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

**TABLE OF CONTENTS**

<table>
<thead>
<tr>
<th>SECTION</th>
<th>PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>GENERAL INFORMATION</td>
<td>4</td>
</tr>
<tr>
<td>System Architecture</td>
<td>4</td>
</tr>
<tr>
<td>Transducers</td>
<td>4</td>
</tr>
<tr>
<td>System Console</td>
<td>4</td>
</tr>
<tr>
<td>User Interface</td>
<td>4</td>
</tr>
<tr>
<td>Display Monitor</td>
<td>5</td>
</tr>
<tr>
<td>OPERATING MODES</td>
<td>5</td>
</tr>
<tr>
<td>WIRELESS IMAGING</td>
<td>5</td>
</tr>
<tr>
<td>Wireless Transducer Technologies</td>
<td>5</td>
</tr>
<tr>
<td>Transducer Disinfection and Sterilization</td>
<td>6</td>
</tr>
<tr>
<td>IMAGING, CONTROLS AND DISPLAY</td>
<td>6</td>
</tr>
<tr>
<td>B-mode</td>
<td>6</td>
</tr>
<tr>
<td>Color Flow Doppler Mode</td>
<td>6</td>
</tr>
<tr>
<td>Controls When Image is Frozen</td>
<td>6</td>
</tr>
<tr>
<td>Control Mechanisms</td>
<td>7</td>
</tr>
<tr>
<td>Display</td>
<td>7</td>
</tr>
<tr>
<td>MEASUREMENTS</td>
<td>8</td>
</tr>
<tr>
<td>EXAM TYPES</td>
<td>8</td>
</tr>
<tr>
<td>DIGITAL PATIENT STUDY STORAGE AND ARCHIVING</td>
<td>8</td>
</tr>
<tr>
<td>FREEZE, SCROLL MEMORY AND CINE CAPTURE</td>
<td>9</td>
</tr>
<tr>
<td>Scroll Memory</td>
<td>9</td>
</tr>
<tr>
<td>Cine Capture</td>
<td>9</td>
</tr>
<tr>
<td>TRANSDUCERS</td>
<td>9</td>
</tr>
<tr>
<td>L8-3</td>
<td>9</td>
</tr>
<tr>
<td>L13-5</td>
<td>9</td>
</tr>
<tr>
<td>C5-2</td>
<td>9</td>
</tr>
<tr>
<td>DICOM 3.0 AND NETWORKING</td>
<td>9</td>
</tr>
<tr>
<td>DOCUMENTATION DEVICE</td>
<td>10</td>
</tr>
<tr>
<td>SYSTEM INPUT/OUTPUT</td>
<td>10</td>
</tr>
<tr>
<td>SIZE AND WEIGHT</td>
<td>10</td>
</tr>
<tr>
<td>System Console</td>
<td>10</td>
</tr>
<tr>
<td>Transducer</td>
<td>10</td>
</tr>
<tr>
<td>Transducer Battery</td>
<td>10</td>
</tr>
<tr>
<td>ELECTRICAL AND ENVIRONMENTAL SPECIFICATIONS</td>
<td>10</td>
</tr>
<tr>
<td>STANDARDS COMPLIANCE</td>
<td>11</td>
</tr>
<tr>
<td>Quality Standards</td>
<td>11</td>
</tr>
<tr>
<td>Design Standards</td>
<td>11</td>
</tr>
<tr>
<td>Acoustic Standards</td>
<td>11</td>
</tr>
<tr>
<td>Wireless Standards</td>
<td>11</td>
</tr>
<tr>
<td>EU AUTHORIZED REPRESENTATIVE</td>
<td>11</td>
</tr>
</tbody>
</table>
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

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

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

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

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

Norwegian
Finnish
Polish
Portuguese
Swedish
Turkish
The ACUSON Freestyle ultrasound system is not commercially available. Due to regulatory reasons, its future availability cannot be guaranteed.

### 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

### Color Flow Doppler Mode

- Controls
  - Freeze
  - Save
  - On / Off
  - Color Gain: 16 settings
  - Color Box: up down position
  - Tools
  - Exam

---

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

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

Display
The imaging screen display includes the following information:
- Image
- Patient Name
- Patient ID
- Institution Name

- 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

Color flow Doppler tools
- Post-processing
- Color Map
- Velocity Invert
Text
- User entry of on-screen annotation
- Pointer
The ACUSON Freestyle ultrasound system is not commercially available. Due to regulatory reasons, its future availability cannot be guaranteed.

**MEASUREMENTS**

- 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

**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.*
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

**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

**TRANSUDCERS**
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.

**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®)

**FREEZE, SCROLL MEMORY AND CINE CAPTURE**

**Scroll Memory**
- Scroll memory: Up to 512 frames

**Cine Capture**
- Cine capture length: Up to 18 seconds

**VIEWING FORMATS**
- Full screen, quad screen, twelve image screen
- Export to USB-compatible storage media: PC-readable JPEG, MOV and XML (patient information)
The ACUSON Freestyle ultrasound system is not commercially available. Due to regulatory reasons, its future availability cannot be guaranteed.

**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

**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

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

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.

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