802.11 is a set of standards carrying out wireless local area network (WLAN) computer communications in the 2.4, 3.6, and 5 GHz frequency bands.
How it is Used in the ACUSON Freestyle	Probe to Main Unit (console) Image Data Transmission (unidirectional)	Probe/Main Unit Control Data Transmission (bidirectional)	System Connection to DICOM Server (bidirectional)
Configuration	Broadcast. Connects only with ACUSON Freestyle main unit (console).	Point-to-Point. Support limited to Bluetooth Serial Port Protocol and connects only to Siemens probes.	Client-Server
Set-Up	Done programmically via the Bluetooth Probe-System link based on system configurations such as mode or probe setting.	Done automatically when a wireless probe is powered on in proximity to an ACUSON Freestyle system or using the Probe page of the ACUSON Freestyle system user interface. On the Probe page you may select from a list of most-recently-used probes or search for probes currently powered on, but not yet connected to an ACUSON Freestyle system.	Done using the Settings / Network page of the ACUSON Freestyle system user interface. Here you may select a wireless network and define the standard networking configuration data required to communicate with the network such as the use of network encryption, authentication, DHCP, IP address, Subnet mask.
Operation	See Chapter 6 of the ACUSON Freestyle User Manual.	See Chapter 6 of the ACUSON Freestyle User Manual.	See Chapter 8 of the ACUSON Freestyle User Manual.
Managing Wireless “Quality of Service”* and Avoiding Wireless Communications Problems	Keep the probe within 3 meters of the main unit and within a line-of-site. Do not obstruct antennas. Keep other operating ACUSON Freestyle systems at least 5 meters away.	Keep the probe within 3 meters of the main unit (console) and within a line-of-site. Do not obstruct antennas. Keep other operating ACUSON Freestyle systems at least 5 meters away.	Wireless network traffic can affect the data transfer rate of the ACUSON Freestyle WiFi connection. Use the DICOM Storage Commitment function to confirm that studies have been successfully transferred to your DICOM PACS server.
Security	The data transmitted over the UWB link is inherently secure. It contains no patient identifiers and can only be processed by an ACUSON Freestyle main unit (console).	The data transmitted over the probe/system Bluetooth link is inherently secure. It contains no patient identifiers and can only be processed by an ACUSON Freestyle main unit (console). Bluetooth communication between the probe and system uses a proprietary command set, and once a probe and main unit are linked, then are no longer discoverable by other Bluetooth devices, thereby preventing unauthorized access.	The ACUSON Freestyle WiFi setup provides a choice of encryption methods and can be configured to require a security password. Your network administrator should be contacted to make sure that you configure the system for secure wireless networking (see Chapter 8, Connectivity in the ACUSON Freestyle User Manual).

* “Quality of Service” refers to a measure of a network’s performance in transmission quality and service availability.

Safety – Wireless Accessory Compatibility

To use the ACUSON Freestyle's IEEE 802.11b/g/n networking capabilities you will need to provide the requisite accessories, a properly configured IEEE 802.11b/g/n router. The ACUSON Freestyle has been designed to have interoperability with standardized products compliant to IEEE 802.11b/g/n, but because of the many variations of products on the market, compatibility cannot be guaranteed with all such accessories. Improved likelihood of compatibility can be achieved by only using high-performance professional-quality products. The following pages list selected specifications for wireless accessories that can improve compatibility with the ACUSON Freestyle.

The specific manufacturer and model numbers of devices that were used to demonstrate compatibility are also listed.

Consult with your IT department when integrating any wireless devices such as an IEEE 802.11b/g/n router with the ACUSON Freestyle. Also, it is very important that you test your wireless accessory setup thoroughly prior to use in patient care applications.

CAUTION: Use of accessories other than those specified here may result in increased electromagnetic emissions or decreased electromagnetic immunity of the ACUSON Freestyle.

The following table lists selected general IEEE 802.11 b/g/n router specifications that have been demonstrated to facilitate compatibility with ACUSON Freestyle's 802.11 b/g/n features.

TABLE 7: *IEEE 802.11 b/g/n Router Specifications*

Feature	*Compatibility*
Data and Routing Protocols	TCP/IP, RIP-1, RIP-2, DHCP PPPoE
Data Rates Supported	1, 2, 5.5, 6, 9, 11, 12, 18, 24, 36, 48, 54 Mbps (autorate capable)
Physical Interface	WAN/LAN: 10/100 Mbps (auto-sensing) Ethernet, RJ45
Network Architecture	Infrastructure
Frequency Band	2.4 to 2.4897 GHz
Modulation	802.11b: DSSS, CCK, BDPSK, DQPSK 802.11g/n: BPSK, QPSK, 16-QAM, 64-QAM
Operating Channels	North America: 11; ETSI: 13, Japan: 14
Nonoverlapping Channels	Three
Antenna	External, diversity supported
Range (typical example)	Indoor: 130 ft (40 m) @ 11 Mbps
Encryption	128-bit (WPA2 supported)
Firewall	Stateful packet inspection (SPI) and DoS attack protection
Compliance	FCC Part 15, EN 55 022 (CISPR 22)

IEEE 802.11 wireless routers tested for compatibility verification with the ACUSON Freestyle included: Cisco Aironet 350, Cisco WRT 320N, Netgear WGR614, Cradlepoint MBR1000, Belkin F6D4230-4, Cisco Linksys E2500 and Zyxel NWA3160N.

Security

IEEE 802.11b/g/n Security

It is important for you to establish and follow effective wireless security policies to guard against unauthorized access to networked resources. In operating the ACUSON Freestyle for wireless networking, consult your IT administrator to insure that institutional policies and practices are being carried out. See Chapter 8, “Connectivity” in the ACUSON Freestyle User Manual for instructions on configuring your ACUSON Freestyle IEEE 802.11b/g/n settings for encrypted operation.

> **NOTE:** A wireless network encrypted with WPA2 is more secure than a network encrypted with an older method such as WEP, because WPA2 uses dynamic key encryption. WPA2 is a better choice for data protection. It is strongly recommended that WPA2 is used for your IEEE 802.11b/g/n communications. If your network does not support WPA2, it is recommended that you upgrade it.

Ultra-Wideband (Wireless Probe) Security

The UWB radio in the ACUSON Freestyle probe transmits continuous streams of digital image data to the main unit. The data is inherently secure because it is contained in a proprietary format that requires the hardware and firmware of the ACUSON Freestyle system to fully process into a displayed image. The likelihood of an unauthorized person being able to receive the ACUSON Freestyle image data into another device and process it for use is extremely low. The likelihood of an unauthorized person successfully generating psuedo-ACUSON Freestyle image data that could be processed by the system as if it were real patient data, is also extremely low. In effect the image data is deeply encrypted and cannot be decoded without the ACUSON Freestyle hardware and firmware.

If, after a brief period of time (approximately ten seconds), the ACUSON Freestyle probe does not receive an acknowledgment that image data is being received by its connected main unit, the probe will cease data transmission. This provides another check against unauthorized eavesdropping or hacking.

Another security feature of the ACUSON Freestyle image data is that it contains no patient identifiers such as patient name and ID. It only contains the image information itself.

Bluetooth (Wireless Probe) Security

For wireless probe operation, the ACUSON Freestyle uses a Bluetooth radio in the probe and in the main unit for the bidirectional communication of control data. This link also has security features and has been designed to minimize the risk of unauthorized access.

When the probe is powered on for wireless operation, the UWB radio transmits a message containing a unique identifier which includes information about the specific Bluetooth radio in the probe. The system “listens” for this, and reads the unique identifier in order to verify that it is a legitimate probe available for linking. The main unit then links its Bluetooth radio with the Bluetooth radio in the probe, using the unique identifier sent from the probe. Once the link is established, the probe and the main unit’s Bluetooth radios go into a mode in which they are not discoverable by another Bluetooth radio. This provides security from unauthorized access. The Bluetooth radios are thereby “locked” to each other, so that another ACUSON Freestyle system will not detect them, and cannot establish a Bluetooth link to them.

The alternative method of linking a probe is to use the Probe Setup Page and select Search. This initiates a search for unconnected probes that are available for discovery, in other words, probes that have been turned on but not yet linked to a main unit. This search uses identifiers unique to the ACUSON Freestyle, so it will not detect non-ACUSON Freestyle probe Bluetooth devices. Once you see your desired probe in the list and select Connect, the probe and main unit will link and enter the non-discoverable mode.

The command set and data formats of the communication are contained in a proprietary format. The Bluetooth radios ignore any invalid commands. This further enhances security.

The data transmitted in the Bluetooth link include configuration and setup data. No patient identifiers are included.

Quality of Service

The term Quality of Service (QoS) refers to an agreed-upon level of performance in a data communications system. This involves parameters such as reliability of data transmission, transfer rate, error rate, and mechanisms and priority levels for time-critical signals. Quality of Service also refers specifically to the capability of a network to provide better service to selected traffic. Formal Quality of Service mechanisms provide enhanced and predictable network service by supporting dedicated bandwidth for critical uses and applications, creating settings needed by real-time traffic, managing network congestion and traffic flow, and setting network traffic priorities.

In IEEE 802.11 operation, Quality of Service refers to formal controls which enable network resources to be shared more efficiently, expediting the handling of mission-critical applications. QoS manages time-sensitive multimedia and voice application traffic to ensure that this traffic receives higher priority, greater bandwidth, and less delay than best-effort data traffic. With QoS, network managers can manage bandwidth more efficiently across LANs and WANs.

The ACUSON Freestyle design for Ultra-wideband and Bluetooth includes a number of features to maintain adequate Quality of Service for these radios. These are also described below.

Quality of Service and IEEE 802.11

In the past, wireless local area networks LANs (WLANs) were used to transport low-bandwidth, data application traffic. WLANs are now used to transport high-bandwidth, intensive data applications in conjunction with time-sensitive multimedia applications. This requirement has led to wireless QoS.

This has been addressed in 802.11e, an approved amendment to the IEEE 802.11 standard that defines a set of Quality of Service enhancements for wireless LAN applications. Amendment 802.11e describes multiple Access Categories of network traffic with varying levels of priority ranging from highest priority to lowest, these categories are:

- **Voice**: Giving voice packets the highest priority enables concurrent Voice over IP (VoIP) calls with minimal latency and the highest quality possible.
- **Video**: By placing video packets in the second tier, QoS prioritizes it over all other data traffic and enables video streaming on a WLAN.
- **Best effort**: Best effort data packets consist of those originating from legacy devices or from applications or devices that lack or do not require QoS standards.
- **Background**: Background priority encompasses file downloads, print jobs and other traffic that does not suffer from increased latency

Not all networks support QoS. A “best-effort” network or service does not support quality of service. An alternative to complex QoS control mechanisms is to provide high quality communication over a best-effort network by providing enough capacity for the expected peak traffic load. The resulting absence of network congestion eliminates the need for QoS mechanisms

IEEE 802.11b/g/n Quality of Service and ACUSON Freestyle IEEE 802.11b/g/n Operation

The ACUSON Freestyle operation of IEEE 802.11b/g/n wireless networking functions in the “best-effort” category. That means it does not require a formal QoS WLAN. That also means that on a QoS network, its data may be given a lower priority than video or voice, if the network carries such traffic. The function of the ACUSON Freestyle’s wireless networking is for sending patient studies to a DICOM PACS system, or getting patient information using DICOM Modality Worklist. These are not “mission-critical,” or related to real-time scanning operations, so the best-efforts approach does not raise issues in conducting and performing exams.

Even a device without formal IEEE 802.11e Quality of Service requirements can benefit from defined network performance specifications. For the ACUSON Freestyle, recommended Quality of Service metrics are listed below. Your 802.11b/g/n network should provide these metrics for ACUSON Freestyle wireless networking.

With the metrics listed on the next page, the data throughput provided would transfer a typical patient study (4.5 MB) to a DICOM Server in less than 30 seconds. If you find that your transfer times exceed this target by more than double that time, it is recommended that you consider switching to the wired Ethernet connection. That is, if your data throughput falls below

~78 KBps, switching to the wired Ethernet connection should be considered as an alternative transfer method.

TABLE 8: *Recommended IEEE 802.11b/g/n Quality of Service Metrics for ACUSON Freestyle IEEE 802.11b/g/n Operation*

Parameter	*Specification*	*Comment*
IEEE 802.11 Level	IEEE 802.11b, g or n	With the metrics listed here, an IEEE 802.11b, an IEEE 802.11g and 802.11n network will achieve the data throughput specified.
Wireless Signal Rate	11 Mbps (IEEE 802.11b) 54 Mbps (IEEE 802.11g) 72 Mbps (IEEE 802.11n)	Stated maximum of the standards. Actual data throughput is lower and is affected by distance from the Access Point and packet error rates, network conditions, environmental factors, building materials, volume of network traffic, network overhead, etc.
Distance to Access Point	< 70 feet (21 meters)	IEEE 802.11b, IEEE 802.11g and 802.11n stated maximum indoor range of 125 feet (38 m) is not typically achieved, especially in hospital settings.
Security Type	WPA2	WPA2 Encryption is recommended for improved security.
Data Throughput	≥ 156 KBps	With this data throughput rate, a typical patient study (4.5 MB) will transfer to a DICOM PACS system in less than 30 seconds. The downloading of patient demographic data from a DICOM Modality Worklist Server would take place in under one second.
Packet Error Rate	< 35%	Many variables affect what packet error rate can be expected. Within this packet error rate range, automatic data retransmission can occur while maintaining the specified data throughput.
Data Latency	< 400 milliseconds	—

Wireless Network Traffic Slowdowns or Problems

How to deal with potential issues related to wireless network traffic slowdowns or problems:

- Make sure that Access Points are as close as possible to the ACUSON Freestyle, with a target maximum of 70 feet (21 meters). Certain hospital settings that may have special shielding in floors and walls, such as in Radiology, present particular challenges that must be addressed in the location of Access Points.
- The downloading of Modality Worklist information for obtaining patient information prior to a study involves very small file sizes, so wireless network traffic should not typically present a problem. In the unlikely event that you do encounter unacceptable delays that may be due to network traffic when obtaining Modality Worklist information, you can always just directly enter the patient name, ID, and other information into the system.
- When sending patient studies to a DICOM PACS system over the IEEE 802.11b/g/n connection, configure the ACUSON Freestyle to use the Storage Commitment feature to notify you that the file has been successfully received by the PACS system. That way, you can check to confirm that the transfer has been completed.
- Schedule the sending of patient studies to the DICOM PACS system such that there is time for the file to be sent even if network traffic is heavy.
- If wireless networking data throughput rates are an issue, shorter transfer times may be achieved using the ACUSON Freestyle wired Ethernet connection.
- The ACUSON Freestyle patient study storage maintains a patient study stored internally until you choose to delete it. This feature provides a back-up to your data transfer. Verify that a patient study has been successfully transferred to the DICOM server before you delete it from the ACUSON Freestyle. The ACUSON Freestyle Patient Study page will show you if the transfer was successful, and using DICOM Storage Commitment provides additional confirmation, but as an extra precaution, it is advisable to inspect the DICOM Server archive itself to make sure the study has been transferred.

Bluetooth and Ultra-Wideband

The ACUSON Freestyle Bluetooth radios (probe control data and headset) and Ultra-wideband radio (probe to main unit image data) use a variety of methods to protect data integrity and throughput.

These radios all operate as short range, point-to-point, best-efforts devices. As best-efforts devices, these radios do not rely on or require formal Quality of Service methods to maintain throughput. Their link capacity is designed to provide adequate bandwidth for continuous data transmission, and the architecture separates the connections from competing traffic.

The following pages provide more detail on Bluetooth and UWB quality of service performance

Quality of Service and ACUSON Freestyle Bluetooth

The ACUSON Freestyle uses Bluetooth radios for probe control data. These radios operate as short range, point-to-point devices. The Bluetooth radios operate as “best-effort” devices. Bluetooth uses frequency hopping, channel coding, and error correction to address interference. In general, the aggregate capacity of Bluetooth is high, and Bluetooth immunity to interference is also high. In addition to excellent density tolerance, the ACUSON Freestyle Bluetooth radio incorporates other methods to insure that your Bluetooth operation is free of quality of service problems. These include:

- ACUSON Freestyle Bluetooth links are point-to-point connections, not multiple master/ slave piconets or scatternets.
- ACUSON Freestyle Bluetooth links are designed for operation at under 3 meters separation; Bluetooth reliability increases with shorter separation distances.
- Mode packets and other control data sent between the probe and the main unit undergo additional checksum verification to insure that data is correctly received without errors.
- Though used during real-time scanning, the Bluetooth radio commands can tolerate latencies or resending of packets without interrupting scanning operation.
- Data packets are small compared to available bandwidth; The probe data packets use approximately 10% of the available bandwidth, thereby increasing reliability.

Tips for Maintaining ACUSON Freestyle Bluetooth Quality

Things you can do to insure that your ACUSON Freestyle Bluetooth links operate without problems include:

- Operate the ACUSON Freestyle probe within 3 meters of the main unit (console), with a direct line-of-sight.
- If you encounter problems, check to see if there are other devices in the vicinity operating in the same frequency range as the ACUSON Freestyle Bluetooth radios. The Bluetooth radio frequency is 2.4 gigahertz (GHz). If so, remove or separate them as much as possible. Other devices may include the following:
  - Other Bluetooth devices
  - Microwave ovens
  - Networks that use the 802.11 wireless protocol

Quality of Service and ACUSON Freestyle Ultra-Wideband

The Ultra-wideband (UWB) radio technology used to transmit image data from the probe to the main unit is also a “best-efforts” device. It utilizes several techniques to protect data throughput and prevent interference from wireless data traffic, such as might be created by other UWB devices operating in the same vicinity. UWB is a very low power, short range method. This inherently reduces the risk of interference from other UWB devices. Other techniques used to insure quality of service include:

- The ACUSON Freestyle UWB radio operates at a center frequency of 7.8 GHz. At this frequency there is minimal competing traffic. Additionally, this frequency requires a line-of-sight orientation which further reduces the risk of interference.
- The UWB receive antennas in the ACUSON Freestyle main unit are directional, oriented towards the front of the system where the probe is located.
- Multiple antennas in the probe and the main unit are constantly monitored so that the antenna pair with the highest quality signal is used for image data transmission.
- The UWB radio operates as a point to point, best-efforts device. Because of the nature of real-time ultrasound imaging, the data transmission rate is maintained during operation. Error correction is used to maintain data integrity.
- Operators are instructed to scan with the wireless probe inside a 3 meters separation distance from the main unit, which happens also to be a practical outer distance for viewing the image on the display screen. This close distance increases the signal quality of the UWB radio.
- The Wireless Signal Quality meter and the Average Noise Level display inform the operator of the status of the UWB wireless link and alerts the operator to the potential for noise being introduced into the image because of problems with the link. See the instructions in Chapter 6 (Wireless Probes) of the ACUSON Freestyle User Manual.

Tips for Maintaining ACUSON Freestyle Ultra-wideband Quality

Things you can do to insure that your ACUSON Freestyle UWB link operates without problems include:

- Operate the ACUSON Freestyle probe within 3 meters of the main unit (console), with a direct line-of-sight.
- Do not place any objects in between the probe and the main unit (console), and ask that persons not stand in between the two.
- Do not cover the probe antennas with your hand; they are located at the end of the probe next to the battery.
- Monitor the Wireless Signal Quality meter in the real-time display, and follow the steps above to make sure that you scan with at least three bars in the meter.
- Monitor the Average Noise Level (ANL) index in the real-time display, and follow the steps above to make sure that the ANL index does not go above 1 dB.
- Do not operate other ACUSON Freestyle probes within 5 meters of your system.
- When changing probes, make sure to turn the original probe off before attempting to use the new probe.
- Do not place any foreign objects, such as metallic labels on the ACUSON Freestyle probe as this could interfere with the operation of the UWB antennas.

For the wireless probe, carefully follow the instructions in Chapter 6 (Wireless Probes) of the ACUSON Freestyle User Manual.

Labels

Labels on the system console and probes contain important information including serial numbers, reminders to consult the User Manual, and safety warnings. Examples of labels are provided on the following page. Symbols used in labels are explained in the Safety and Care chapter of the ACUSON Freestyle User Manual.

> **NOTE:** Labels on your product may not include some information shown in the examples, and they may include some information that is not shown in the examples.

System Console Label

Manufacturer Name and Address
SIEMENS
Siemens Medical Solutions USA, Inc.
685 East Middlefield Road
Mountain View, CA 94043, USA

Model: ACUSON Freestyle
Diagnostic Ultrasound System

(1P) Model No.: 11002300
(S) Serial No.: XXXXXX

Siemens Medical Solutions USA, Inc.
5168 Campus Drive
Plymouth Meeting, PA 19462, USA

System IVK
CLASSIFIED MET c us
Electrical Safety E113535
CE 0123
07/2014

EC REP
Siemens AG
Medical Solutions
Henkestrasse 127
91052 Erlangen
Germany

Contains TX FCC ID:
ED9LMX9838, RYK-WUBR507N
Contains TX IC:
1520A-LMX9838, 6158A-WUBR507N

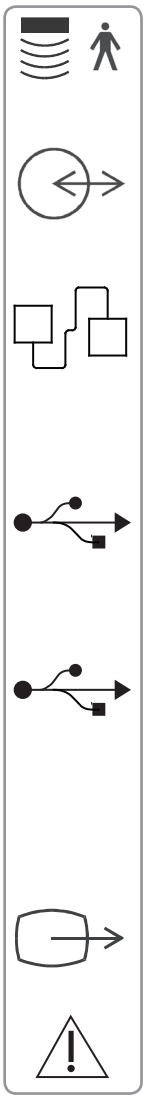
System Console Power Entry Label

Input: 100 - 240 V ~
50 / 60 Hz
1.5 / 0.7 Amps

3.0A SB-250V
5 x 20mm

DISCONNECT SUPPLY BEFORE SERVICING.
COUPER L'ALIMENTATION AVANT L'ENTRETIEN ET LE DEPANNAGE.

System Console I/O Label



System Console Warning Label

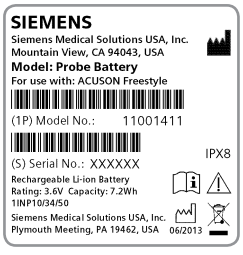
ATTENTION, CONSULT ACCOMPANYING DOCUMENTS.
ATTENTION, CONSULTER LES DOCUMENTS FOURNIS.

WARNING	RISK OF FIRE. REPLACE FUSE AS MARKED.
ATTENTION	RISQUE D'INCENDIE. REMPLACE LE FUSIBLE COMME INDIQUE.
CAUTION	NO OPERATOR SERVICABLE PARTS INSIDE. REFER SERVICING TO QUALIFIED PERSONNEL.
ATTENTION	ENTRETIEN ET REPARATION INTERNES NE SONT. AUTORISE QU'AU PERSONNEL TECHNIQUE QUALIFIE.
DANGER	POSSIBLE EXPLOSION HAZARD IF USED IN THE PRESENCE OF FLAMMABLE ANESTHETICS.
DANGER	RISQUE D'EXPLOSION EN PRESENCE D'ANESTHESIQUES INFLAMMABLES.
CAUTION	TOTAL SYSTEM CHASSIS RISK CURRENT SHOULD NOT EXCEED 100 MICROAMPS.
ATTENTION	LE COURANT DE RISQUE TOTAL ADMISSIBLE AU CHASSIS NE DOIT PAS DEPASSER 100 MICROAMPS.

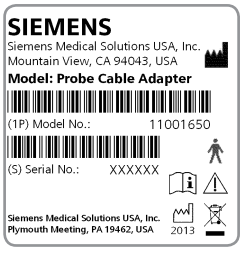
System Console Power Cord Label

(U.S.A.) Grounding Reliability Can Only Be Achieved When Equipment Is Connected to an Equivalent Receptacle Marked Hospital Grade.

Probe Label



Probe Battery Label



Probe Cable Adapter Label

Open Source Software

This product contains Open Source Software developed by third parties and licensed under Open Source Software licenses. These Open Source Software files are protected by copyright.

For a complete Open Source Usage Declaration, as well as a copy of the Open Source Software licenses and the Open Source code used in this product please send a request with the name and ID number of the product to:

Siemens Medical Solutions
Ultrasound Legal Department
685 E. Middlefield Rd.
Mountain View CA 94043-4045
USA

Alternatively you can also send your specific requests to the following e-mail address:
ultrasoundosslegal.healthcare@siemens.com

SIEMENS

Datasheet

ACUSON Freestyle™ Ultrasound System

Release 3.0

www.siemens.com/ultrasound

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TABLE OF CONTENTS

ACUSON Freestyle Ultrasound System

The ACUSON Freestyle™ ultrasound system is designed to meet the needs of Point-of-Care clinicians during ultrasound-guided procedures. Developed with pioneering technology from Siemens, this is the first Point-of-Care ultrasound system with wireless transducers. The system provides freedom from cables and cable management, flexibility to scan up to 3 meters away from the system, and the ability to operate the system from the transducer with integrated system controls – bringing a new level of workflow and ease of use into the hospital or clinical setting.

GENERAL INFORMATION

System Architecture

- Lossless digital image data high speed transfer using proprietary ultra-wideband wireless technology
- Pixelformer™ image processing architecture provides ideal target focusing at each pixel
- Proprietary cordless transducer design provides direct electronic connection from the ultrasound transducer array to the transmit/receive circuitry for high-resolution, low-noise signal processing
- Proprietary high speed antenna polling system provides optimal wireless link quality
- Dedicated embedded real-time operating system (RTOS) for fast boot-up time and built to be safe from PC viruses

Transducers

- Miniaturized ultrasound front-end and digital signal processing subsystem with high data rate ultra-wideband radio
- Cordless operation with adapter cable option
- Lightweight, ergonomic design
- Flat transducer base allows transducer to stand on end for single operator transducer cover placement
- Remotely control the ultrasound system
- Removable battery

System Console

- Small footprint mobile roll stand, tabletop-mountable, or zero footprint wall-mountable
- Compact and lightweight module with high-resolution display and streamlined user interface
- AC or internal battery power
- Integrated dual transducer battery chargers

User Interface

- On-screen display and Operator's Manual are available in the following languages:
  - English
  - French
  - Italian
  - German
  - Spanish
  - Danish
  - Dutch

- Norwegian
- Finnish
- Polish
- Portuguese
- Swedish
- Turkish

Display Monitor

- 15 inch (38.1 cm) high-bright LED LCD
- Resolution: 1024 x 768 pixels
- Energy saving display power management
- High contrast ratio
- Wide viewing angles

OPERATING MODES

- B-mode
- Color Flow Doppler Velocity Mode
- Color Flow Doppler Power Mode

WIRELESS IMAGING

- Lossless digital image data high speed wireless transmission using a proprietary 7.8 GHz ultra-wideband radio
- 500 MHz minimum bandwidth
- Scanning distance from transducer to system console: Up to 3 meters
- Multiple antennas in the transducers and system console combined with proprietary high speed antenna switching system provide optimal wireless link
- Wireless signal quality meter provides real-time feedback
- Average Noise Level display provides real-time quantified measure of wireless imaging signal quality
- Backchannel Bluetooth® radio used for bidirectional control data communication

Wireless Transducer Technologies

- Multiple antennas integrated in transducers for optimal data link quality
- Transducer-integrated capacitive control softkeys: slider and two softkeys labeled for +/- control
- Two additional softkeys in the middle of the transducer can be used as shortcuts for **Save** (saves the current image) and **Color** (activates/deactivates Color Flow mode)
- Auto-freeze automatically freezes image after timeout period during non-scanning to conserve battery life
- Transducer On/Off LED/index marker
- Up to 90 minutes of continuous scanning with fully charged transducer battery
- Low battery level warning messages
- Removable wireless transducer battery
- Transducer battery charger
  - Dual charger integrated into system console
  - Charging transducer batteries requires either of the following:
    - System console is connected to AC main power; or
    - System console batteries are charged
  - LED indicator of charging activity on battery
  - Indicator and readout of battery charge level on system console screen
- Transducer location
  - Audio tone for transducer status
  - Integrated Bluetooth radio aids in location tracking

Transducer Disinfection and Sterilization

- Transducer and transducer battery immersible for cleaning and disinfection
- STERRAD® 100S system sterilizable

IMAGING, CONTROLS AND DISPLAY

- Fully digital signal processing
- Wide-bandwidth transducer technology
- Processing channels: Up to 2,048 channels
- "Beam-free" synthetic aperture and Pixelformer image processing architecture focuses at each individual pixel, eliminating the need for the user to adjust focal zones which can introduce zone artifacts and reduce frame rate
- Spatial Compounding provides multiple steering angles from a single frameset for improved contrast resolution and reduced speckle size without reduction in frame rate
- Spatial Compounding remains on in Color Flow Doppler Mode, maintaining high quality B-mode images during Color Flow scanning
- Speckle Filter provides advanced speckle reduction/edge enhancement
- Time/Gain compensation function automatically adjusts depth-gain parameters and is integrated into the transducers

B-mode

- Controls
  - Freeze
  - Save
  - Gain: (B-mode) 16 settings
  - Depth: 2 – 24 cm, transducer dependent
  - Color
  - Near Gain: 10 settings
  - Tools
  - Exam
- Tools (Live Scanning)
  - Post Processing: 5 settings
  - Dynamic Range: 3 settings
  - Spatial Compounding: 4 settings
  - Speckle Filter: 9 settings
  - Left-Right Reverse
  - Mid-Line: on-screen midline of image display marker

Color Flow Doppler Mode

- Controls
  - Freeze
  - Save
  - On / Off
  - Color Gain: 16 settings
  - Color Box: up down position
  - Tools
  - Exam
- Tools
  - Color Map: Velocity Mode and 2 Power Modes
  - Velocity Invert
  - Priority: 4 settings
  - Color Persistence: 4 settings
  - Color Filter: (high pass) 4 settings
  - Color Scale: 4 settings

Controls When Image is Frozen

- Unfreeze
- Save
- Scroll
- Cine
- B-mode tools
  - Post-processing
  - Speckle Filter
  - Dynamic Range

- Color flow Doppler tools
  - Post-processing
  - Color Map
  - Velocity Invert
- Text
  - User entry of on-screen annotation
  - Pointer

Control Mechanisms

- Intuitive and flexible user interface control mechanisms
- Real-time scanning controls accessible from:
  - System console: dual rotary controls, side panel softkeys, trackball and trackball keys
  - Transducer slider and softkeys
  - Compatible external USB mouse
- System console
  - Lower panel softkeys
    - Setup
    - Patient (New Patient)
    - Measure
    - View
  - Side panel softkeys
    - B-mode and Color Flow Controls
      - › Selection
      - › On/off toggle for select functions
  - Dual rotary controls
    - B-mode and Color Flow controls:
      - › Selection
      - › On/off toggle for select functions
      - › Value adjustment for all controls
- Transducer slider and softkeys
  - B-mode and Color Flow controls
    - Selection
    - On/off toggle for select functions
    - Value adjustment for all controls

Display

The imaging screen display includes the following information:

- Image
- Patient Name
- Patient ID
- Institution Name

- Time (12 hr or 24 hr)
- Date
- Real-time control window: B-mode and Color Flow controls
- Lower panel softkeys
- Transducer battery status
- System battery status
- Real-time controls settings
- Transducer battery charger bay status

MEASUREMENTS

- Distance
- Area
- Ellipse

EXAM TYPES

The ACUSON Freestyle system is designed to support a wide range of point-of-care applications. Factory-defined imaging presets have been clinically optimized for each exam and transducer to provide consistency, reliability and increased productivity. User-defined presets provide flexibility to customize system settings to suit individual preferences.

- Abdominal
  - Deep
  - General
  - Vascular
  - Renal
- General
- Musculoskeletal
  - Deep
  - Elbow
  - Foot/Ankle
  - General
  - Hand/Wrist
  - Hip
  - Knee
  - Shoulder
  - Superficial
  - Tendon/Muscle
- Nerve
  - Deep
  - General
  - Superficial
- Obstetrics/Gynecology
  - Gynecology
  - Obstetric
- Small Parts
  - Breast
  - Deep
  - General
  - Superficial
  - Thyroid
- Vascular
  - Arterial
  - Carotid
  - General
  - Venous Difficult
  - Venous Lower Extremity
  - Venous Superficial
  - Venous Upper Extremity

DIGITAL PATIENT STUDY STORAGE AND ARCHIVING

- Digital storage of still frames and clips
- Storage capacity
  - 16 GB solid state flash memory
  - Approximately 100,000 image frames
- Onboard patient study list
- Study viewing capability

- Viewing formats, full screen, quad screen, twelve image screen
- Export to USB-compatible storage media: PC-readable JPEG, MOV and XML (patient information)

FREEZE, SCROLL MEMORY AND CINE CAPTURE

Scroll Memory

- Scroll memory: Up to 512 frames

Cine Capture

- Cine capture length: Up to 18 seconds

TRANSDUCERS

Intended use for the L8-3, L13-5, and C5-2 transducers include the following: Fetal, Abdominal, Intraoperative, Intraoperative Neurological, Pediatric, Small Organs, Neonatal Cephalic, Cardiac, Peripheral Vessel and Vascular, and Musculoskeletal.

L8-3

- Array type: Linear
- Number of elements: 128
- Depth 2.5 – 9.0 cm
- Frequency bandwidth: 3.0 – 8.0 MHz
- Footprint: 38.4 mm x 5.0 mm
- B-Mode, Color Doppler, Amplitude Doppler
- Needle Guide Kit available

L13-5

- Array type: Linear
- Number of elements: 128
- Depth 2.0 – 6.0 cm
- Frequency bandwidth: 5.0 – 13.0 MHz
- Footprint 25.6 mm x 4.0 mm
- B-Mode, Color Doppler, Amplitude Doppler
- Needle Guide Kit available

C5-2

- Array type: Curvilinear
- Number of elements: 128
- Depth 8.0 – 24.0 cm
- Frequency bandwidth: 2.0 – 5.0 MHz
- Footprint 13.0 x 67.2 mm (60.0 mm radius of curvature)
- Field of view: 64°
- B-Mode, Color Doppler, Amplitude Doppler

DICOM 3.0 AND NETWORKING

- DICOM-compatible system providing PACS connectivity
- DICOM Storage Class
- DICOM Storage Commitment
- DICOM Modality Worklist
- DICOM Echo
- Connectivity over ethernet
- Storage over USB-compatible storage media
- Wired ethernet networking
- IEEE 802.11 b/g wireless networking (Wi-Fi®)

DOCUMENTATION DEVICE

- Optional Video Printer
  - B/W printer (Sony UPD 897 MD)

SYSTEM INPUT/OUTPUT

- Input/Output
  - Transducer cable adapter
  - Ethernet RJ45 (10BaseT/100BaseT)
  - (2) USB-A
- Output
  - VGA (15 pin D-sub miniature) 1024 x 768, 60 Hz

SIZE AND WEIGHT

System Console

- Height: 335 mm (13.2 in)
- Width: 373 mm (14.7 in)
- Depth: 121 mm (4.8 in)
- Weight 4.8 kg (10.5 lbs)

Transducer

- Height: 34 mm (1.3 in)
- Width: 65 mm (2.6 in)
- Length: 153 mm (6.0 in)
- Weight (without battery): 172 g (6.0 oz)

Transducer Battery

- Height: 20 mm (0.8 in)
- Width: 41 mm (1.6 in)
- Length: 58 mm (2.3 in)
- Weight: 71 g (2.5 oz)

ELECTRICAL AND ENVIRONMENTAL SPECIFICATIONS

- Voltage: 100 - 240 V (50/60 Hz)
- Power consumption: maximum 0.08 kVA (may vary with configuration)
- Atmospheric pressure range: 700 – 1060 hPa (525 – 795 mm Hg) or up to 3050 m (10,000 ft)
- Ambient operating temperature range: +10° to +40°C (50° to 104°F)
- Humidity operating: 10 – 75%, non-condensing
- Maximum heat output: 273 BTU/hr

STANDARDS COMPLIANCE

Quality Standards

- FDA QSR 21 CFR Part 820

Design Standards

- ANSI/AAMI ES60601-1
- EN 60601-1 and IEC 60601-1
- EN 60601-1-1 and IEC 60601-1-1
- EN 60601-1-2 and IEC 60601-1-2 (Class A)
- EN 60601-2-37 and IEC60601-2-37
- IEC 62366
- ISO 14971
- EN 62304 and IEC 62304

Acoustic Standards

- IEC 61157 (Declaration of Acoustic Power)
- IEC 62359 (Test Methods for the Determination of TI and MI)
- AIUM/NEMA UD-2, Acoustic Output Measurement Standard for Diagnostic Ultrasound
- AIUM/NEMA UD-3, Standard for Real-time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment

Wireless Standards

- FCC 47 CFR Part 15(b) : 15.503(d), 15.519
- ETSI EN 302 065
- IEEE 802.11 b/g
- Bluetooth 2.0 Class 2

CE DECLARATION

CE 0123 This product is provided with a CE marking in accordance with the regulations stated in Council Directive 93/42/EEC of June 14, 1993 concerning Medical Devices. The CE marking only applies to medical devices that have been put on the market according to the above referenced Council Directive. Unauthorized changes to this product are not covered by the CE marking and the related Declaration of Conformity.

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