Datasheet

ACUSON Freestyle™
Ultrasound System

Release 3.0

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ACUSON Freestyle Ultrasound System

The ACUSON Freestyle™ ultrasound system is a high-performance, compact and portable ultrasound imaging solution with the world’s first wireless transducers. The ACUSON Freestyle system delivers exceptional clinical performance across a variety of applications with outstanding image quality. With its innovative wireless transducers, intuitive user interface, and Freehand wireless real-time system control, the system provides unparalleled advantages for point-of-care practitioners performing ultrasound-guided procedures.

GENERAL INFORMATION

System Architecture
- Fully digital synthetic focusing design with super high data rate ultra-wideband wireless technology
- 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
- Lossless digital image data high speed wireless transmission
- Proprietary high speed antenna polling system provides optimal wireless link quality
- Pixelformer™ image processing architecture provides ideal target focusing at each pixel

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

System Console
- Remotely control the ultrasound system
- Removable battery

User Interface
- On-screen display and Operator’s Manual are available in the following languages:
  - English
  - French
  - Italian
  - German
  - Spanish
  - Swedish
**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 remote control softkeys: slider and two softkeys labeled for +/- control
- Auto-freeze automatically freezes image after timeout period during non-scanning to conserve battery life
- Auto-unfreeze automatically unfreezes image after sensing user grasp of a transducer that has entered Auto-freeze
- 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
- "Beam-free" synthetic aperture and pixelformer design 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
- Advanced speckle reduction/edge enhancement filters
- 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 – 22 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)
**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)

**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 UP 897)

**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
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 IEC 60601-2-37
- 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

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