

Datasheet

ACUSON Freestyle™ Ultrasound System

Release 3.0

This page left intentionally blank.

TABLE OF CONTENTS

GENERAL INFORMATION	4
System Architecture	
Transducers	4
System Console	4
User Interface	4
Display Monitor	5
OPERATING MODES	5
WIRELESS IMAGING	5
Wireless Transducer Technologies	
Transducer Disinfection and Sterilization	6
IMAGING, CONTROLS AND DISPLAY	6
B-mode	6
Color Flow Doppler Mode	
Controls When Image is Frozen	
Control Mechanisms	
Display	7
MEASUREMENTS	8
EXAM TYPES	8
DIGITAL PATIENT STUDY STORAGE AND ARCHIVING	8
FREEZE, SCROLL MEMORY AND	
CINE CAPTURE	9
Scroll Memory	9
Cine Capture	9
TRANSDUCERS	9
L8-3	9
L13-5	9
C5-2	9
DICOM 3.0 AND NETWORKING	9
DOCUMENTATION DEVICE	10
SYSTEM INPUT/OUTPUT	10
SIZE AND WEIGHT	10
System Console	
Transducer	
Transducer Battery	10

.4 .4	ELECTRICAL AND ENVIRONMENTAL SPECIFICATIONS	10
.4	STANDARDS COMPLIANCE	11
.4	Quality Standards	
.4	Design Standards	11
<u>.</u> 5	Acoustic Standards	
5	Wireless Standards	11
5	EU AUTHORIZED REPRESENTATIVE	11

The ACUSON Freestyle ultrasound system is not commercially available. Due to regulatory reasons, its future availability cannot be guaranteed.

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.



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, tabletopmountable, or zero footprint wall-mountable
- Compact and lightweight module with highresolution 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

The ACUSON Freestyle ultrasound system is not commercially available. Due to regulatory reasons, its future availability cannot be guaranteed.

- 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 ultrawideband 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

The ACUSON Freestyle ultrasound system is not commercially available. Due to regulatory reasons, its future availability cannot be guaranteed.

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

The ACUSON Freestyle ultrasound system is not commercially available. Due to regulatory reasons, its future availability cannot be guaranteed.



- 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

The ACUSON Freestyle ultrasound system is not commercially available. Due to regulatory reasons, its future availability cannot be guaranteed.

- 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

The ACUSON Freestyle ultrasound system is not commercially available. Due to regulatory reasons, its future availability cannot be guaranteed.

- 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

The ACUSON Freestyle ultrasound system is not commercially available. Due to regulatory reasons, its future availability cannot be guaranteed.



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), 15.517(c), 15.517(d) and 15.517(e)
- ETSI EN 302 065
- IEEE 802.11 b/g
- Bluetooth 2.0 Class 2

EU AUTHORIZED REPRESENTATIVE

Siemens AG Healthcare Sector Henkestrasse 127 91052 Erlangen Germany

phone: +49 9131 84 0

Siemens reserves the right to modify the design and specifications contained herein without prior notice. Please contact your local Siemens Healthcare Sales Representative for the most current information.

The ACUSON Freestyle ultrasound system is not commercially available. Due to regulatory reasons, its future availability cannot be guaranteed.

ACUSON Freestyle and Pixelformer are trademarks of Siemens Medical Solutions USA, Inc.

The Bluetooth® word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks by Siemens is under license.

STERRAD is a registered trademark of ADVANCED STERILIZATION PRODUCTS, division of Ethicon Inc., a Johnson & Johnson company

Wi-Fi® is a trademark of the Wi-Fi Alliance.

DS 0513 | © 05.2013, Siemens Medical Solutions USA, Inc.

Global Siemens Headquarters

Siemens AG Wittelsbacherplatz 2 80333 Muenchen Germany

Global Siemens Healthcare Headquarters

Siemens AG Healthcare Sector Henkestrasse 127 91052 Erlangen

Telephone: +49 9131 84-0

Germany

www.siemens.com/healthcare

Legal Manufacturer

Siemens Medical Solutions USA, Inc. Ultrasound 685 E Middlefield Road Mountain View, CA 94043 USA

Telephone: 1-888-826-9702 www.siemens.com/ultrasound