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1. OVERVIEW

1.1. Site~Rite® 8 Ultrasound System Device Description

The Site~Rite® 8 Ultrasound System is a portable device that features real-time 2D ultrasound imaging, customized vascular access applications, procedure documentation, vessel measurement tools, and electronic connectivity (if enabled).

1.2. Needle Guidance (if enabled)

The Site~Rite® 8 Ultrasound System has two optional needle guidance technologies available depending on the selected probe.

Both available needle guidance technologies are designed to track and display the location and trajectory of a needle under ultrasound guidance. The technologies consist of software installed on an ultrasound system and sensors incorporated into the ultrasound probes. The sensors detect a passive magnetic field emitted from the needle. The software interprets the data from the sensors and creates a virtual image of the needle on the ultrasound display, providing clinicians with a visual representation of the needle during the insertion process.

1.2.1. Cue™ Needle Tracking System Description

Cue™ Needle Tracking System requires the use of a Cue™ 20mm Linear Probe, the Cue™ Needle Tracking System Activator and a Cue™ compatible needle. The Cue™ 20mm Linear Probe contains sensors for tracking Cue™ compatible needles (following magnetization by the Cue™ Needle Tracking System Activator). The tracked needle’s current position, trajectory, and Intersection Window are displayed over the ultrasound image.

1.2.2. Pinpoint™ GT Needle Technology Description

Pinpoint™ GT Needle Technology requires the use of a 20mm Pinpoint™ GT Linear Probe and a Pinpoint™ GT Safety Introducer Needle. The 20mm Pinpoint™ GT Linear Probe contains sensors for tracking Pinpoint™ GT Safety Introducer Needles, which contain a permanent magnet within the safety canister of the needle. The tracked needle’s current position, trajectory, and point of intersection with the ultrasound plane are displayed over the ultrasound image.
1.3. Site~Rite® Ultrasound System Indications for Use

The Site~Rite® 8 Ultrasound System is intended for diagnostic ultrasound imaging of the human body. Specific clinical applications include:

- Pediatric
- Peripheral Vessel and Vascular Access
- Small Organ (breast, thyroid, parathyroid, testicles)
- Musculo-skeletal (conventional and superficial)
- Cardiac (adult and pediatric)

Typical examinations performed using the Site~Rite® 8 Ultrasound System include:

<table>
<thead>
<tr>
<th>Imaging Applications</th>
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<tbody>
<tr>
<td>Vessel</td>
<td>Assessment of vessels in the extremities and neck (e.g., jugular, carotid) leading to or coming from the heart, superficial veins in the arms and legs (e.g., basilic, cephalic, brachial, femoral, radial, saphenous), and vessel mapping. Assessment of superficial thoracic vessels (e.g., axillary, innominate, subclavian)</td>
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<tr>
<td>Vascular Access</td>
<td>Guidance for PICC, CVC, dialysis catheter, port, PIV, midline, arterial line placement, access to fistula and grafts, and general vein and artery access</td>
</tr>
<tr>
<td>Interventional</td>
<td>Guidance for biopsy and drainage</td>
</tr>
<tr>
<td>Superficial</td>
<td>Assessment of breast, thyroid, parathyroid, testicle, lymph nodes, hae, musculoskeletal procedures (e.g., joints, ligaments, tendons), soft tissue structures, and surrounding anatomical structures</td>
</tr>
</tbody>
</table>

Cue™ Needle Tracking System and Pinpoint™ GT Needle Technology are each intended to provide visual needle tracking to assist with ultrasound guided vascular access.

1.4. Clinical Applications for Cue™ Needle Tracking System

Clinical applications which are appropriate when using the Pinpoint™ GT Needle Technology are:

- Peripheral Vessel
- Vascular Access

1.5. Clinical Applications for Pinpoint™ GT Needle Technology

Clinical applications which are appropriate when using the Pinpoint™ GT Needle Technology are:

- Peripheral Vessel
- Vascular Access

1.6. Site~Rite® 8 Ultrasound System Components

Site~Rite® 8 Ultrasound System Components include:

- Console
- Linear 32mm Probe
- Linear 20mm Cue™ Needle Tracking System Probe
- Linear 20mm Pinpoint™ GT Needle Technology Probe
- Cue™ Activator
1.7. Site~Rite® 8 Ultrasound System Compatible Accessories

The Site~Rite® 8 Ultrasound System with Cue™ Needle Tracking System and Pinpoint™ GT Needle Technology is compatible with the following accessories:

- Cue™ Activator mounting arm
- Pinpoint™ GT Needle Guides
- Site~Rite® Needle Guides
- Site~Rite® Probe Covers
- MER Roll Stand
- Optional printers with mounting hardware
- Kickstand mounting accessory
- Probe holder accessory
- Site~Rite® Keyboard
- USB storage device (flash/pen drive) with no external power connection
- Silex® Wireless Bridge

1.8. Cue™ Needle Tracking Compatible Accessories

Cue™ Needle Tracking is compatible with all Site~Rite® 8 Ultrasound System compatible accessories listed in Section 1.7 EXCEPT:

- Site~Rite® Needle Guides

Warning: Cue™ Needle Tracking is not qualified for use with Site~Rite® Needle Guides. Using Site~Rite® Needle Guides with Cue™ Needle Tracking may result in injury to the patient.

1.9. Needles for Use with Cue™ Needle Tracking System

Needles for use with Cue™ Needle Tracking System:

- Cue™ Needle Tracking System Compatible needles, marked with Cue™ compatibility symbol

1.10. Pinpoint™ GT Needle Technology Compatible Accessories

Pinpoint™ GT Needle Technology is compatible with all Site~Rite® 8 Ultrasound System compatible accessories listed in Section 1.7 EXCEPT:

- Site~Rite® Needle Guides

Warning: Pinpoint™ GT Needle Technology is not qualified for use with Site~Rite® Needle Guides. Using Site~Rite® Needle Guides with the Pinpoint™ GT Needle Technology may result in injury to the patient.

1.11. Needles for Use with Pinpoint™ GT Needle Technology

Needles for use with Pinpoint™ GT Needle Technology:

- Pinpoint™ GT Safety Introducer Needle
2. WARNINGS AND CAUTIONS

2.1. Site~Rite® 8 Ultrasound System Warnings

Warning: Do not operate the Site~Rite® 8 Ultrasound System or the AC adapter in the presence of flammable anesthetics or gases; explosion may result.

Warning: Use only the Site~Rite® 8 Ultrasound System AC adapter to charge the system. Using any other device to charge the system may damage the battery, cause intermittent or unpredictable operation, damage the system, result in injury, and will void the warranty.

Warning: The following actions will void the warranty of the Site~Rite® 8 Ultrasound System and may result in injury or equipment damage:

- Opening or servicing any component by anyone other than service personnel authorized by Bard Access Systems.
- Removing system labels by anyone other than service personnel authorized by Bard Access Systems.
- Connecting the Site~Rite® 8 Ultrasound System to any AC adapter other than the system adapter.
- Connecting the Site~Rite® 8 Ultrasound System to any unauthorized accessory. Refer to the list of authorized accessories in the “Overview” section.
- Installing unauthorized software.
- Modification of system software without authorization by Bard Access Systems.

Warning: Inspect the AC adapter and battery cord for damage. If any of the prongs are damaged, use battery power until a replacement cord is obtained.

Warning: Verify that all accessories attached to the system comply with applicable safety standards. Use of non-compliant accessories may increase the risk to the patient or user.

Warning: The use of accessories other than those specified in the “Overview” section may result in increased emissions or decreased immunity of the Site~Rite® 8 Ultrasound System.

Warning: Equipment that relies on basic insulation only should not be used with this system. Failure to comply could result in increased risk to the patient or user.

Warning: Do not pull on cables or overload the roll stand; doing so may cause the system to tip. Refer to the roll stand instructions for weight limits or additional warnings.

Warning: Prior to use each time, inspect the system for damage. If any problems are found, discontinue use immediately and contact service personnel authorized by Bard Access Systems. Using a damaged system could cause injury to a patient or user.

Warning: Unapproved power cords should not be used with this system; doing so may increase risk to the patient or user and/or damage the system.

Warning: This product should only be operated by qualified medical personnel.

Warning: Do not use the Site~Rite® 8 Ultrasound System for ophthalmic indications; ophthalmic use may cause patient injury.

Warning: Misuse of the Site~Rite® 8 Ultrasound System may result in damage to the equipment or increase risk to the patient or user.

Warning: When using Site~Rite® Needle Guides and Pinpoint™ GT Needle Guides, use the sterile legally marketed plastic probe cover included in the kit with the needle guides. To ensure proper performance, follow the Site~Rite® Needle Guides instructions for use.

Warning: Do not place and/or use the Site~Rite® 8 Ultrasound System and its components or accessories in the presence of strong magnetic fields such as Magnetic Resonance Imaging (MRI) devices. The high magnetic fields created by an MRI device will attract the equipment with a force sufficient to cause death or serious injury to persons between the equipment and the MRI device. This magnetic attraction may also damage the equipment. If a needle tracking technology is enabled, the magnetic and the RF fields associated with the MRI environment may interfere with the display of needle location. Consult the MRI manufacturer for more information.
### 2.2. Cue™ Needle Tracking System Warnings (if enabled)

**Warning:** Use only Cue™ Needle Tracking System compatible needles with the Cue™ Needle Tracking System. Use of unapproved needles may result in patient injury.

**Warning:** Misuse of the Cue™ Needle Tracking System may result in damage to the equipment or personal injury.

**Warning:** Cue™ Needle Tracking is not qualified for use with Site~Rite® Needle Guides. Using Site~Rite® Needle Guides with Cue™ Needle Tracking may result in injury to the patient.

**Warning:** The Cue™ Activator contains strong magnets which may affect devices sensitive to magnetic fields.

### 2.3. Pinpoint™ GT Needle Technology Warnings (if enabled)

**Warning:** Use only Pinpoint™ GT Needles with the Pinpoint™ GT Needle Technology. Use of unapproved needles may result in patient injury or equipment damage.

**Warning:** Pinpoint™ GT Needle Technology is not qualified for use with Site~Rite® Needle Guides. Using Site~Rite® Needle Guides with the Pinpoint™ GT Needle Technology may result in injury to the patient.

**Warning:** Misuse of the Pinpoint™ GT Needle Technology may result in damage to the equipment or personal injury.

### 2.4. Site~Rite® 8 Ultrasound System Cautions

**Caution:** To avoid unnecessary strain on the user, use the medical device in a manner that is comfortable.

**Caution:** During use, the AC connector needs to be easily accessible. In case of emergency, remove the power cord as soon as possible.

**Caution:** Do not force connections; improper installation may damage the connector or system.

**Caution:** Use only Bard Access Systems cleaning and disinfection procedures. Failure to do so may damage the device.

**Caution:** Use only approved or recommended cleaners or disinfectants to avoid damaging the device.

**Caution:** Do not attempt to sterilize the Site~Rite® 8 Ultrasound System or probe; damage to the equipment may occur as a result.

**Caution:** When attaching the system to the roll stand or kickstand, do not over-tighten the screws; doing so may damage the system.

**Caution:** Use only the screws provided in the packaging. Ensure the unit is secure against the roll-stand or kickstand mount. Failure to do so may cause the display to disconnect from the mount.

**Caution:** The Site~Rite® 8 Ultrasound System contains an internal battery. Dispose of dead battery packs in accordance with local regulations; improper disposal may present an environmental hazard.

**Caution:** Do not allow liquid to enter the system, AC adapter, connectors, or ports; damage to the equipment may occur.

**Caution:** Only qualified personnel should attempt to service this equipment. The Site~Rite® 8 Ultrasound System contains static sensitive components and circuits. Failure to observe proper static-control procedures may result in damage to the system.

**Caution:** To avoid damage to the device operating system, shut down the device through the power control window (see Section 5).

**Caution:** The adverse biological effects of ultrasound on tissue appear to be threshold effects. When tissue is repeatedly exposed to ultrasound, with intervals in between, there will likely be no cumulative biological effect. If, however, a certain threshold has been passed, biological effects may occur. While the Site~Rite® 8 Ultrasound System acoustic-output parameters fall well below all US Food and Drug Administration (FDA) thresholds for adverse biological effects, any given ultrasound procedure should be performed using the principle of ALARA (As Low As Reasonably Achievable). The licensed medical practitioner should limit the time of patient exposure to ultrasonic radiation using the principles of ALARA.

**Caution:** Hot water (in excess of 113°F or 45°C) may damage the system or the probe.

**Caution:** Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

**Caution:** Cardiac-rhythm disturbances during perfusion studies using gas ultrasound contrast agents have been observed in the diagnostic range of Mechanical Index (MI) values. See the specific package insert for the specific contrast agent being used for details.

**Caution:** Do not twist, bend, swing, or pull the probe cable in excess of that required during normal use of the probe. Excessive force on the cable may cause equipment failure, intermittent operation, or unpredictable operation.
Caution: When using the Site–Rite® 8 Ultrasound System probe in a sterile environment, the probe and part of the probe cable must be covered with a sterile, acoustically transparent plastic probe cover.

Caution: When disinfecting the probe with a liquid disinfectant, do not soak the probe cable, cable bend relief, or probe buttons; doing so may damage the probe.

Caution: Apply to the acoustic window (or face) of the probe only commercially available ultrasonic couplant that has been specifically formulated for use in medical applications.

Caution: Use water or rubbing alcohol and a soft cloth to remove ultrasonic couplant from the acoustic window (or face) of the probe; failure to do so may scratch the acoustic window.

Caution: Do not allow the ultrasonic couplant to dry on the acoustic window (or face) of the probe. If the couplant should dry, use water or rubbing alcohol and a soft cloth to remove it. Never use a tool of any kind to remove dry ultrasonic couplant from the acoustic window (or face) of the probe.


Caution: Always snap the needle guides on the probe hook. Do not slide the needle guide onto the needle-guide hook, as the sterile cover may tear.

Caution: Do not subject the probe to excessive vibration; doing so may dislodge sensitive components and cause intermittent or unpredictable operation.

Caution: If a probe is damaged in any way, discontinue using it immediately, as damage to the system may occur.

Caution: Avoid subjecting the system or probe to excessive mechanical shock (e.g., throw and/or drop); damage to the system may occur as a result.

Caution: Do not use the probe with high-frequency surgical equipment; doing so may damage the Site–Rite® 8 Ultrasound System.

Caution: Do not connect to an unsecured network; doing so may compromise data security.

Caution: This equipment is not designed to meet the standards for Home Healthcare Environments in accordance with IEC 60601-1-11:2010. This equipment should be operated in clinical environments only.

Caution: Do not submerge the probe in liquid or allow fluid to enter the connectors. Damage to the equipment may occur.

Caution: Prior to each use, inspect the integrity of all power cords and connectors as well as the integrity of the unit itself. If any problems are found, discontinue use immediately and contact an authorized service representative. Use of a damaged power cord could damage the machine.

Caution: Do not force the probe connector; damage to the connector and system could result.

⚠️ If operating the device in temperatures exceeding 90°F (32°C), the battery charging functionality may be disabled to protect the battery. To charge the battery in temperatures exceeding 90°F (32°C), the system may need to be turned off.

Caution
2.5. **Cue™ Needle Tracking System Cautions (if enabled)**

- **Caution:** Keep the needle and any ferromagnetic objects, e.g., wired undergarments, metal instruments, watches, jewelry, Cue™ Activator, electronics, metal bed rails, etc. at least 3 feet away from probe when calibrating. Failure to do so may impact the accuracy of needle tracking.

- **Caution:** Equipment operating in close proximity may emit strong electromagnetic or radio frequency interference which could affect the performance of this device. Avoid operating the device near pumps, cauterizers, diathermy equipment, cellular phones, or other portable and mobile radio frequency communications equipment. Maintain equipment separation of at least 3 feet.

- **Caution:** Excessive movement of the probe may result in a temporary loss of needle tracking.

- **Caution:** The Activator produces a magnetic field. It should be kept away from any device that is sensitive to magnetic fields.

- **Caution:** Follow all care, handling and/or installation instructions included in this guide and on the packaging provided with the Activator and needles.

- **Caution:** Single-use items (e.g., needle trays, needle guides, needles and sheaths/ covers) must not be reused under any circumstances.

- **Caution:** Movement of the probe during calibration may result in calibration error.

- **Caution:** If needle tracking is not functioning properly, discontinue use of Cue™ Needle Tracking System.

- **Caution:** Improper technique and environmental conditions may introduce variation in accuracy.

2.6. **Pinpoint™ GT Needle Technology Cautions (if enabled)**

- **Caution:** Keep the needle and any ferromagnetic objects, e.g., wired undergarments, metal instruments, watches, jewelry, electronics, metal bed rails, etc. at least 2 feet away from probe when calibrating. Failure to do so may impact needle tracking.

- **Caution:** Equipment operating in close proximity may emit strong electromagnetic or radio frequency interference which could affect the performance of this device. Avoid operating the device near pumps, cauterizers, diathermy equipment, cellular phones, or other portable and mobile radio frequency communications equipment. Maintain equipment separation of at least 5 feet (1.5m).

- **Caution:** Excessive movement of the probe after calibration may result in reduced needle tracking accuracy.

- **Caution:** During insertion, use a light touch to prevent needle deflection and/or bending. Needle deflection and/or needle bending may reduce needle tracking accuracy.

- **Caution:** To ensure accuracy, do not apply force or pressure that may leverage the needle. This may result in needle deflection, bending or altering needle trajectory.

- **Caution:** Movement of the probe during calibration may result in calibration error.

- **Caution:** If needle tracking is not functioning properly, discontinue use of Pinpoint™ GT Needle Technology.

- **Caution:** To avoid reduced needle tracking accuracy, prior to insertion do not modify the straightness of the needle by bending.

- **Caution:** Improper technique and environmental conditions may introduce variation in accuracy.
3. PHYSICAL FEATURES

3.1. Console Features

For installation of approved mounting accessories, please see the appropriate assembly instructions.

**Caution:** When attaching the system to the roll stand or kickstand, do not over tighten the screws; doing so may damage the system.

**Caution:** Use only the screws provided in the packaging. Ensure the unit is secure against the roll-stand or kickstand mount. Failure to do so may cause the display to disconnect from the mount.
3.2. Compatible Probes

Linear 32mm Probe  Linear 20mm Cue™ Needle Tracking System Probe  Linear 20mm Pinpoint™ GT Needle Technology Probe

3.3. Connecting the Ultrasound Probe (if applicable)

To connect the probe:

1. Align the probe connector and gently insert the probe into the console.

Note: If the EC204 error appears, connect/reconnect the probe and restart the system.

Caution: Do not force the probe connector; damage to the connector and system could result.

To remove the probe:

1. Press the two latches on the probe connector.
2. Gently pull on the connector to disconnect the probe.
3.4. LED Status Indicators

The LED icons, shown below, are located along the top of the display.

- **Power**
  - Green indicates the unit is on.

- **WiFi**
  - Green indicates WiFi is enabled (if enabled).

- **Ethernet**
  - Green indicates the Ethernet connection is active (if enabled).

- **Battery Life**
  - Red and blinking when the battery power is low.
  - Green and blinking when the system is off and the battery is charging.
  - Green and static when the system is off and the battery is fully charged.

- **Bluetooth™ Wireless Technology** (if enabled)

4. CONNECTING THE BATTERY

During shipping or storage, the battery may be disconnected from the system to allow extended storage life. To enable the system to be powered from the battery, the battery switch must be turned on prior to use.

To activate the battery, open the battery cover on the back of the system. Move the switch to the **position.

To extend the storage life of the battery, return the switch to the X position prior to prolonged storage. Failure to do so will degrade battery life.
5. POWER OPTIONS

5.1. Power On

To turn on the system, press the power switch on the upper left side of the unit.

5.2. Power Menu

The power menu can be accessed the following ways:

1. To access the power menu, press the power switch on the side of the device.
2. To access the power menu using the probe or touch screen, select the settings button on the main ultrasound screen. Select the power button on the top right of the settings screen.

6. NAVIGATING THE DISPLAY

To navigate through the different features shown on the screen, you can use the touch screen, USB keyboard, or probe. Each one of these methods is described in more detail below.

When using the USB keyboard or probe, the button navigation is tracked via highlight as shown below:

6.1. Touch Screen

Any feature or control can be selected by touching the corresponding button on the screen.

6.2. USB Keyboard (optional)

The keyboard can be used to enter data into the system. The arrows and enter key on the USB keyboard can be used to navigate through procedurally applicable buttons.
6.3. Probe

The probe controls can be used to navigate procedurally applicable buttons.

### Linear 32mm Probe

- **Cursor Up**: Press to move cursor up.
- **Cursor Left**: Press to move cursor left.
- **OK**: Press to select the current control.
- **Cursor Down**: Press to move cursor down.
- **Cursor Right**: Press to move cursor right.

### Linear 20mm Cue™ Needle Tracking System Probe

- **Cursor Up**: Press to move cursor up.
- **Cursor Left**: Press to move cursor left.
- **Cursor Down**: Press to move cursor down.
- **Cursor Right**: Press to move cursor right.
- **OK**: Press to select the current control.

### Linear 20mm Pinpoint™ GT Needle Technology Probe

- **Cursor Up**: Press to move cursor up.
- **Cursor Left**: Press to move cursor left.
- **OK**: Press to select the current control.
- **Cursor Down**: Press to move cursor down.
- **Cursor Right**: Press to move cursor right.
7. MAIN ULTRASOUND SCREEN

After starting the system, the main ultrasound screen will appear.

An explanation of the various parts of the main ultrasound screen is provided below.

7.1. Information Bar

The information bar is located at the top of the ultrasound screen. This bar contains the following information:

- Time
- Patient Information
- File Management
- Date
- Catheter Trim Length
- Exit Site Marking
- Battery Information
7.1.1. **Time**

The time is displayed in 24-hour format, as follows: hour:minute:second.

7.1.2. **Date**

The date is displayed in the following format: year-month-day.

7.1.3. **Patient Information**

To enter patient information, select the button shown. The patient information screen will appear, allowing you to enter information. For instructions on this process, refer to Section 12.

7.1.4. **Catheter Trim Length**

This is optional and is intended to allow the clinician to note the trim length of the catheter. If the trim length button is selected, a window will open with a numeric keypad. If a numeric value is entered, the number shall appear on the trim length button.

7.1.5. **Exit Site Marking**

This is optional and is intended to allow the clinician to note the exit site marking of the catheter. If the Catheter Exit Site button is selected, a window will open with a numeric keypad. If a numeric value is entered, the number shall appear on the Catheter Exit Site button.

7.1.6. **File Management – Accessing Saved Patient Images**

By selecting this button, previously saved images can be viewed, saved, printed, or sent to your configured PACS server. For instructions on these actions, refer to Section 14.

7.1.7. **Battery Information**

- **Five green bars** indicate 81%–100% of the battery's power remains.
- **Four green bars** indicate 61%–80% of the battery's power remains.
- **Three green bars** indicate 41%–60% of the battery's power remains.
- **Two yellow bars** indicate 21%–40% of the battery's power remains.

One blinking red bar indicates 0%–20% of the battery's power remains. In this case, connect the system to AC power to continue operation and/or recharge the battery. While the system charges, the icon of the battery will progressively be filled with green bars until it reaches full battery charge.

The charging icon indicates that the battery is connected to AC power and is charging. A red exclamation point indicates a battery malfunction. See Section 16 for troubleshooting.
7.2. Catheter Icons

Catheter Icons
Toggles through available catheter icon sizes.

The catheter icons are displayed in proportion to the vessel image at a selected depth. Icons assist clinicians in determining the appropriate catheter size for the vessel being imaged.

7.3. Main Toolbar

The main toolbar is located at the bottom of the main ultrasound screen and contains the following buttons:

- Depth
- Gain
- Freeze
- SHERLOCK 3CG™ Tip Confirmation System (TCS) Mode (if enabled)
- Pinpoint™ GT Needle Technology Mode (if enabled)
- Settings

7.3.1. Depth

When the user selects the depth button, the image depth will toggle through the depths selected in the ultrasound settings (see Section 11.1). The circle indicators that are greyed out correspond to depths that have been disabled in the ultrasound settings. Adjusting the depth also adjusts the focus of the ultrasound. Adjust the depth to place the structure of interest in the middle of the ultrasound image. This will provide the appropriate focus.

7.3.2. Gain

Selecting gain will change the brightness of the entire image. Select the gain that provides the best ultrasound image for the targeted structure.

7.3.3. Freeze

Selecting the freeze button will show a static image of the last acquired ultrasound frame. Additional tools are available, as described in Section 8.

7.3.4. Pinpoint™ GT Needle Technology Mode (if enabled)

If Pinpoint™ GT Needle Technology Mode is enabled, the Pinpoint™ GT Needle Technology button shall appear as shown. If Pinpoint™ GT Needle Technology Mode is not enabled on the system, the Pinpoint™ GT Needle Technology button shall not be shown. When selected, the Pinpoint™ GT Needle Technology button shall switch the system to Pinpoint™ GT Needle Technology Mode.

7.3.5. SHERLOCK 3CG™ TCS Mode (if enabled)

If SHERLOCK 3CG™ TCS Mode is enabled, the SHERLOCK 3CG™ TCS button shall appear as shown. If SHERLOCK 3CG™ TCS Mode is not enabled on the system, the SHERLOCK 3CG™ TCS button shall not be shown. When selected, the SHERLOCK 3CG™ TCS button shall switch the system to SHERLOCK 3CG™ TCS Mode. For further instructions, refer to the applicable SHERLOCK 3CG™ TCS Instructions for Use.

7.3.6. Settings

The settings button shall appear as shown. When selected, the system settings window shall appear. Refer to Section 11.
7.4. Depth Markers and Image Depth Scale

7.5. Probe Orientation

The probe orientation icon corresponds to the button pad on the ultrasound probe.

When using the Site–Rite® 8 Ultrasound System probe for vascular access, hold it so that the side with the Needle Guide hook and button pad points away from the patient’s heart.
8. FREEZE MODE

Access freeze mode by pressing the freeze button on the main ultrasound screen. The following screen will appear.

8.1. Save/Print

When the Save/Print button is selected, the current ultrasound image is saved to the system hard drive and any attached USB storage devices. The image is also printed if a compatible printer is connected.

8.2. Measurement Tool

The Site–Rite® 8 Ultrasound System Measurement Tool is used to estimate the vessel occupancy percentage of the selected catheter in a vessel. It also allows for measurements of vessel area and diameter.

The following steps describe how to take measurements with the Site–Rite® 8 Ultrasound System Measurement Tool.

1. After freezing an ultrasound image, select the measurement tool button.
2. Select the desired catheter size. Additional catheter icon sizes can be selected by pressing the Catheter Icons button.
3. Place the Catheter in the middle of the vessel by pressing and holding the catheter icon and dragging it to the desired location.

4. Evaluate whether or not the vessel complies with the user specified rule.

   - If the Vessel Occupancy Rule Circle is **smaller** than the vessel, the selected catheter complies with the user-specified rule.

   - If the Vessel Occupancy Rule Circle is **larger** than the vessel, the selected catheter does *NOT* comply with the specified rule. Select a smaller catheter, or find a larger vessel to comply with the user-specified rule.
5. To manually resize the Vessel Occupancy Circle to the target vessel, align the top middle of the Vessel Occupancy Circle with the top middle of the vessel by pressing and holding the middle of the icon and dragging it to the desired location. Drag the resizing marker up or down in order to make the Vessel Occupancy Circle match the target vessel size.

**Note:** When the Vessel Occupancy Circle is resized, the Vessel Occupancy Percentage will change from the user-defined rule.

6. The area and diameter of the vessel Occupancy Circle will be displayed as shown below.

**Note:** See Section 24 for system measurement error information.
9. **CUE™ NEEDLE TRACKING SYSTEM MODE (if enabled)**

9.1. Enabling **Cue™ Needle Tracking System**

Ensure the Cue™ Probe is attached (see Section 3.2). Turn on the system and ensure the ultrasound system is scanning. The Cue™ Activator icon will appear, as shown below, when the Cue™ Probe is attached. Turn on the system and ensure the system images. Connect the provided USB cable to the Cue™ Activator. Then connect the other end of the USB cable to a USB port on the ultrasound system.

Ensure the Activator icon indicates a connection.

![Cue™ Activator Icon](image)

9.2. Activating the **Cue™ Needle Tracking System Compatible Needle**

Place a tray containing a Cue™ Needle Tracking System compatible needle on the Cue™ Activator as shown.

**Note:** Ensure the tray is fully seated in the Activator, making complete contact with the Activator.

When the needle is activated, the following window shall appear.

![Cue™ Needle Tracking Window](image)

If selected, this window will not be shown for the currently selected Clinician (see Section 13).

The Cue™ Needle Tracking System compatible needle and software are now activated.
9.3. **Cue™ Needle Tracking System Home Screen**

The probe face overlay shows the needle position with respect to the probe face.

### 9.3.1. Probe Face Overlay

The probe face overlay shows the needle position with respect to the probe face.

**Out-of-Plane Insertion**

The probe face overlay for an out-of-plane insertion may be turned off in the Cue™ Needle Tracking System settings screen (see Section 11.2).
In-Plane Insertion

When the needle is well aligned with the probe face, the needle graphic is green.

Probe View

When the needle is not aligned with the probe face, the needle graphic is red.

Probe View
### 9.3.2. Performance Indicator

The Performance Indicator measures the quality of the magnetic environment around the probe. Stray magnetic fields can inhibit the probe’s ability to detect an activated needle. More bars indicate a “cleaner” magnetic environment for detecting an activated needle.

<table>
<thead>
<tr>
<th>Performance Indicator</th>
<th>Indication:</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="3-5 bars" /></td>
<td>Low magnetic fields are present. Conditions are optimal for the Cue™ Needle Tracking System.</td>
</tr>
<tr>
<td><img src="image" alt="1-2 bars" /></td>
<td>Moderate magnetic fields are present. Conditions are moderate for the Cue™ Needle Tracking System.</td>
</tr>
<tr>
<td><img src="image" alt="0 bars" /></td>
<td>Strong magnetic fields are present. Conditions are poor for the Cue™ Needle Tracking System, and needle tracking is disabled.</td>
</tr>
<tr>
<td><img src="image" alt="Blinking bars" /></td>
<td>The system is detecting probe movement. Hold the probe still and wait for the Performance Indicator to stop blinking.</td>
</tr>
<tr>
<td><img src="image" alt="Loading Cue™ Needle Tracking System" /></td>
<td>The system is restarting the Cue™ Needle Tracking System in order to load in a new needle or to recover from an error. Please wait until the loading is complete.</td>
</tr>
<tr>
<td><img src="image" alt="Cue™ Needle Tracking System Error" /></td>
<td>The Cue™ Needle Tracking System has encountered an error. Refer to Section 16.2.</td>
</tr>
</tbody>
</table>

Perform the following steps to improve the Performance Indicator:

1. Hold the probe still
2. If the Performance Indicator decreases during needle approach, withdraw the needle and slowly re-approach.
3. Remove metal, magnetic, and electronic objects in close proximity to the probe (bed rails, jewelry, mobile phone, pumps, bed/table frames, Cue™ Activator, etc.).
4. If problem persists, hold the probe stationary in the air away from all metal, magnetic, and electronic devices.
   a. If the Performance Indicator improves, review previous troubleshooting tips
   b. If the Performance Indicator remains low, calibration may be required. This should be uncommon (see Section 11.2.1).
9.4. Cue™ Needle Tracking System Overlay

9.4.1. Out-of-Plane Insertion

When the needle overlay advances through the Intersection Window, the needle flash will appear within the Intersection Window.

**Note:** Adjusting the angle of the needle up or down or changing the distance between the needle and probe will change the position of the Intersection Window.

A flat angle is required for shallow insertion.

A steep angle is required for deeper insertion.

When the needle overlay advances through the Intersection Window, the needle flash will appear within the Intersection Window.
Actual View

On-Screen View

- Needle Shaft
- Needle Tip
- Needle Trajectory
- Intersection Window
- Ultrasound Beam
9.4.2. In-Plane Insertion

Actual View

On-Screen View

- Needle Shaft
- Needle Tip
- Needle Trajectory
- Ultrasound Beam

- Needle Shaft
- Needle Tip
- Needle Trajectory
- Ultrasound Beam
10. PINPOINT™ GT NEEDLE TECHNOLOGY MODE (if enabled)


Access Pinpoint™ GT Needle Technology Mode by pressing the Pinpoint™ GT Needle Technology button on the main ultrasound screen. The following screen will appear:

The calibration status of the Pinpoint

<table>
<thead>
<tr>
<th>Calibration Status Border</th>
</tr>
</thead>
<tbody>
<tr>
<td>This border indicates the calibration status of Pinpoint™ GT Needle Technology.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Calibration Status Icon</th>
</tr>
</thead>
<tbody>
<tr>
<td>This icon indicates the current calibration status of Pinpoint™ GT Needle Technology.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Freeze Button</th>
</tr>
</thead>
<tbody>
<tr>
<td>Freeze the Pinpoint™ GT Needle Technology virtual needle image by pressing the freeze button.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Back Button</th>
</tr>
</thead>
<tbody>
<tr>
<td>Returns the system to active imaging mode.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>SHERLOCK 3CG™ TCS Mode</th>
</tr>
</thead>
<tbody>
<tr>
<td>Switches to SHERLOCK 3CG™ TCS mode when selected (if enabled).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Calibrate Button</th>
</tr>
</thead>
<tbody>
<tr>
<td>This button calibrates Pinpoint™ GT Needle Technology. This icon will have focus and flash upon entering Pinpoint™ GT Needle Technology Mode.</td>
</tr>
</tbody>
</table>
10.2. **Pinpoint™ GT Needle Technology Calibration**

Selecting this button will calibrate Pinpoint™ Technology. The button also indicates the status of calibration.

A calibration step is required to establish a baseline before bringing the needle close to the probe. Calibration is only required prior to inserting the needle into the patient. The following screens will appear:

- **Calibration Status Icon**
  - Prior to calibrating Pinpoint™ GT Needle Technology, the calibration icon is a yellow triangle.

- **Calibrate Button**
  - This button calibrates Pinpoint™ GT Needle Technology.
  - This icon will have focus and flash upon entering Pinpoint™ GT Needle Technology Mode and whenever calibration is required.

- **Freeze Button**
  - Not accessible during calibration of Pinpoint™ GT Needle Technology.

- **Calibration Status Icon**
  - Upon selecting the calibrate button, an animation will appear indicating the calibration status of Pinpoint™ GT Needle Technology.

- **Freeze Button**
  - Not accessible during calibration of Pinpoint™ GT Needle Technology.

- **Calibration Status Border**
  - This border indicates the calibration status of Pinpoint™ GT Needle Technology.

- **Yellow Border – “CALIBRATION REQUIRED”**
  - System is Calibrating. Do not move the probe.

- **Calibration Status Border**
  - This border indicates the calibration status of Pinpoint™ GT Needle Technology.

- **Yellow Border – “CALIBRATING… HOLD PROBE STILL”**
  - System is Calibrating. Do not move the probe.
10.3. **Pinpoint™ GT Needle Technology Needle Tracking**

Once Pinpoint™ GT Needle Technology has finished calibrating, the system is ready to begin tracking Pinpoint™ GT Needle Technology compatible needles.

**Caution:** Movement of the probe during calibration may result in calibration error.

**Caution:** Keep the needle and any ferromagnetic objects, e.g., wired undergarments, metal instruments, watches, jewelry, electronics metal bed rails, etc. at least 2 feet away from probe when calibrating. Failure to do so may impact the accuracy of needle tracking.

**Caution:** Equipment operating in close proximity may emit strong electromagnetic or radio frequency interference which could affect the performance of this device. Avoid operating the device near pumps, cauterizers, diathermy equipment, cellular phones, or other portable and mobile radio frequency communications equipment. Maintain equipment separation of at least 5 feet (1.5m).

**Caution:** Excessive movement of the probe after calibration may result in reduced needle tracking accuracy.
10.4. **Pinpoint™ GT Needle Technology Freeze Mode**

Access Pinpoint™ GT Needle Technology freeze mode by pressing the freeze button. The following screen will appear:

- **Pinpoint™ GT Needle Technology Virtual Needle Image**
  Virtual needle image of the Pinpoint™ GT Safety Introducer Needle.

- **Save/Print**
  See Section 10.4.1.

- **Unfreeze**
  Returns to Pinpoint™ GT Needle Technology Mode.

**10.4.1. Save/Print**

When the Save/Print button is selected, the current ultrasound image with Pinpoint™ GT Needle Technology Virtual Needle Image is saved to the system hard drive and any attached USB storage devices. The image is also printed if a compatible printer is connected.
10.5. Pinpoint™ GT Needle Technology Errors

Pinpoint™ GT Needle Technology Error. Refer to Section 16.3, Troubleshooting.

Error Icon and Number
This icon indicates that a Pinpoint™ GT Needle Technology malfunction has occurred. Refer to Section 16.3, Troubleshooting, for addressing errors.

Calibration Status Border
This border indicates the calibration status of Pinpoint™ GT Needle Technology.


**Actual View**

**On-Screen View**

**Note:** Adjusting the angle of the needle up or down will change the position of the ultrasound beam point of intersection circle.

A flat angle is required for shallow insertion.

A steep angle is required for deeper insertion.

**Note:** Adjusting the angle of the needle up or down will change the position of the ultrasound beam point of intersection circle.
When the needle passes through the Point of Intersection Circle, the circle changes color from violet to green. Any portion of the needle that lies beyond the Point of Intersection Circle changes color from yellow to violet.

**Note:** When the virtual needle image changes from yellow to violet, it does **NOT** necessarily mean that you have advanced your needle beyond the target structure, it means the needle is beyond the ultrasound plane.

**Caution:** To avoid reduced needle tracking accuracy, prior to insertion, do **NOT** modify the straightness of the needle by bending.

**Caution:** During insertion, use a light touch to prevent needle deflection and/or bending. Needle deflection and/or needle bending ay reduce needle tracking accuracy.
10.7. Pinpoint™ GT Needle Technology Virtual Needle Image – In Plane Needle Insertion

Actual View

On-Screen View

[Diagram showing the needle, needle shaft, needle tip, ultrasound beam, and needle trajectory.]
When the needle is positioned for In-Plane insertion, a rectangular box representing the probe face appears on the bottom right side of the screen. Since the needle is inserted “in plane” to the ultrasound beam, the Pinpoint™ GT Needle Technology Virtual Needle Image does not show a Point of Intersection Circle.

Note: When the needle is positioned back to an Out-of-Plane placement, the In-Plane box is not displayed and the Pinpoint™ GT Needle Technology Virtual Image includes the Point of Intersection Circle.
Well Aligned – In-Plane Box and Needle Trajectory are **Green**

**Probe View**

![Probe View Image]

**In-Plane Box View**

![In-Plane Box View Image]

Misaligned – In-Plane Box and Needle Trajectory are **Violet**

**Probe View**

![Probe View Image]

**In-Plane Box View**

![In-Plane Box View Image]
11. SYSTEM SETTINGS

To access the system settings, press the 'Settings' button on the main ultrasound screen.

The Settings window consists of several tabs:

- Ultrasound Settings
- Connectivity Settings
- General Settings
- System Information
- Power Menu
- Name of Clinician (if entered)
- Connect to Network
- Update Software

11.1. Ultrasound Settings

To access the ultrasound settings, click on the 'Ultrasound Settings' tab at the top of the settings screen. The following screen will appear:

- Toggles the depth markers On/Off.
- Selects Low/High contrast image.
- Sets the Vessel Occupancy Percentage to be calculated by Diameter or Area.
- % Occupied (Diameter) = \( \frac{\text{Diameter of Catheter}}{\text{Diameter of Vessel Occupancy Circle}} \times 100 \)
- % Occupied (Area) = \( \frac{\text{Area of Catheter}}{\text{Area of Vessel Occupancy Circle}} \times 100 \)
- Toggles the catheter icons On/Off.
11.2. **Cue™ Needle Tracking System Settings (if enabled)**

To access the Cue™ Needle Tracking System settings, click on the ‘Cue™ Needle Tracking System’ settings tab at the top of the settings screen. The following screen will appear:

- **Launches the Cue™ Needle Tracking System tutorial.**
- **Toggles the portion of the needle tracking overlay representing the needle On/Off.**
- **Toggles the Probe Face Overlay for out-of-plane insertions On/Off (The Probe Face Overlay will always appear for in-plane insertions).**
- **Enters the calibration screen.**
- **Toggles the portion of the needle tracking overlay representing the needle On/Off.**
- **Displays information on how to improve the Performance Indicator.**
- **Performance Indicator (see Section 9.3.2).**
- **Provides information regarding the Cue™ Needle.
11.2.1. Calibration

Calibration may be required when the Performance Indicator (see Section 9.3.2) measures a poor magnetic environment. To determine if calibration is necessary, hold the Cue™ Probe Stationary in the air away from all metal, magnetic, and electronic devices. If the Performance Indicator improves, calibration is not required.

For tips on how to improve the Performance Indicator when calibration is not required, press the ‘Performance Indicator Help’ button.

The following steps will calibrate the probe:

1. Select the calibrate button on the Cue™ Needle Tracking System settings screen.
2. Follow the on-screen instructions to hold the probe in the air, at least 3 feet from any metal, magnetic, or electronic devices (including watches, cell phones, etc.).

3. While holding the probe still in the air, press the calibration button. Maintain this position until the system indicates that calibration is complete.
4. Upon completion of calibration, the Performance Indicator should improve. A Performance Indicator of 3 bars or higher is recommended before beginning any procedure.

Note: Maintain a distance of 4 inches between the Cue™ probe and Cue™ Activator to minimize the potential need for calibration.
11.3. General Settings

To access the general settings, click on the ‘General Settings’ tab at the top of the settings screen. The following screen will appear:

11.3.1. Add Feature Activation Key

Optional features are available on this device. Selecting this button will allow the user to enter in licensing keys for additional features. The activation key will be provided after purchase of the optional feature. Contact your Bard sales representative for additional information about optional features. Some features may need additional hardware to function.

To add a feature using the activation key:

1. Type in the Bard provided activation key into the appropriate field corresponding to the feature.
2. Press the unlock button.
3. A correct key will result in a green check mark and activate the feature. An incorrect key will result in a red X. If activation failed, re-enter the activation key. If problem continues, call Customer Service at: 1-800-545-0890.
4. Once the feature is activated, it cannot be removed from the system by the user.
11.3.2. System Password

To configure password protection, enable the password option in the general settings tab.

The first-time password protection is enabled, the system will display a prompt to create an administrator password.

The administrator password will be used to make any future configuration changes to the system password. If the administrator password is forgotten, contact customer service for a temporary password.

Upon creating or entering the administrator password, the following options will be displayed:

- Disable password protection.
- Enable PIN password protection.
- Enable Active Directory Authentication.
- Ensure connectivity settings are configured (see either Section 11.4.1 or 11.4.2).
- Enable Multi-Factor password protection.
- PIN password settings (see Section 11.3.2.2).
- Active Directory Authentication settings (see Section 11.3.2.2).
- Save password configuration settings.

When password protection is enabled, the system will only prompt for the password upon system reboot or when the lock button is selected from the power menu (see Section 5.2).

The lock screen will appear as shown below:

**PIN Authentication**

- PIN
- Active Directory
- Multi-Factor (PIN + Active Directory)

**Active Directory Authentication**

- User Name:
- Password:
- Domain:

**Bypass password:**
Select to enable basic system functions without a password. Patient information will not be accessible.
11.3.2.1. Pin Password Settings

- Enter any numeric password between 1 and 10 digits.
- Exit and return to password configuration screen without saving.
- Enable and set the number of days until the PIN expires.
- Save password and return to password configuration screen.

11.3.2.2. Active Directory Authentication Settings

- Select to delete active directory configuration.
- Select to edit active directory configuration.
- Enter the name of the active directory domain.
- Select to validate active directory domain.
- Select to use offline authentication.
- Select to allow offline authentication indefinitely.
- Select number of times a user can incorrectly attempt authentication offline.
- Select number of days a user can authenticate offline.
11.3.3. Patient/Clinician Backup/Restore

To backup and restore patient and clinician data, select the 'Backup/Restore' button in the General Settings Tab (the admin password is required for access).

11.4. Connectivity Settings

**Note:** The actions described in this section should only be taken by authorized personal. To configure the Site~Rite® 8 Ultrasound System, contact your network administrator or a PACS administrator.

To access the connectivity settings, click on the 'Connectivity Settings' tab at the top of the settings screen. The following screen will appear:
11.4.1. WiFi Networks

Select the ‘WiFi Network’ button to access and connect to WiFi networks. See Sections 24 and 25 for technical specifications.

To connect the Site~Rite® 8 Ultrasound System to WiFi, perform the following steps:

1. Select the ‘Settings’ button.

2. In the Settings window, select the ‘WiFi/Connectivity Settings’.

3. Enable WiFi (if not already enabled).

4. Select the ‘WiFi’ Profile button.
5. Add a visible WiFi network or select “Add WiFi Network” button to add a custom or hidden WiFi network.

Step 5

6. Fill in the required information. After the information is filled in, select

Step 6

7. The system should now be connected to the WiFi network.

11.4.2. Configure Network Settings

Press the ‘Settings’ button to configure network settings for either WiFi or Ethernet.

WiFi

Ethernet

Select ‘Auto Configuration’ to automatically configure the network settings.

Select ‘Static Configuration’ to manually configure the network settings.
11.4.3. DICOM (if enabled)

To configure DICOM settings, press the ‘DICOM Settings’ button.

Fill in the information to configure the PACS server:

- Sends a standardized DICOM ECHO request to the specified PACS system. A green ✓ indicates success and a red ‘X’ indicates a failure.
- Shift / Display additional Characters.
- Exports a client certificate to USB for Secure DICOM server-client authentication.
- Opens a window to allow a PING to a specified IP address.
  - IP Address
  - PING
  - Input the IP address and select the PING button.

Multiple PACS servers may be configured. To select from configured PACS servers or to add/modify a PACS server, press the ‘DICOM Settings’ button.

- Delete PACS server.
- Edit PACS server settings.
- Add new PACS server.

Select desired configured PACS server. Highlight indicates currently selected PACS server.
11.4.4. DICOM Conformance Statement

Files are formatted according to Digital Imaging and Communications in Medicine. The DICOM conformance statement is available upon request. Call Customer Service at 1-800-545-0890.

11.4.5. Bluetooth™ Wireless Technology (if enabled)

To pair a Bluetooth™ Wireless Technology device and adjust Bluetooth™ Wireless Technology settings, press the Bluetooth™ Wireless Technology settings button.

11.5. System Information

To access the system information, click on the system information tab at the top of the settings screen. The following screen will appear:

- Customer Service contact information.
- Alternate contact number (if available).
- Site~Rite® 8 Ultrasound System software version number.
- Site~Rite® 8 Ultrasound System serial number.
12. PATIENT INFORMATION

Instructions to enter patient information into the Site~Rite® 8 Ultrasound System are as follows:

1. Select the 'Patient Information' button.

   ![Image of patient information input screen]

   - **11:39PM**
   - **2015-05-12**
   - **89%**

2. The following options will appear:

   - **Add new patient.** Previously unsaved patient data will be deleted.
   - **Allows the user to edit existing patient information.** These changes will be applied to previously saved images for the current patient.
   - **Returns to the previous screen.**

3. Enter the desired patient information. All fields are optional and entered data will be saved with images.

4. Select the green arrow button to retain the information and exit this screen.

   **Note:** See Section 14 for information on how to delete patient data.
13. CLINICIAN PRESETS

The Site~Rite® 8 Ultrasound System allows individual clinicians to retain their unique settings.

Clinician Presets will automatically retain the following settings for each clinician name:

- Ultrasound image depth
- Ultrasound image gain
- All settings in the ultrasound settings tab (see Section 11.1)
- Patient information custom fields (left side) and hospital (see Section 12)

To access a preset, select the clinician name from the dropdown menu on the patient information screen. Any changes made to the settings above will be saved to the selected clinician name.

To create a preset:

1. In the Patient Information window, select the ‘Clinician’ button next to the Clinician dropdown menu.
2. In the window that appears, type the clinician name.
3. Adjust the system settings as desired.

To delete a clinician preset, select the Clinician in the dropdown menu and press the ‘Delete’ button.

14. ACCESSING SAVED PATIENT IMAGES

The Site~Rite® 8 Ultrasound System allows you to view and manage saved images. To access saved images, do the following:

1. Select the ‘File Management’ button on the information bar (see Section 7.1).

2. A list of all saved patients appears in the window. Select patients to view their respective images.
3. After selecting the patients, select all images to be managed.

4. To preview an image, touch the center of the image in the images list. The following image preview will appear:

5. Once the desired image(s) have been selected, choose an action to perform from the bottom toolbar.

Note: To delete all patient data from the system, select all the patients in the patient list (see Step 2) and press the delete button.
15. OPERATING THE SITE~RITE® 8 ULTRASOUND SYSTEM

The basic steps for operating the system in a procedure are as follows:

1. Turn on the system (by pressing the power switch on the upper left side of the system).

2. Verify the battery change is sufficient for the procedure; otherwise, connect the power adapter to the Site~Rite® 8 Ultrasound System.

3. Enter patient information as needed.

4. Position the patient and perform ultrasound assessment.

5. Apply conductive gel and probe covers per the Site~Rite® Probe Cover Instructions for Use. Refer to all notes, cautions, and warnings at the end of this section. To drape the probe for sterile use, do the following:
   a. Place the probe in the holder
   b. Apply a layer of ultrasonic coupling gel on the acoustic window of the probe head
   c. Make sure that the prove cover is fully rolled up
   d. Place the probe cover over the probe head, being careful not to wipe off the coupling gel
   e. Cover the probe and cable with the probe cover
   f. Smooth the probe cover over the acoustic window of the probe head to remove any air bubbles or folds in the cover
   g. Use the latex-free poly-bands to hold the probe cover in place
   h. Apply a layer of sterile coupling gel to the covered acoustic window

6. Attach needle guide to the probe, if needed, as described in the Site~Rite® Needle Guide and Pinpoint™ GT Needle Guide Instructions for Use.

7. Adjust the image, as necessary.

8. Perform the procedure.

9. After use, the probe cover should be removed and disposed according to the facility protocol. For cleaning the system, refer to “Cleaning and Disinfecting the Equipment,” Section 17.

WARNING: When using Site~Rite® Needle Guides and Pinpoint™ GT Needle Guides, use the sterile legally marketed plastic probe cover in the kit with the needle guides. To ensure proper performance, follow the Site~Rite® Needle Guide and Pinpoint™ GT Needle Guide Instructions for Use.

CAUTION: When using the Site~Rite® Ultrasound System probe in a sterile environment, the probe and part of the probe cable must be covered with a sterile, acoustically transparent plastic probe cover.


CAUTION: Always snap the needle guides on the probe hook. Do not slide the needle guide on to the needle guide hook, as the sterile cover may tear.

15.1. **Access using the Cue™ Needle Tracking System (if enabled)**

1. Prepare the Site~Rite® Ultrasound System:
   a. Verify the battery charge is sufficient for the procedure; otherwise connect the power adapter to the Site~Rite® 8 Ultrasound System
   b. Enter the patient information as needed
2. Position the patient and perform the ultrasound assessment
3. Prepare the sterile field:
   a. Ensure all metallic objects are removed from the surrounding location (at least 4 inches away). If an object, such as a bed rail, cannot be moved, take precautions to make the object stationary during the procedure
   b. Ensure all magnetic objects (e.g., magnets, mobile phones, electric motors, etc.) are removed from the surrounding location (at least 3 feet away)
   c. Retrieve the Cue™ Needle Tracking System compatible device and place the tray completely onto the Activator. When ready, remove the tray from the Activator and drop the device into the sterile field (see Section 9.2).
   d. Drape the ultrasound probe for sterile use (refer to Probe Cover Instructions for Use)
   e. If applicable, anesthetize the insertion site (per institution protocol)
4. Prepare for insertion:
   a. Re-scan the anatomy of interest using the Site~Rite® 8 Ultrasound System
   b. Ensure the Performance Indicator indicates and adequate environment for needle tracking (see Section 9.3.2.)

**Caution:**
- Keep the needle and any ferromagnetic objects, e.g., wired undergarments, metal instruments, watches, jewelry, Activator, electronics, metal bed rails, etc., at least 3 feet away from the probe when calibrating. Failure to do so may impact the accuracy of needle tracking.
- Equipment operating in close proximity may emit strong electromagnetic or radio frequency interference which could affect the performance of this device. Avoid operating the device near pumps, cautery, diathermy equipment, cellular phones, or other portable and mobile radio frequency communications equipment. Maintain equipment separation of at least 3 feet.
- Excessive movement of the probe may result in a temporary loss of needle tracking.

5a. **Out-of-Plane Ultrasound Guided Insertion using the Cue™ Needle Tracking System:**
   a. Retrieve the activated needle and move it towards the probe hook at a 45° angle until it is within 0.5cm from the probe. Ensure the Cue™ Needle Tracking System virtual needle overlay appears on the display and follows needle movement

**Caution:**
- If needle tracking is not functioning properly, discontinue use of Cue™ Needle Tracking System.
   b. Position the needle by adjusting the insertion angle and distance from the probe to align the Intersection Window with the intended target structure. A steeper insertion angle may be necessary for deep structures while a shallow angle may be appropriate for superficial anatomy
   c. While maintaining the needle angle, insert the Cue™ Needle Tracking System compatible needle into the skin. Refer to the specific device’s Instruction for Use for more information
d. Proceed with insertion – watch needle advancement onscreen. The solid green lines represent the needle shaft and tip. The green square represents the area where the needle will intersect the ultrasound plane
e. During advancement, maintain the Intersection Window centered with the intended target structure
f. When the solid green lines reach the Intersection Window, it means the needle has intersected the plane of the ultrasound beam within the Intersection window. It does not mean insertion has been successful or the structure of insert has been reached.

g. When attempting vessel access, watch for:
   • Anterior vessel wall indenting (once the puncture occurs the vessel will return to normal shape)
   • Blood return in the device
   • Needle reflection of the needle tip) on the ultrasound image
h. Complete Procedure per suggested institutional guidelines

5b. In-Plane Ultrasound Guided Insertion Using the Cue™ Needle Tracking System
   a. Retrieve the activated needle and move it towards the side of the probe at a 45° angle until it is within 0.5cm from the probe. Ensure the Cue™ Needle Tracking System virtual needle overlay appears on the display and follows needle movement

   Caution: If needle tracking is not functioning properly, discontinue use of Cue™ Needle Tracking System.

   b. Position the needle by adjusting the insertion angle and distance from the probe to align the Cue™ Needle Tracking System Overlay with intended target structure

   Note: In-Plane Mode does not have an Intersection Window.
c. While maintaining the desired needle angle, insert the needle into the skin. Refer to the specific device’s Instruction for Use for more information.
d. Proceed with insertion – watch needle advancement onscreen. The solid green lines represent the needle shaft and tip.
e. During advancement, maintain the needle trajectory in the center of the intended target structure. Maintain the needle so that the virtual needle is centered in the Probe Face Overlay and the virtual needle is green.
f. When attempting vessel access, watch for the following:
   - Anterior vessel wall indenting (once the puncture occurs the vessel will return to normal shape)
   - Blood return in the device
   - Needle reflection (flash of the needle tip) on the ultrasound image

g. Complete procedure per suggested institutional guidelines

15.2. Access Using Pinpoint™ GT Needle Technology (if enabled)

1. Prepare the Site~Rite® 8 Ultrasound System.
   a. Verify the battery charge is sufficient for the procedure; otherwise, connect the power adapter to the Site~Rite® 8 Ultrasound System.
   b. Enter patient information as needed.

2. Position the patient and perform ultrasound assessment.

3. Prepare the sterile field:
   a. Ensure all metallic objects are removed from the surrounding location (at least 2 feet away). If an object, such as a bed rail, cannot be moved, take precautions to make the object stationary during the procedure.
   b. Retrieve and open the Pinpoint™ GT Safety Introducer Needle. Place contents in a location consistent with current introducer practice.
   c. Drape the ultrasound prove for sterile use (refer to Probe Cover Instructions for Use).
   d. If applicable, anesthetize the insertion site (per institution protocol).

4. Pinpoint™ GT Needle Technology Calibration:
   a. Using the Pinpoint™ GT Needle Technology Probe navigation controls select the GT button (refer to Section 10).

   Note: When the GT button is selected, the “CALIBRATION REQUIRED” message is displayed.

   b. Re-scan the anatomy of interest using the Site~Rite® 8 Ultrasound System.
   c. Verify that the calibrate button is highlighted (refer to Section 10.2).
   d. Place needle at least 2 feet away from probe.
   e. Hold the probe stationary and upright, press the ‘OK’ button on the probe to begin calibration. Calibration is only required prior to inserting the needle into the patient.

   Note: When the calibration cycle begins, the status banner will display “CALIBRATING…HOLD PROBE STILL”. Once the system is calibrated, the status banner will display “READY…LIMIT PROBE MOVEMENT”. Keep the needle 2 feet away from the probe until the calibration cycle is complete.

   Caution: Movement of the probe during calibration may result in calibration error.

   Caution: Keep the needle and any ferromagnetic objects, e.g., wired undergarments, metal instruments, watches, jewelry, electronics, metal bed rails, etc. at least 2 feet away from probe when calibrating. Failure to do so may impact the accuracy of needle tracking.

   Caution: Equipment operating in close proximity may emit strong electromagnetic or radio frequency interference which could affect the performance of this device. Avoid operating the device near pumps, cauterizers, diathermy equipment, cellular phones, or other portable and mobile radio frequency communications equipment. Maintain equipment separation of at least 5 feet (1.5m).

   Caution: Excessive movement of the probe after calibration may result in reduced needle tracking accuracy.

   a. When the system is calibrated, retrieve the Pinpoint™ GT Safety Introducer Needle and move the Needle toward the center of the probe at a 45° angle until the Pinpoint™ GT Needle Technology virtual needle image appears on the ultrasound display. Confirm the virtual needle image motion on the ultrasound display mirrors actual needle movement.

   Caution: If needle tracking is not functioning properly, discontinue use of Pinpoint™ GT Needle Technology.
b. Modify the angle of the needle (up or down) to place the Point of Intersection Circle in the center of the intended target structure. A steeper insertion angle may be necessary for deep structures while a shallow angle may be appropriate for superficial anatomy.

c. While maintaining the needle angle, insert the Pinpoint™ GT Safety Introducer Needle into the skin. Refer to the Pinpoint™ GT Safety Introducer Needle Instructions for Use for more information.

d. To maintain accuracy, use a ‘light touch,’ (defined as minimal stress, force, or pressure on the needle during insertion)

Note: Once the needle enters the skin, it may be helpful to release pressure on the needle hub to assess Pinpoint™ GT Needle Technology System alignment with the structure of interest.

Caution: During insertion, use a light touch to prevent needle deflection and/or bending. Needle deflection and/or needle bending may reduce needle tracking accuracy.

Caution: To ensure accuracy, do not apply force or pressure that may leverage the needle. This may result in needle deflection, bending or altering needle trajectory.

e. Without leveraging the needle, proceed with insertion – watch needle advancement onscreen. The yellow line represents the needle shaft and tip. The violet circle represents where the needle will intersect the ultrasound plane.

f. During advancement, maintain the Point of Intersection Circle in the center of the intended target structure.

g. Once the Pinpoint™ GT Safety Introducer Needle tip intersects the ultrasound beam, the Point of Intersection Circle will change from violet to green. When the Point of Intersection Circle changes to green, it means the introducer needle has intersected the plane of the ultrasound beam. It does NOT necessarily mean insertion has been successful or the structure of interest has been reached.

h. If the needle passes through the Point of Intersection Circle, the circle changes color from violet to green and the portion of the needle that lies beyond the Point of Intersection Circle changes color from yellow to violet.

Note: When the virtual needle image changes from yellow to violet, it does NOT necessarily mean that you have advanced your needle beyond the target structure, it means the needle is beyond the ultrasound plane.
i. When attempting vessel access, watch for the following:
   - Anterior vessel wall indenting (once the puncture occurs the vessel will return to normal shape)
   - Blood return in the device
   - Needle reflection (flash of the needle tip) on the ultrasound image

   **Note:** When the virtual needle tip passes the ultrasound plane the color of the virtual needle shaft will change but still represents the virtual needle tip position.

j. Complete procedure per suggested institutional guidelines

5b. **In-Plane Ultrasound Guided Insertion Using Pinpoint™ GT Needle Technology.**

   a. When the system is calibrated, retrieve the Pinpoint™ GT Safety Introducer Needle and move the Needle toward the side of the probe at a 45° angle until the Pinpoint™ GT Needle Technology virtual needle image appears on the ultrasound image (refer to figure at right). Confirm the virtual needle image motion on the ultrasound display mirrors actual needle movement

   **Caution:** If needle tracking is not functioning properly, discontinue use of Pinpoint™ GT Needle Technology.

   b. Center the virtual needle image in the In-Plane box may modifying the position and angle of the needle. Confirm needle alignment with the intended target structure.

   **Note:** In-Plane Mode does not have a Point of Intersection Circle. When the needle trajectory is centered in the In-Plane Box, the box will turn green.

   c. While maintaining the desired needle angle, insert the Pinpoint™ GT Safety Introducer Needle into the skin. Refer to Pinpoint™ GT Safety Introducer Needle IFU for more information

      - To maintain accuracy, use a ‘light touch,’ (which is defined as minimal stress, force, or pressure on the needle during insertion)

   **Note:** Once the needle enters the skin, it may be helpful to release pressure on the needle hub to assess Pinpoint™ GT Needle Technology System alignment with the structure of interest.

   **Caution:** During insertion, use a light touch to prevent needle deflection and/or bending. Needle deflection and/or needle bending may reduce needle tracking accuracy.

   **Caution:** To ensure accuracy, do not apply force or pressure that may leverage the needle. This may result in needle deflection, bending, or altering needle trajectory.

   d. Without leveraging the needle, proceed with insertion – watch needle advancement onscreen. The solid yellow line represents the needle shaft and tip.

   e. During advancement, maintain the needle trajectory in the center of the intended target structure. Maintain the needle so that the trajectory is centered in the In-Plane Box and the In-Plane Box is green.

   f. When attempting vessel access, watch for:

      - Anterior vessel wall indenting (once the puncture occurs the vessel will return to normal shape)
      - Blood return in the device
      - Needle reflection (flash of the needle tip) on the ultrasound image

   g. Complete procedure per suggested institutional guidelines
### 16. TROUBLESHOOTING

#### 16.1. Site~Rite® 8 Ultrasound System Troubleshooting

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<tr>
<th>SYMPTOM</th>
<th>DESCRIPTION</th>
<th>SOLUTIONS</th>
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</table>
Note: If error persists, call Customer Service at: 1-800-545-0890. An alternate number may be available in the System Information Tab (Section 11.5). |
| Error Code EC:204                | Probe Disconnect Error              | If applicable, ensure the probe is securely connected to the system. See Section 3.3.  
Note: If error persists, call Customer Service at: 1-800-545-0890. An alternate number may be available in the System Information Tab (Section 11.5). |
| Error Code EC:101                | System temperature too high         | Shut down the system and allow to cool.  
Note: If error persists, call Customer Service at: 1-800-545-0890. An alternate number may be available in the System Information Tab (Section 11.5). |
| System plays a sound every minute. | Low Battery                         | Connect system to power for continued operation and to recharge battery. |
| Error Code EC:110                | Battery Error                       | Connect AC adapter for operation. Ensure the battery switch is in the “✓” position (Section 4).  
Note: If error persists, call Customer Service at: 1-800-545-0890. An alternate number may be available in the System Information Tab (Section 11.5). |
| Power Problem                    | System will not turn on or turns on but immediately turns off | 1. Press and hold the power switch for at least 2 seconds to turn the system on.  
2. Connect the system to AC power for operation and to recharge the battery.  
Note: If error persists, call Customer Service at: 1-800-545-0890. An alternate number may be available in the System Information Tab (Section 11.5). |
| A/C adapter indicator does not change states when A/C power is connected | Connection Error                   | 1. Unplug the AC adapter and plug it back into the system.  
2. Restart the system if necessary.  
Note: If error persists, call Customer Service at: 1-800-545-0890. An alternate number may be available in the System Information Tab (Section 11.5). |
| System Does Not Charge           | Battery Charging Failure            | 1. Unplug the AC adapter and plug it back into the system.  
2. Charge the battery in temperatures exceeding 32°C, the system may need to be turned off.  
Note: If error persists, call Customer Service at: 1-800-545-0890. An alternate number may be available in the System Information Tab (see Section 11.5). |
| Error Code EC:102                | USB Storage Device Error            | The USB storage device may be full or may not be a compatible USB storage device. Replace the USB storage device.  
Note: If error persists, call Customer Service at: 1-800-545-0890. An alternate number may be available in the System Information Tab (see Section 11.5). |
| Error Code EC:103                | Hard Drive Error                    | Restart the system.  
Note: If error persists, call Customer Service at: 1-800-545-0890. An alternate number may be available in the System Information Tab (see Section 11.5). |
<table>
<thead>
<tr>
<th>SYMPTOM</th>
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| Error Code EC:104             | Printer Error              | 1. Verify that the printer is on.  
2. Verify that the printer has paper.  
3. Check the printer’s power cable and connection to the system.  
4. Refer to Printer Instructions for Use.  
**Note:** If error persists, call Customer Service at: 1-800-545-0890. An alternate number may be available in the System Information Tab (see Section 11.5). |
| Poor Image                    |                            | 1. Adjust the image settings.  
- Depth (Section 7.3.1)  
- Gain (Section 7.3.2)  
- Contrast (Section 11.1)  
- Image Filter (Section 11.1)  
2. Lack of couplant. Apply ultrasound gel.  
**Note:** If error persists, call Customer Service at: 1-800-545-0890. An alternate number may be available in the System Information Tab (Section 11.5). |
| System Becomes Unresponsive   |                            | Press and hold the power switch on the side of the device until the system shuts down (note: This will take approximately 10 seconds). Turn on the system.  
**Note:** If error persists, call Customer Service at: 1-800-545-0890. An alternate number may be available in the System Information Tab (Section 11.5). |
| Cannot Connect to Desired Network |                            | 1. Confirm that the DICOM features are activated on the system (see Section 11.3.1).  
2. Confirm WiFi is enabled or the Ethernet cable is connected to your device. The corresponding LED at the top of the device should be on (Section 3.4).  
3. If using WiFi, check the WiFi signal strength.  
4. Contact your network administrator (see Section 11.4.2).  
**Note:** If error persists, call Customer Service at: 1-800-545-0890. An alternate number may be available in the System Information Tab (Section 11.5). |
| Cannot Install Optional Features |                            | 1. The feature activation key is system specific. Ensure that the key you are using has the serial number of your system.  
**Note:** If error persists, call Customer Service at: 1-800-545-0890. An alternate number may be available in the System Information Tab (Section 11.5). |
| System Password is Lost        |                            | 1. Contact customer service and provide the System Data and Serial Number for a temporary password.  
**Note:** If error persists, call Customer Service at: 1-800-545-0890. An alternate number may be available in the System Information Tab (Section 11.5). |
| Error Code EC:105             | Deleting Error             | 1. Restart the system. Attempt to delete the file(s).  
**Note:** If error persists, call Customer Service at: 1-800-545-0890. An alternate number may be available in the System Information Tab (Section 11.5). |
| Error Code EC:106             | Network Error              | 1. Ensure the device is connected to the desired network via WiFi or Ethernet.  
2. If using a Static IP Address, verify the Static Network Settings.  
3. Contact your network administrator.  
**Note:** If error persists, call Customer Service at: 1-800-545-0890. An alternate number may be available in the System Information Tab (Section 11.5). |
| Error Code EC:107             | PACS Error                 | 1. Ensure you are connected to the desired network.  
2. Ensure that the system DICOM settings are compatible with the destination PACS system settings.  
3. Contact your network administrator.  
**Note:** If error persists, call Customer Service at: 1-800-545-0890. An alternate number may be available in the System Information Tab (Section 11.5). |
| Error Code EC:108             | PACS ECHO Error            | 1. Ensure you are connected to desired network.  
2. Ensure that the system DICOM settings are compatible with the destination PACS system settings.  
3. Contact your network administrator.  
**Note:** If error persists, call Customer Service at: 1-800-545-0890. An alternate number may be available in the System Information Tab (see Section 11.5). |
## Troubleshooting – Site~Rite® 8 Ultrasound System

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<tr>
<th>SYMPTOM</th>
<th>DESCRIPTION</th>
<th>SOLUTIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Error Code EC:111</td>
<td>System Error</td>
<td>1. Restart the system.&lt;br&gt;<strong>Note:</strong> If error persists, call Customer Service at 1-800-545-0890. An alternate number may be available in the System Information Tab (Section 11.5).</td>
</tr>
<tr>
<td>Error Code EC:113</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Error Code EC:199</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Error Code EC:112</td>
<td>File Reading Error</td>
<td>2. Failed to read configuration file. Some user settings may be lost.&lt;br&gt;<strong>Note:</strong> If error persists, call Customer Service at: 1-800-545-0890. An alternate number may be available in the System Information Tab (see Section 11.5).</td>
</tr>
<tr>
<td>Error in WiFi Networks List</td>
<td>WiFi Connection Error</td>
<td>1. Ensure the security key is correct.&lt;br&gt;2. Ensure WiFi configuration is correct.&lt;br&gt;3. Contact your network administrator.&lt;br&gt;<strong>Note:</strong> If error persists, call Customer Service at: 1-800-545-0890. An alternate number may be available in the System Information Tab (see Section 11.5).</td>
</tr>
<tr>
<td>Screen not oriented properly or cut off when HDMI cable is plugged in</td>
<td></td>
<td>1. Plug the USB keyboard.&lt;br&gt;2. With the system in the main ultrasound screen, press “ctrl+shift+right arrow”. The screen should rotate.&lt;br&gt;3. Press “ctrl+shift+q” to restart the application.&lt;br&gt;This must be repeated every power cycle.</td>
</tr>
<tr>
<td>Patient/Clinician Backup Error</td>
<td></td>
<td>1. System is approaching file capacity limit. Backup cannot be performed. Consider removing patient data or backups in order to free up space.</td>
</tr>
</tbody>
</table>

**Note:** This device is equipped with a lithium ion battery. Lithium ion battery performance is known to degrade over time based on environmental and use conditions. These messages are intended to help manage the life of the battery.

| Pre-Critical Warning | This window appears when the battery is approaching the end of its useful life. It is recommended that the battery be replaced. |
| Critical Warning | This window appears when the battery’s integrity has reached a critical stage, indicating the system detected the battery has reached the end of its useful life and that without AC power, the system is likely to shut down. The message will only disappear at startup when the system is connected to AC power. |
### 16.2. **Cue™ Needle Tracking System Troubleshooting (if enabled)**

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<tr>
<th>SYMPTOM</th>
<th>DESCRIPTION</th>
<th>SOLUTIONS</th>
</tr>
</thead>
</table>
| Error Code EC:501 | Cue™ Needle Tacking System Sensor Disconnect Error | 1. Ensure the Cue™ Needle Tacking System Probe is securely connected to the system.  
2. Restart the system.  
*Note:* If error persists, call Customer Service at: 1-800-545-0890. An alternate number may be available in the System Information Tab (see Section 11.5). |
| Error Code EC:502 | Calibration Error | 1. Restart the system.  
2. Ensure the probe is held in the air during calibration (see Section 11.2.1).  
*Note:* If error persists, call Customer Service at: 1-800-545-0890. An alternate number may be available in the System Information Tab (see Section 11.5). |
| Error Code EC:503-508 | Cue™ Needle Tacking System Error | Restart the system.  
*Note:* If error persists, call Customer Service at: 1-800-545-0890. An alternate number may be available in the System Information Tab (see Section 11.5). |
| **Likely Cause:** The Activator is not plugged in | |  
1. Check connection at both ends of the cable into the Activator and the console.  
2. Verify the Activator icon is illuminated.  
3. Re-activate the needle. |
| **Likely Cause:** The needle tray is incorrectly placed on the Activator | | Review the Activation section (see Section 9.2). |
| **Likely Cause:** The system is in freeze mode | | Select the freeze button to exit freeze mode. |
| **Likely Cause:** The needle was introduced or re-introduced too quickly | | If tracking signal drops during needle approach, remove the needle at least two feet (61cm) away from the probe for at least three seconds. Allow the Performance Indicator to stabilize and slowly re-approach the probe. |
| **Likely Cause:** Magnetic Field Interference | | If the Performance Indicator is low, perform the following steps:  
1. Hold the probe still.  
2. If the Performance Indicator decreases during needle approach, withdraw the needle and slowly re-approach.  
3. Remove metal, magnetic, and electronic objects in close proximity to the probe (bed rails, jewelry, mobile phone, pumps, bed/table frames, Cue™ Activator, etc.).  
4. If problem persists, hold the probe stationary in the air away from all metal, magnetic, and electronic devices.  
If the Performance Indicator improves, review previous troubleshooting tips. If the performance Indicator remains low, calibration may be required. This should be uncommon (see Section 11.2.1). |
| **Likely Cause:** Probe needs to be calibrated | | If problem persists, hold the probe stationary in the air away from all metal, magnetic, and electronic devices.  
If the Performance Indicator improves, review previous troubleshooting tips. If the Performance Indicator remains low, calibration may be required. This should be uncommon (see Section 11.2.1).  
*Note:* If error persists, call Customer Service at: 1-800-545-0890. An alternate number may be available in the System Information Tab (see Section 11.5). |
<table>
<thead>
<tr>
<th>Issue</th>
<th>Likely Cause</th>
<th>Steps</th>
</tr>
</thead>
</table>
| Needle tracking virtual needle image has erratic behavior             | **Likely Cause:** Magnetic Field Interference | 1. Hold the probe still.  
2. If the Performance Indicator decreases during needle approach, withdraw the needle and slowly re-approach.  
3. Remove metal, magnetic, and electronic objects in close proximity to the probe (bed rails, jewelry, mobile phone, pumps, bed/table frames, Cue™ Activator, etc.).  
4. If problem persists, hold the probe stationary in the air away from all metal, magnetic, and electronic devices.  
If the Performance Indicator improves, review previous troubleshooting tips.  
If the performance Indicator remains low, calibration may be required. This should be uncommon (see Section 11.2.1).  
**Note:** If error persists, call Customer Service at: 1-800-545-0890. An alternate number may be available in the System Information Tab (see Section 11.5). |
| Difficulty aligning and maintaining the Intersection Window on the target structure | **Likely cause:** Excessive movement of probe and/or needle | 1. Anchor the probe in a stationary and upright position.  
2. Stabilize the hand holding the needle.  
Only modify the position of the needle to change the location of the Intersection Window. |
| Drop out – the needle overlay disappears during insertion             | **Likely cause:** Needle detection reset is required | 1. If prior to insertion, withdraw the needle and slowly re-approach.  
2. If after needle insertion, withdraw the probe away from the needle and slowly re-approach.  
3. If problem persists, activate a new needle. |

<table>
<thead>
<tr>
<th>Issue</th>
<th>Likely cause</th>
<th>Steps</th>
</tr>
</thead>
</table>
| Drop out – the needle overlay disappears during insertion             | **Likely cause:** Performance Indicator too low | 1. Hold the probe still  
2. If the Performance Indicator decreases during needle approach, withdraw the needle and slowly re-approach.  
3. Remove metal, magnetic, and electronic objects in close proximity to the probe (bed rails, jewelry, mobile phone, pumps, bed/table frames, Cue™ Activator, etc.).  
4. If problem persists, hold the probe stationary in the air away from all metal, magnetic, and electronic devices.  
If the Performance Indicator improves, review previous troubleshooting tips.  
If the performance Indicator remains low, calibration may be required. This should be uncommon (see Section 11.2.1).  
**Note:** If error persists, call Customer Service at: 1-800-545-0890. An alternate number may be available in the System Information Tab (see Section 11.5). |
16.2.1. Cue™ Needle Tracking System Troubleshooting

To test the functionality of the Cue™ Needle Tracking System, perform the following steps:

1. Move all metal objects (including the needle) at least 4 inches away from the Cue™ Needle Tracking System Probe.
2. Move all active electronic devices and magnetic articles at least 3 feet away.
3. Obtain a small container of water.
4. Immerse the end of the probe into the container of water.
5. Check the Performance Indicator bars. Verify there are three or more bars. If there are less than three bars, perform calibration.
6. Introduce the needle to the probe slowly to observe the overlay. Place the Intersection Window at 1 cm depth below the ultrasound beam.
7. Advance the needle to the Intersection Window until there is a strong needle flash in the Intersection Window.
8. Observe the location of the needle flash and the needle advancement lines, making sure they contact the Intersection Window and the needle flash appears in the Intersection Window.

16.3. Pinpoint™ GT Needle Technology Troubleshooting (if enabled)

| Troubleshooting - Pinpoint™ GT Needle Technology (if enabled) |
|-----------------------------------------------|-------------------------------------|------------------|
| SYMPTOM                                      | DESCRIPTION                        | SOLUTIONS        |
| Error Code EC: 401-402                       | Likely cause: Interference caused by magnetic field due to: |
|                                              | 1. Probe movement during calibration. |
|                                              | 2. Probe movement post calibration. |
|                                              | 3. The Pinpoint™ GT Safety Introducer Needle is not at least 2 feet (61 cm) away from the probe when calibration is initiated. |
|                                              | 4. Moving the Pinpoint™ GT Safety Introducer Needle close to the probe during calibration. |
|                                              | 5. Interference by proximate electro-mechanical devices. |
|                                              | 6. Interference by proximate ferrous articles. |
|                                              | 7. Interference by proximate magnetic articles. |
|                                              | 1. Move all metal objects including the needle at least 2 feet (61 cm) away from the Pinpoint™ GT Needle Technology Probe. |
|                                              | 2. Lower bed rails. |
|                                              | 3. Move all active electronic devices at least 5 feet (1.5 m) away. |
|                                              | 4. Do not move the Pinpoint™ GT Needle Technology Probe and ask the patient to remain still. |
|                                              | 5. Re-calibrate. |
|                                              | **Note:** If error persists, call Customer Service at: 1-800-545-0890. An alternate number may be available in the System Information Tab (see Section 11.5). |

|                                              | 1. Turn off and restart the system |
|                                              | **Note:** If error persists, call Customer Service at: 1-800-545-0890. An alternate number may be available in the System Information Tab (see Section 11.5). |
### Troubleshooting - Pinpoint™ GT Needle Technology (if enabled)

<table>
<thead>
<tr>
<th>SYMPTOM</th>
<th>DESCRIPTION</th>
<th>SOLUTIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pinpoint™ GT Needle Technology Probe does not detect Pinpoint™ GT Safety Introduction Needle.</td>
<td>Likely cause: The system is in freeze mode.</td>
<td>1. Select the freeze button to exit freeze mode.</td>
</tr>
</tbody>
</table>
|                                                                         | Likely cause: Magnetic fields have changed since calibration.                | 1. Move all metal objects including the needle at least 2 feet (61cm) away from the Pinpoint™ GT Needle Technology Probe.  
2. Lower bed rails.                                                     | 3. Move all active electronic devices at least 5 feet (1.5m) away.  
4. Do not move the Pinpoint™ GT Needle Technology Probe and ask the patient to remain still.  
5. Re-calibrate.                                                         |
|                                                                         | **Note**: If error persists, call Customer Service at: 1-800-545-0890. An alternate number may be available in the System Information Tab (see Section 11.5). |                                                                                                |
| Needle tracking virtual needle image has erratic behavior.              | Likely causes: Magnetic interference OR Magnetic fields have changed since calibration. | 1. Move all metal objects including the needle at least 2 feet (61cm) away from the Pinpoint™ GT Needle Technology Probe.  
2. Lower bed rails.                                                     | 3. Move all active electronic devices at least 5 feet (1.5m) away.  
4. Do not move the Pinpoint™ GT Needle Technology Probe and ask the patient to remain still.  
5. Re-calibrate.                                                         |
|                                                                         | **Note**: If error persists, call Customer Service at: 1-800-545-0890. An alternate number may be available in the System Information Tab (see Section 11.5). |                                                                                                |
| Difficulty aligning and maintaining the Point of Intersection Circle in the vein | Likely cause: Excessive movement of probe and/or needle.                     | 1. Anchor the probe in a stationary and upright position.                                     |
|                                                                         | Likely cause: Leveraging/Bending of the needle.                             | 2. Only modify the position of the needle to change the location of the point of insertion circle. |
|                                                                         | **Note**: If error persists, call Customer Service at: 1-800-545-0890. An alternate number may be available in the System Information Tab (see Section 11.5). |                                                                                                |

### 16.3.1. Pinpoint™ GT Needle Technology Troubleshooting Steps

To test the functionality of the Pinpoint™ GT Needle Technology System, perform the following steps:

1. Attach a Site~Rite® Needle Guide onto the probe.
2. Move all metal objects (including the needle) at least 2 feet (61cm) away from the Pinpoint™ GT Needle Technology Probe.
3. Move all active electronic devices and magnetic articles at least 5 feet (1.5m) away.
4. Obtain a small container of water.
5. Immerse the end of the probe into the container of water.
6. Calibrate.
7. Insert needle into needle guide. Advance the needle to the end of the needle guide and release the needle. Observe the location of the Point of Intersection Circle and verify that the violet circle is located at the depth of the chosen needle guide.
8. Advance the needle halfway to the needle guide depth and release the needle. Observe the location of the Point of Intersection Circle and verify that the circle is located at the depth of the chosen needle guide. Observe the virtual needle image – it should be approximately halfway to the needle guide depth.
9. Advance the needle until the needle visualization appears on the ultrasound image.
10. Compare the location of the needle visualization to the Point of Intersection Circle. The Point of Intersection Circle should remain at the needle guide depth and should be green. The needle visualization should appear at the needle guide depth.
17. **CLEAN AND DISINFECTING THE EQUIPMENT**

17.1. **Cleaning and Intermediate Disinfection Procedure using PDI® Super Sani-Cloths®**

Step 1: Use one or more new towelettes to remove visible soil.

Step 2: Use two or more new towelettes to clean surfaces for at least two minutes.

Step 3 (Probe Only): Repeat Step 2 using two new towelettes for an additional two minutes.

**Note:** This procedure achieves Intermediate Disinfection per the FDA guidance “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling,” only when the probe is wet for a total of four minutes and when all other surfaces are wet for a total of two minutes.

**Note:** Please follow PDA® Super Sani-Cloths® instructions for use including wet time, dry time, and the use of personal protective equipment.

**Note:** If only cleaning is required, follow Steps 1 and 2.

17.2. **Additional Cleaning and Compatible Chemical Information**

For a list of additional disinfectants that are chemically compatible with the Site~Rite® 8 Ultrasound System and probe, contact Bard Access Systems for the “Site~Rite® 8 Ultrasound System Compatible Solutions” document or call Customer Service at: 1-800-545-0890.

**Caution:** Do not allow liquid to enter the system, AC adapter, connectors, or ports; damage to the equipment may occur.

**Caution:** Do not attempt to sterilize the Site~Rite® 8 Ultrasound System or probe; damage to the equipment may occur as a result.

**Caution:** Use only Bard Access System cleaning and disinfection procedures. Failure to do so may damage the device.

**Caution:** Use only approved or recommended cleaners or disinfectants to avoid damaging the equipment.

**Note:** Do not spray cleaners directly onto the Site~Rite® 8 Ultrasound System display.

**Note:** If disinfecting the probe with a liquid disinfectant, do not soak the probe, cable, cable bend relief, or probe buttons.

<table>
<thead>
<tr>
<th>Linear 32mm Probe</th>
<th>Linear 20mm Cue™ Needle Tracking System Probe</th>
<th>Linear 20mm Pinpoint™ GT Needle Technology Probe</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Image](Linear 32mm Probe)</td>
<td>![Image](Linear 20mm Cue™ Needle Tracking System Probe)</td>
<td>![Image](Linear 20mm Pinpoint™ GT Needle Technology Probe)</td>
</tr>
</tbody>
</table>
18. WARRANTY

Bard Access Systems Inc. warrants to the original purchaser that this product will be free from defects in material and workmanship for a period of one (1) year from the date of purchase. If this product proves to be so defective, purchaser may return same to Bard Access Systems Inc. for repair, replacement, refund, or credit at Bard Access Systems Inc.’s option. All returns must be authorized in advance in accordance with Bard Access Systems Inc.’s Returned Goods Policy found in its then current Price List. The warranty on the repaired or replaced unit continues from the purchase date of the original unit. The liability of Bard Access Systems Inc. under this limited warranty does not extend to any abuse, misuse, modification, improper storage, alteration, further manufacture, packaging or processing of this product or repair by anyone other than a Bard Access Systems Inc. representative.

The following will also void this limited warranty:

- Opening or servicing any component of the Site~Rite® 8 Ultrasound System by anyone other than Bard Access Systems authorized service personnel.
- Removing system labels by anyone other than service personnel authorized by Bard Access Systems.
- Connecting the Site~Rite® 8 Ultrasound System display to any AC adapter other than the system adapter.
- Connecting the Site~Rite® 8 Ultrasound System to any unauthorized accessory. Refer to the list of authorized accessories in the “Overview” section.
- Installing unauthorized software.
- Modification of system software without authorization by Bard Access Systems.

THIS LIMITED PRODUCT WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, (INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). THE LIABILITY AND REMEDY STATED IN THIS LIMITED PRODUCT WARRANTY WILL BE THE SOLE LIABILITY OF BARD ACCESS SYSTEMS INC. AND REMEDY AVAILABLE TO PURCHASER FOR THIS PRODUCT, WHETHER IN CONTRACT, TORT (INCLUDING NEGLIGENCE) OR OTHERWISE, AND BARD ACCESS SYSTEMS INC. WILL NOT BE LIABLE TO PURCHASERS FOR ANY INDIRECT, SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES ARISING OUT OF ITS HANDLING OR USE.

Some states/countries do not allow an exclusion of implied warranties, incidental or consequential damages. You may be entitled to additional remedies under the laws of your state/country.

19. SERVICE AND REPAIR

The Site~Rite® 8 Ultrasound System does not require any scheduled maintenance, system checks, or calibration. For servicing information or to return your Site~Rite® 8 Ultrasound System for repair, please contact Bard Access Systems technical/clinical support at: 1-800-443-3385.

20. UPGRADING

Contact your local Bard Access Systems representative for a USB drive with the latest version of Bard Access Systems applications. For U.S. customers only, available upgrades may also be obtained by visiting: www.bardaccess.com/products/ultrasound.

To upgrade a Site~Rite® 8 Ultrasound System, do the following:

1. Insert USB drive into one of the USB ports on the Site~Rite® 8 Ultrasound System.
2. Answer yes when prompted to proceed with the upgrade.
3. **Do not attempt to cancel the upgrade procedure or remove the USB drive, as this may cause applications to malfunction.** Follow the onscreen prompts to complete the software upgrade. If an error occurs during upgrading procedure, reboot the system and repeat the upgrade procedure again. If the error persists, contact the Bard Access Systems technical/clinical support at: 1-800-443-3385.
4. Restart the system.
5. Confirm desired software version is displayed in the system information (see Section 11.5). Now it is safe to remove the USB drive.

21. DISPOSAL INFORMATION

To return the Site~Rite® 8 Ultrasound System for end-of-life recycling, please contact your nearest Bard sales or distribution office in the country of purchase.

Caution: The Site~Rite® 8 Ultrasound System contains an internal battery. Dispose of dead battery packs in accordance with local regulations; improper disposal may present an environmental hazard.
### 22. ACOUSTIC INFORMATION

#### 22.1. Acoustic Output Summary Table

<table>
<thead>
<tr>
<th>Description of Probe</th>
<th>Operating Mode</th>
<th>$I_{pta.X}$ (X denotes statistically determined maximum)</th>
<th>FDA $I_{pta.X}$ Published Values</th>
<th>$M/I X$ (X denotes statistically determined maximum)</th>
<th>FDA $M/I$ Published Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Linear 32mm Probe</td>
<td>B</td>
<td>10.1 mW/cm²</td>
<td>Peripheral Vessel: &lt; 720 mW/cm²</td>
<td>0.649</td>
<td>Peripheral Vessel: &lt; 1.9</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Cardiac: &lt; 430 mW/cm²</td>
<td></td>
<td>Cardiac: &lt; 1.9</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Fetal Imaging &amp; Other**: &lt; 94 mW/cm²</td>
<td></td>
<td>Fetal Imaging &amp; Other**: &lt; 1.9</td>
</tr>
<tr>
<td>20mm Linear Cue™ Needle Tracking System Probe</td>
<td>B</td>
<td>11.1 mW/cm²</td>
<td>Peripheral Vessel: &lt; 720 mW/cm²</td>
<td>0.58</td>
<td>Peripheral Vessel: &lt; 1.9</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Cardiac: &lt; 430 mW/cm²</td>
<td></td>
<td>Cardiac: &lt; 1.9</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Fetal Imaging &amp; Other**: &lt; 94 mW/cm²</td>
<td></td>
<td>Fetal Imaging &amp; Other**: &lt; 1.9</td>
</tr>
<tr>
<td>Pinpoint™ GT 20mm Linear Probe</td>
<td>B</td>
<td>22.0 mW/cm²</td>
<td>Peripheral Vessel: &lt; 720 mW/cm²</td>
<td>0.871</td>
<td>Peripheral Vessel: &lt; 1.9</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Cardiac: &lt; 430 mW/cm²</td>
<td></td>
<td>Cardiac: &lt; 1.9</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Fetal Imaging &amp; Other**: &lt; 94 mW/cm²</td>
<td></td>
<td>Fetal Imaging &amp; Other**: &lt; 1.9</td>
</tr>
</tbody>
</table>

** Abdominal, Intraoperative, Pediatric, Small Organ (breast, thyroid, testes, etc.), Neonate Cephalic, Adult Cephalic.
### 22.2. Acoustic Output Reporting Table – Linear Probe 32mm

**Transducer Model:** Linear Probe 32mm  
**Operating Mode:** B-Mode

<table>
<thead>
<tr>
<th>Index Label</th>
<th>MI</th>
<th>TIS</th>
<th>TIB</th>
<th>TIC</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Scan</td>
<td>Non-scan</td>
<td>$A_{apart\leq1cm^2}$</td>
</tr>
<tr>
<td>Maximum index value</td>
<td>0.543</td>
<td>0.0418</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

**Associated acoustic parameter**

<p>| | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>$p_{3.3}$ (MPa)</td>
<td>1.40</td>
<td></td>
<td></td>
</tr>
<tr>
<td>$W_0$ (mW)</td>
<td>3.22</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>min of $[W_0(z_1), I_{2a,3}(z_1)]$ (mW)</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>$Z_1$ (cm)</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>$Z_{ap}$ (cm)</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>$d_{eq}(Z_{ap})$ (cm)</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>$f_c$ (MHz)</td>
<td>6.69</td>
<td>6.69</td>
<td>-</td>
</tr>
<tr>
<td>Dim of $A_{apart}$</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>X (cm)</td>
<td>0.70</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Y (cm)</td>
<td>0.400</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

**Other Information**

<p>| | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>PD (µsec)</td>
<td>0.185</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PRF (Hz)</td>
<td>7420</td>
<td></td>
<td></td>
</tr>
<tr>
<td>$p_{3.3}$ at PII max (MPa)</td>
<td>1.92</td>
<td></td>
<td></td>
</tr>
<tr>
<td>$d_{eq}$ at PII max (cm)</td>
<td>-</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Focal Length</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>$F_{L_x}$ (cm)</td>
<td>0.0683</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>$F_{L_y}$ (cm)</td>
<td>0.134</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>$I_{pa,3}$ at max. MI (W/m²)</td>
<td>110</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Operating Control Conditions**

- 116 Hz scan rate
- 3.2cm scan length
- 64 lines per scan
- Focal depth 14mm
- Frequency 7.5 MHz

**Note 1:** Information need not be provided for any formulation of TIS not yielding the maximum value of TIS for that mode.

**Note 2:** Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

**Note 3:** Information on MI and TI need not be provided if the equipment meets both the exemption clauses given in 51.2 aa) and 51.2 dd).

**Note 4:** Intended use does not include cephalic so TIC is not computed.

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>(a)</td>
<td>No data reported.</td>
</tr>
</tbody>
</table>

**Note 4:** The thermal indices and the mechanical index are below 1.0 for all device settings.
### 22.3. Acoustic Output Reporting Table – Linear 20mm Cue™ Needle Tracking System Probe

**Transducer Model:** Linear 20mm Cue™ Needle Tracking System Probe  
**Operating Mode:** B-Mode

<table>
<thead>
<tr>
<th>Index Label</th>
<th>MI</th>
<th>TIS Scan</th>
<th>TIS Non-scan</th>
<th>TIB Scan</th>
<th>TIB Non-scan</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>A_{aprt}≤1cm²</td>
<td>A_{aprt}&gt;1cm²</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maximum index value</td>
<td>0.517</td>
<td>0.134</td>
<td>-</td>
<td>-</td>
<td>- (a)</td>
</tr>
<tr>
<td>Associated acoustic parameter</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>( \mu_r ) (MPa)</td>
<td>1.40</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>( W_0 ) (mW)</td>
<td>3.95</td>
<td>-</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>min of ( W_{0,3}(z_1), I_{pa,3}(z_1) ) (mW)</td>
<td>1.40</td>
<td>-</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>( z_1 ) (cm)</td>
<td>-</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>( z_{bp} ) (cm)</td>
<td>-</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>( f_c ) (MHz)</td>
<td>7.34</td>
<td>7.12</td>
<td>-</td>
<td>-</td>
<td>- (a)</td>
</tr>
<tr>
<td>Dim of A_{aprt}</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(a)</td>
</tr>
<tr>
<td>( X ) (cm)</td>
<td>0.80</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>- (a)</td>
</tr>
<tr>
<td>( Y ) (cm)</td>
<td>0.40</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>- (a)</td>
</tr>
<tr>
<td>Other Information</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PD (usec)</td>
<td>0.134</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PRF (Hz)</td>
<td>7420</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>( \mu_r ) at PII_{max} (MPa)</td>
<td>2.00</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>( d_{eq} ) at PII_{max} (cm)</td>
<td>-</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Focal Length</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>( FL_x ) (cm)</td>
<td>0.107</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>( FL_y ) (cm)</td>
<td>0.138</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>( I_{pa,3} ) at max. MI (W/cm²)</td>
<td>153</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Operating Control Conditions**
- 116 Hz scan rate
- 1.92cm scan length
- 64 lines per scan
- Focal depth 20mm
- Frequency 7.5 MHz, 10 MHz

**Note 1:** Information need not be provided for any formulation of TIS not yielding the maximum value of TIS for that mode.

**Note 2:** Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

**Note 3:** Information on MI and TI need not be provided if the equipment is not capable of exceeding a TI or MI of 1.0.

(a) Intended use does not include cephalic so TIC is not computed

# No data reported.
### 22.4. Acoustic Output Reporting Table – Linear 20mm Pinpoint™ GT Needle Technology Probe

**Transducer Model:** Linear 20mm Pinpoint™ GT Needle Technology Probe  
**Operating Mode:** B-Mode

<table>
<thead>
<tr>
<th>Index Label</th>
<th>MI</th>
<th>TIS Scan</th>
<th>TIB Non-scan</th>
<th>TIC</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Scan</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Non-scan</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>A&lt;sub&gt;apr&lt;/sub&gt;≤1cm&lt;sup&gt;2&lt;/sup&gt;</td>
<td>A&lt;sub&gt;apr&lt;/sub&gt;&gt;1cm&lt;sup&gt;2&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td>Maximum index value</td>
<td></td>
<td>0.690</td>
<td>0.113</td>
<td>-</td>
</tr>
</tbody>
</table>

**Associated acoustic parameter**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Unit</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>p&lt;sub&gt;r.3&lt;/sub&gt;</td>
<td>MPa</td>
<td>1.82</td>
</tr>
<tr>
<td>W&lt;sub&gt;0&lt;/sub&gt;</td>
<td>mW</td>
<td>4.86</td>
</tr>
<tr>
<td>min of [W&lt;sub&gt;3&lt;/sub&gt;(z&lt;sub&gt;1&lt;/sub&gt;), I&lt;sub&gt;TA,3&lt;/sub&gt;(z&lt;sub&gt;1&lt;/sub&gt;)]</td>
<td>mW</td>
<td>-</td>
</tr>
<tr>
<td>Z&lt;sub&gt;1&lt;/sub&gt;</td>
<td>cm</td>
<td>-</td>
</tr>
<tr>
<td>Z&lt;sub&gt;bp&lt;/sub&gt;</td>
<td>cm</td>
<td>-</td>
</tr>
<tr>
<td>Z&lt;sub&gt;sp&lt;/sub&gt;</td>
<td>cm</td>
<td>-</td>
</tr>
<tr>
<td>d&lt;sub&gt;0&lt;/sub&gt;(z&lt;sub&gt;0&lt;/sub&gt;)</td>
<td>cm</td>
<td>-</td>
</tr>
<tr>
<td>f&lt;sub&gt;c&lt;/sub&gt;</td>
<td>MHz</td>
<td>6.96</td>
</tr>
<tr>
<td>Dim of A&lt;sub&gt;aprt&lt;/sub&gt;</td>
<td>X (cm)</td>
<td>0.48</td>
</tr>
<tr>
<td></td>
<td>Y (cm)</td>
<td>0.400</td>
</tr>
</tbody>
</table>

**Other Information**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Unit</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>PD</td>
<td>µsec</td>
<td>0.184</td>
</tr>
<tr>
<td>PRF</td>
<td>Hz</td>
<td>7420</td>
</tr>
<tr>
<td>p&lt;sub&gt;r&lt;/sub&gt; at PII&lt;sub&gt;max&lt;/sub&gt;</td>
<td>MPa</td>
<td>2.45</td>
</tr>
<tr>
<td>d&lt;sub&gt;eq&lt;/sub&gt; at PII&lt;sub&gt;max&lt;/sub&gt;</td>
<td>cm</td>
<td>-</td>
</tr>
<tr>
<td>Focal Length</td>
<td>FL&lt;sub&gt;x&lt;/sub&gt; (cm)</td>
<td>0.0853</td>
</tr>
<tr>
<td></td>
<td>FL&lt;sub&gt;y&lt;/sub&gt; (cm)</td>
<td>0.113</td>
</tr>
<tr>
<td>I&lt;sub&gt;pA.3&lt;/sub&gt; at max. MI</td>
<td>(W/cm²)</td>
<td>179</td>
</tr>
</tbody>
</table>

**Operating Control Conditions**

116 Hz scan rate  
1.92 cm scan length  
64 lines per scan  
Focal depth 15 mm  
Frequency 7.5 MHz

**Note 1:** Information need not be provided for any formulation of TIS not yielding the maximum value of TIS for that mode.

**Note 2:** Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

**Note 3:** Information on MI and TI need not be provided if the equipment meets both the exemption clauses given in 51.2 aa) and 51.2 dd).

(a) Intended use does not include cephalic so TIC is not computed

# No data reported.
23. EMC TABLES

Warning: The use of accessories other than those specified in the “Overview” section may result in increased emissions or decreased immunity of the Site–Rite® 8 Ultrasound System.

Site–Rite® 8 Ultrasound System EMC Tables

<table>
<thead>
<tr>
<th>Guidance and Manufacturer’s Declaration - Emissions</th>
<th>Electromagnetic Environment – Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Site–Rite® 8 Ultrasound System is intended for use in the electromagnetic environment specified below. The customer or user of the Site–Rite® 8 Ultrasound System should ensure that it is used in such an environment.</td>
<td>The Site–Rite® 8 Ultrasound System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Emissions Test</th>
<th>Compliance</th>
<th>Electromagnetic Environment – Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF Emissions</td>
<td>Group 1</td>
<td>The Site–Rite® 8 Ultrasound System is suitable for use in all establishments, other than domestic, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td>
</tr>
<tr>
<td>CISPR 11 / EN55011</td>
<td>Class A</td>
<td></td>
</tr>
<tr>
<td>Harmonics</td>
<td>Class A</td>
<td></td>
</tr>
<tr>
<td>IEC 61000-3-2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flicker</td>
<td>Complies</td>
<td></td>
</tr>
<tr>
<td>IEC 61000-3-3</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Guidance and Manufacturer’s Declaration – Immunity</th>
<th>Electromagnetic Environment – Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Site–Rite® 8 Ultrasound System is intended for use in the electromagnetic environment specified below. The customer or user of the Site–Rite® 8 Ultrasound System should ensure that it is used in such an environment.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>EN/IEC 60601 Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment – Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>ESD</td>
<td>±6kV Contact</td>
<td>±6kV Contact</td>
<td>Floors should be wood, concrete or ceramic tile. If floors are synthetic, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td>EN/IEC 61000-4-2</td>
<td>±8kV Air</td>
<td>±8kV Air</td>
<td></td>
</tr>
<tr>
<td>EFT</td>
<td>±2kV Mains</td>
<td>±2kV Mains</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>EN/IEC 61000-4-4</td>
<td>±1kV Input/Output Lines</td>
<td>±1kV Input/Output Lines</td>
<td></td>
</tr>
<tr>
<td>Surge</td>
<td>±1kV Differential</td>
<td>±1kV Differential</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>EN/IEC 61000-4-5</td>
<td>±2kV Common</td>
<td>±2kV Common</td>
<td></td>
</tr>
<tr>
<td>Voltage Dips/Dropout</td>
<td>&gt;95% Dip for 0.5 Cycle</td>
<td>&gt;95% Dip for 0.5 Cycle</td>
<td>Mains power quality should be that of a typical commercial or hospital environment. If the user of the Site–Rite® 8 Ultrasound System requires continued operation during power mains interruptions, it is recommended that the Site–Rite® 8 Ultrasound System be powered from an uninterruptible power supply or battery.</td>
</tr>
<tr>
<td>EN/IEC 61000-4-11</td>
<td>60% Dip for 5 Cycles</td>
<td>60% Dip for 5 Cycles</td>
<td></td>
</tr>
<tr>
<td></td>
<td>30% Dip for 25 Cycles</td>
<td>30% Dip for 25 Cycles</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&gt;95% Dip for 5 Seconds</td>
<td>&gt;95% Dip for 5 Seconds</td>
<td></td>
</tr>
<tr>
<td>Power Frequency</td>
<td>3 A/m</td>
<td>3 A/m</td>
<td>Power frequency magnetic fields should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>50/60 Hz Magnetic Field</td>
<td>EN/IEC 61000-4-8</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Guidance and Manufacturer’s Declaration – Emissions

The Site~Rite® 8 Ultrasound System is intended for use in the electromagnetic environment specified below. The customer or user of the Site~Rite® 8 Ultrasound System should ensure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>EN/IEC 60601 Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment – Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conducted RF</td>
<td>EN/IEC 61000-4-6</td>
<td>3 Vrms 150 kHz to 80 MHz</td>
<td>Portable and mobile communications equipment should be separated from the Site~Rite® 8 Ultrasound System by no less than the distances calculated/listed below:</td>
</tr>
<tr>
<td>Radiated RF</td>
<td>EN/IEC 61000-4-3</td>
<td>3 V/m 80 MHz to 2.5 GHz</td>
<td>D = 1.2 (√ P) 80 MHz to 2.5 GHz</td>
</tr>
</tbody>
</table>

Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels.

Interference may occur in the vicinity of equipment containing a transmitter.

### Recommended Separation Distances between portable and mobile RF Communications equipment and the Site~Rite® 8 Ultrasound System

The Site~Rite® 8 Ultrasound System is intended for use in the electromagnetic environment in which radiated disturbances are controlled. The customer or user of the Site~Rite® 8 Ultrasound System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment and the Site~Rite® 8 Ultrasound System as recommended below, according to the maximum output power of the communications equipment.

<table>
<thead>
<tr>
<th>Max Output Power (Watts)</th>
<th>Separation (m) 150 kHz to 80 MHz D = 1.2 (√ P)</th>
<th>Separation (m) 80 to 800 MHz D = 1.2 (√ P)</th>
<th>Separation (m) 800 MHz to 2.5 GHz D =2.3 (√ P)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.01</td>
<td>0.1166</td>
<td>0.1166</td>
<td>0.2333</td>
</tr>
<tr>
<td>0.1</td>
<td>0.3689</td>
<td>0.3689</td>
<td>0.7378</td>
</tr>
<tr>
<td>1</td>
<td>1.1666</td>
<td>1.1666</td>
<td>2.3333</td>
</tr>
<tr>
<td>10</td>
<td>3.6893</td>
<td>3.6893</td>
<td>7.3786</td>
</tr>
<tr>
<td>100</td>
<td>11.6666</td>
<td>11.6666</td>
<td>23.3333</td>
</tr>
</tbody>
</table>
24. TECHNICAL SPECIFICATIONS

### Operating and Storage Conditions

<table>
<thead>
<tr>
<th>Condition</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating Temperature</td>
<td>50° F to 104° F (10°C to 40°C)</td>
</tr>
<tr>
<td>Storage Temperature</td>
<td>-0° F to 104° F (-18°C to 40°C)</td>
</tr>
<tr>
<td>Operating Humidity</td>
<td>≤ 90% Relative Humidity (non-condensing)</td>
</tr>
<tr>
<td>Storage Humidity</td>
<td>≤ 95% Relative Humidity (non-condensing)</td>
</tr>
</tbody>
</table>

**Pinpoint™ GT Needle Technology Operating and Storage Conditions (if enabled)**

<table>
<thead>
<tr>
<th>Condition</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating Temperature</td>
<td>50° F to 90° F (10°C to 32°C)</td>
</tr>
<tr>
<td>Storage Temperature</td>
<td>-0° F to 104° F (-18°C to 40°C)</td>
</tr>
<tr>
<td>Operating Humidity</td>
<td>≤ 85% Relative Humidity (non-condensing)</td>
</tr>
<tr>
<td>Storage Humidity</td>
<td>≤ 95% Relative Humidity (non-condensing)</td>
</tr>
</tbody>
</table>

If operating the device in temperatures exceeding 90°F (32°C), the battery charging functionality may be disabled to protect the battery. To charge the battery in temperatures exceeding 90°F (32°C), the system may need to be turned off.

### System Specifications

<table>
<thead>
<tr>
<th>Specification</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dimensions</td>
<td>12in x 9in x 2.5in (30cm x 22cm x 6cm)</td>
</tr>
<tr>
<td>Weight</td>
<td>5.4 lb (2.4kg)</td>
</tr>
<tr>
<td>Power Sources</td>
<td>A/C adapter, Internal Battery Pack</td>
</tr>
<tr>
<td>Power Consumption</td>
<td>60 Watts</td>
</tr>
<tr>
<td>IEC 60601-1</td>
<td>Class II, Type BF Applied Part, Continuous Operation, Internally Powered Equipment, Not Category AP or APG Equipment, IPX1.</td>
</tr>
</tbody>
</table>

### System Battery Specifications

<table>
<thead>
<tr>
<th>Specification</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Battery Chemistry</td>
<td>Lithium Ion</td>
</tr>
<tr>
<td>Battery Capacity (Full Charge)</td>
<td>6500mAh</td>
</tr>
<tr>
<td>Nominal Battery Output Voltage</td>
<td>10.8VDC</td>
</tr>
<tr>
<td>Battery Output Current (Max)</td>
<td>4.5A</td>
</tr>
<tr>
<td>System Run Time on Full Charge</td>
<td>Up to 3 Hours</td>
</tr>
<tr>
<td>Charge Time (Full)</td>
<td>8.0 Hours</td>
</tr>
</tbody>
</table>

### System AC Adapter Specifications

<table>
<thead>
<tr>
<th>Specification</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Input voltage</td>
<td>100-240 VAC, 50/60 Hz</td>
</tr>
<tr>
<td>Input Current (Max)</td>
<td>1.62A</td>
</tr>
<tr>
<td>Output Voltage</td>
<td>15V</td>
</tr>
<tr>
<td>Output Current (Max)</td>
<td>4.2A</td>
</tr>
</tbody>
</table>

### Probe Specifications - 32mm Linear

<table>
<thead>
<tr>
<th>Specification</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequency</td>
<td>7.5–10 MHz</td>
</tr>
<tr>
<td>Elevation Focus</td>
<td>19mm</td>
</tr>
<tr>
<td>Maximum Scan Depth</td>
<td>6cm</td>
</tr>
<tr>
<td>Scan Width</td>
<td>32mm</td>
</tr>
</tbody>
</table>

### Probe Specifications – Linear 20mm Cue™ Needle Tracking System Probe

<table>
<thead>
<tr>
<th>Specification</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequency</td>
<td>7.5–13 MHz</td>
</tr>
<tr>
<td>Elevation Focus</td>
<td>18mm</td>
</tr>
<tr>
<td>Maximum Scan Depth</td>
<td>6cm</td>
</tr>
<tr>
<td>Scan Width</td>
<td>20mm</td>
</tr>
</tbody>
</table>

### Probe Specifications – Linear 20mm Pinpoint™ GT Needle Technology Probe

<table>
<thead>
<tr>
<th>Specification</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequency</td>
<td>7.5–10 MHz</td>
</tr>
<tr>
<td>Elevation Focus</td>
<td>18mm</td>
</tr>
<tr>
<td>Maximum Scan Depth</td>
<td>6cm</td>
</tr>
<tr>
<td>Scan Width</td>
<td>20mm</td>
</tr>
</tbody>
</table>
### System Accuracy with Needle Guides

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Error</th>
<th>Range‡</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vertical</td>
<td>≤ 1.5mm</td>
<td>5–35mm</td>
</tr>
<tr>
<td>Horizontal</td>
<td>≤ 1.5mm</td>
<td>5–35mm</td>
</tr>
</tbody>
</table>

‡ Available depth range of the Site~Rite® Needle Guide and Pinpoint™ GT Needle Guide

### Measurement Tool Error

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Error</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Area</td>
<td>&lt; 10%</td>
<td>0–804mm²</td>
</tr>
<tr>
<td>Diameter</td>
<td>&lt; 10%</td>
<td>0–32mm</td>
</tr>
<tr>
<td>Area Ratio</td>
<td>&lt; 10%</td>
<td>0–100%</td>
</tr>
<tr>
<td>Diameter Ratio</td>
<td>&lt; 10%</td>
<td>0–100%</td>
</tr>
</tbody>
</table>

### Cue™ Needle Tracking System Accuracy

Accuracy is within the Intersection Window*

* Results have 95% confidence with 99.4% reliability from bench top testing in a controlled environment.

**Caution:** Improper technique and environmental conditions may introduce variation in accuracy.

### Pinpoint™ GT Needle Technology System Accuracy

±1.45mm*

* Results have 95% confidence with 96% reliability from bench top testing in a controlled environment.

**Caution:** Improper technique and environmental conditions may introduce variation in accuracy.
25. SITE~RITE® 8 ULTRASOUND SYSTEM WIRELESS TECHNOlogIES (if enabled)

The Site~Rite® 8 Ultrasound System incorporates a standard IEEE 802.11 b/g/n transceiver to provide a wireless Ethernet connection to DICOM servers and network PC's. This connection can be used for archiving data. Bluetooth™ capabilities are also included for wireless pairing to approved accessories. The Cue™ Activator contains an RFID reader.

<table>
<thead>
<tr>
<th>RF and Wireless Technology Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Function</strong></td>
</tr>
<tr>
<td><strong>Technology</strong></td>
</tr>
<tr>
<td><strong>Transmit/Receive</strong></td>
</tr>
<tr>
<td><strong>Frequency</strong></td>
</tr>
<tr>
<td><strong>Modulation</strong></td>
</tr>
<tr>
<td><strong>Bandwidth</strong></td>
</tr>
<tr>
<td><strong>Effective Radiated Power Output</strong></td>
</tr>
<tr>
<td><strong>Operating Range (meters)</strong></td>
</tr>
</tbody>
</table>

**Quality of Service (QoS)**
Since the Site~Rite® 8 Ultrasound System uses WLAN to transmit patient data to a DICOM system and does not relate to real-time scanning operations, these communications are on a best-efforts basis, where other data on the network may be given higher priority if there is a bandwidth conflict.

**Quality of Service (QoS) – Wireless Ethernet**
The wireless Ethernet on the Site~Rite® 8 Ultrasound System operates as a best-efforts device, as it does not directly involve or interfere with active scanning. As such, it does not require a formal QoS WLAN. If used on a QoS network, its transmitted data may receive a lower priority than video or voice that is also transmitted on the same network. The following table provides recommended metrics to achieve a high level of performance from the Site~Rite® 8 Ultrasound System wireless configuration.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>IEEE 802.11 Level</td>
<td>IEEE 802.11b or g or n</td>
<td></td>
</tr>
<tr>
<td>Wireless Signal Rate</td>
<td>11 Mbps (IEEE 802.11b) 54 Mbps (IEEE 802.11g) 150 Mbps (IEEE 802.11n)</td>
<td>Stated maximum for each standard. Data transfer will be lower and is directly affected by separation distance between the console and the wireless access point, network conditions, building layout, etc.</td>
</tr>
<tr>
<td>Distance to Access Point</td>
<td>&lt; 34 meters</td>
<td>Though the stated maximum may be 150 feet, it is not usually achievable in hospital settings.</td>
</tr>
<tr>
<td>Security type*</td>
<td>WPA2</td>
<td>WPA2 provides better security than former methods.</td>
</tr>
<tr>
<td>Encryption Types</td>
<td>AES, TKIP</td>
<td>-</td>
</tr>
</tbody>
</table>

*If WPA2 Enterprise is required, the Silex® Wireless Bridge may be used. Please contact Customer Service at: 1-800-545-0890.
Quality of Service (QoS) – Bluetooth
The Bluetooth™ functionality for the Site~Rite® 8 Ultrasound System operates on a best efforts basis, since latency in data transmission will not affect critical ultrasound imaging. As these connections are point to point, they do not require or rely on a formal QoS WLAN. The link capacity between devices is designed to provide the necessary bandwidth for proper data transmission, without competition for resources between devices.

To ensure a proper connection, keep the separation distance between Bluetooth™ devices and the Site~Rite® 8 Ultrasound System console as short as possible. The maximum operating distance for Bluetooth™ technology is < 10 meters. Bluetooth™ devices generally perform better at shorter distances however, on the order of ~3 meters, with a direct line of sight preferable.

IEEE 802.11b/g/n Wireless Security
To guard against unauthorized access to network resources, ensure that the Site~Rite® 8 Ultrasound System is connected to a secure network. Use of WPA2 security is preferred over older protocols, such as WEP, as it provides a more secure network. Contact your local IT administrator for more information on which networks can be used and what settings should be used.

Bluetooth™ Security
The Site~Rite® 8 Ultrasound System employs Bluetooth™ connectivity for use with approved accessories. Bluetooth™ technology does not provide rigorous security measures to prevent unauthorized access, as wifi does. As such, appropriate measures should be taken to ensure that access is limited to approved accessories to be used with the system.

Wireless coexistence issues and mitigations:
There is a potential for wireless conflicts, as 802.11b/g/n and Bluetooth™ both operate on the 2.4 GHz frequency band, as well as interference from other RF devices. If you encounter problems connecting to a network or Bluetooth™ device, remove or separate possible interfering sources as much as possible. Objects and people obstructing line of sight connections between wireless devices can also cause interference. Maintain a clear path between the Site~Rite® 8 Ultrasound System and paired accessories as much as possible to ensure highest performance.