This document is intended to provide an overview of the Site~Rite® 8 Ultrasound System with Pinpoint™ GT Technology and integrated SHERLOCK 3CG™ Diamond TCS.

Please consult product labels and inserts for any indications, contraindications, hazards, warnings, precautions and directions for use.
Site~Rite® 8 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
- 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>
<th>Exam Type (Adult and Pediatric)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vascular</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>
</tr>
<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, hernias, musculoskeletal procedures (e.g., joints, ligaments, tendons), soft tissue structures, and surrounding anatomical structures</td>
</tr>
</tbody>
</table>

Pinpoint™ GT Technology is intended to provide clinicians with visual tools for passive magnetic tracking of a needle with respect to ultrasound image data.

Warning: Pinpoint™ GT Technology is not qualified for use with Site~Rite® Needle Guides. Using Site~Rite® Needle Guides with the Pinpoint™ GT Technology may result in injury to the patient.
Site~Rite® 8 Ultrasound System

• **SHERLOCK 3CG™ Diamond Tip Confirmation System (TCS) Indications for Use:**
  
  – The SHERLOCK 3CG™ Tip Confirmation System (TCS) is indicated for guidance and positioning of Peripherally Inserted Central Catheters (PICCs). The SHERLOCK 3CG™ TCS provides real-time PICC tip location information by using passive magnet tracking and the patient’s cardiac electrical activity (ECG). When relying on the patient’s ECG signal, the SHERLOCK 3CG™ TCS is indicated for use as an alternative method to chest X-ray and fluoroscopy for PICC tip placement confirmation in adult patients.

  – Limiting but not contraindicated situations for this technique are in patients where alterations of cardiac rhythm change the presentation of the P-wave as in atrial fibrillation, atrial flutter, severe tachycardia, and pacemaker driven rhythm. In such patients, who are easily identifiable prior to catheter insertion, the use of an additional method is required to confirm PICC tip location.

• **Pinpoint™ GT Safety Introducer Needle Indications for Use:**
  
  – The Pinpoint™ GT Safety Introducer Needle is intended for patients requiring percutaneous access to place a guidewire for subsequent placement of catheters or other medical procedures requiring introducer needle access. The Pinpoint™ GT Safety Introducer Needle may be used in any appropriate patient population.
Site~Rite® 8 Ultrasound System Overview

- The Site~Rite® 8 Ultrasound System is portable, intuitive, and is designed to simplify the placement of vascular devices by giving clinicians:
  - Touch screen capability
  - Vessel measurements
  - Personalized clinical presets / settings
  - Customized fields for documentation
  - Connectivity
  - Visual needle guidance technology (with Pinpoint™ GT Technology)
  - Visual catheter tracking and tip confirmation (with integrated SHERLOCK 3CG™ Diamond TCS)
Site~Rite® 8 Ultrasound System
Overview

System Specifications
• Capacitive touch screen
• 4 USB ports
• 1 HDMI port
• Ethernet port
• Up to 3 hour battery life (lithium ion)
• Intel Celeron processor (1.83 GHz, quad core)
• System storage = 128G
• Intel Bay Trail HD Graphics
• 1024x768 screen resolution
• Console weight = ~5 lbs
• 7.5-10 MHz probe
• 16 channel beam former
• Monitor size = 10.4”
• Hardwire probe options
  – Linear 20mm Pinpoint™ GT Technology Probe
  – Linear 32mm Probe
Site~Rite® 8 Ultrasound System
Overview

• Upon removal from the box, activate the battery
  – Note: The battery is disconnected from the system to extend storage life

Battery Switch Cover

Battery switch
Site~Rite® 8 Ultrasound System
Overview

- USB 2.0 (3 ports)
- USB 3.0
- HDMI video out
- Ethernet
- Power Connection
- Power Button
- Kensington Slot (for security cable)
Site~Rite® 8 Ultrasound System Overview

- Site~Rite® 8 Ultrasound Linear Probe Options

  **Linear 20mm Pinpoint™ GT Technology Probe**

  **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.
Site~Rite® 8 Ultrasound System
System Overview

MAIN ULTRASOUND SCREEN

Information Bar

Image Depth Scale

Main Toolbar

Catheter Icons

Center / Depth Markers
Site~Rite® 8 Ultrasound System
System Overview

**INFORMATION BAR**

- Time
- Patient Information
- Catheter Trim Length
- Exit Site Marking
- Date
- Battery Information
- File Management
1. Select the Patient Information button to enter patient information
2. A screen will appear with 3 options
   a) (Pencil) – Edit current patient information
   b) (Patient +) – Add new patient (previously unsaved patient data will be deleted)
      • Note: once a new patient is added, the previous patient’s information cannot be edited
   c) (Back arrow) – Return to previous screen
3. Select add new patient to begin a new procedure
Site~Rite® 8 Ultrasound System
System Overview

PATIENT INFORMATION

- Select the clinician drop down menu to select the clinician performing the procedure.
- If the clinician performing the procedure is not in the system, select the button to add a new clinician. Any ultrasound setting changes will save to the selected clinician profile
  - To delete a clinician, select the name of the clinician in the drop down menu and then the delete button (trash can)
Site~Rite® 8 Ultrasound System
System Overview

**Patient Information**

- Input the information required per *your procedure protocol* (name, ID, etc.)
  - Note: accession number is used for transferring images to the PACS System via DICOM
Site~Rite® 8 Ultrasound System

System Overview

**PATIENT INFORMATION**

- **Custom** fields are provided to document clinically relevant information (and the left side is retained as a clinician preset)
  - Procedure specific information can be placed in the column to the right of custom fields
  - The “notes” field is for additional procedure specific information
- Select the green arrow to save patient information and return to the main ultrasound screen
FILE MANAGEMENT
To print, send, or manage files, select the File Management (folder) button.

1) Select patient files by touching the box in front of the patient’s name. To select all files, select the box in the header field next to Name.
2) By default, files are sorted by time of procedure. However, files can also be sorted by selecting Name, Clinician, Patient ID, etc.
FILE MANAGEMENT
To print, send, or manage files, select the File Management (folder) button.

3) Select this box to select all or deselect all images

4) To preview an image, select the thumbnail
Site~Rite® 8 Ultrasound System
System Overview

CATHETER TRIM LENGTH

• Select the catheter trim length button to enter the catheter’s trim length
Site~Rite® 8 Ultrasound System
System Overview

**EXIT SITE MARKING**

- Select the Exit Site Marking button to enter and note the exit site marking of the catheter (i.e., the length of catheter left outside the patient)
The system is equipped with catheter icons (reference markers for catheter size):

- PICCs
- CVCs
- Acute Dialysis
- PIVs

Select the button to toggle through available catheter icon sizes.
Site~Rite® 8 Ultrasound System

System Overview

MAIN TOOLBAR

Pinpoint™ GT Technology Mode (if enabled)

Depth  Gain  Freeze  SHERLOCK 3CG™ TCS Mode (if enabled)  Settings

Button Selected  Button Not Selected
Site~Rite® 8 Ultrasound System

System Overview

- Ultrasound Image Adjustments
  - Select the “Settings” button in the Main Toolbar
  - Select the Ultrasound Settings tab
  - Select the Image Contrast button (low or high) to adjust the ultrasound image
  - Select “image filter” icons to adjust the sharpness or smoothness of the ultrasound image
Vessel Measurements
Site~Rite® 8 Ultrasound System

Measuring Vessels

1. To create the Vessel Measurement / Occupancy Rule, select the Settings button in the Main Toolbar
2. Select the Ultrasound Settings Tab
3. In the ultrasound settings menu, select a Vessel Measurement option – either by diameter or area. The occupancy rule for either method is calculated in the following manner:

\[
\text{% Occupied (Diameter)} = \frac{\text{Diameter of Catheter}}{\text{Diameter of Vessel Occupancy Circle}} \times 100
\]

\[
\text{% Occupied (Area)} = \frac{\text{Area of Catheter}}{\text{Area of Vessel Occupancy Circle}} \times 100
\]

4. Use the + or – buttons to set the desired Vessel Occupancy Percentage Rule
Site~Rite® 8 Ultrasound System

Measuring Vessels

1. To measure the vessel, find and select a vein.
2. On the Main Toolbar, select the Freeze button to pause the image.
Site~Rite® 8 Ultrasound System

Measuring Vessels

1. Select the measurement tool button to begin measuring the vessel
2. Next, select the desired catheter size
3. Note: the gray inner Catheter Icon represents the catheter French size. The dotted circle represents the pre-established Vessel Occupancy Percentage Rule. If the dotted circle is smaller than the vessel, the selected catheter complies with the user-specified rule.
Site~Rite® 8 Ultrasound System
Measuring Vessels

1. Align the top of the dotted circle with the top middle of the vessel (see image below)

2. Touch the resizing marker (blue circle) and drag down until the dotted blue circle fills the vessel

3. A customized Vessel Occupancy Percent Measurement for the catheter selected (along with the next smaller and larger catheter sizes) can be found in the bottom right corner of the display

4. The diameter and area of the dotted circle can be found on the left corner of the display

5. Select the save/print button to save or print the image
Pinpoint™ GT Technology
1. Retrieve the Pinpoint™ GT Safety Introducer Needle and place in a location consistent with practice
2. Follow institutional protocols to prepare for vascular access
3. Use the Site~Rite® 8 Ultrasound System to find the vessel
4. Select the GT button
5. Limit probe movement and keep the probe perpendicular to the insertion site (do not tilt or angle the probe)
6. Calibrate the system by selecting the calibrate button
   - Note: keep the needle 2 feet away from the ultrasound probe during calibration
   - Ferromagnetic objects, must be at least two feet away from the ultrasound probe to perform calibration.
   - Ensure all metallic objects including keys, cell phones, and jewelry are at least two feet away from the imaging site
   - Limit probe movement
   - Excessive movement of the probe after calibration may result in reduced needle tracking accuracy
   - Do not use the technology in the presence of strong magnetic fields (such as MRI)
   - Keep a 5 foot distance between SR 8 and equipment with strong electromagnetic or radio frequency interference
1. Once the system is calibrated, bring the needle toward the probe at a 45 degree angle until virtual needle image appears on the display
   1. Confirm that virtual needle movement matches actual needle movement
2. Limit probe movement
3. Virtual needle image description
   1. Yellow = Needle shaft
   2. Green = Needle Trajectory
   3. Violet = Point of Intersection Circle (location where the needle intersects the ultrasound plane)
4. Modify the needle angle up or down to place the violet (Point of Intersection) circle in the center of the intended target structure
   1. If needle tracking is not functioning properly, discontinue use
1. To maintain accuracy, always use a “light touch” (defined as minimal force, stress, or pressure on the needle) when inserting the needle.

2. When the needle intersects the ultrasound plane Point of Intersection Circle (and the circle turns green), it does not necessarily mean the vessel is successfully accessed.

3. To confirm access, watch for:
   1. Blood return in the needle hub
   2. Anterior vessel wall indentation
   3. Needle reflection (or flash)

4. Complete procedure per suggested institutional guidelines.
SHERLOCK 3CG™ Diamond TCS
Site~Rite® 8 Ultrasound System with Integrated SHERLOCK 3CG™ Diamond TCS

Select the SHERLOCK 3CG™ TCS Mode Button

Ultrasound Mode
Calibrate Button
Audio
Freeze
Print/Save
ECG Menu
Site~Rite® 8 Ultrasound System with Integrated SHERLOCK 3CG™ Diamond TCS

Stylet Icon Change
- Green diamond indicates stylet tip at max P-wave

P-Wave Highlighting
- Yellow emphasis during tracking
- Green highlight indicates Max P-wave

Real Time ECG Display
Reference ECG Display
Site~Rite® 8 Ultrasound System with Integrated SHERLOCK 3CG™ Diamond TCS

- Occasionally, tracking may stop. When this happens, the symbol will remain stationary and depict the last known location of the tracking system.
- ECG will remain active and functional.
Site~Rite® 8 Ultrasound System
with Integrated SHERLOCK 3CG™ Diamond TCS

- To adjust the ECG waveforms, select the ECG Menu Button

Waveform
Scale/Amplitude

Waveform Level

Speed (Sweep)

Exit
Tools
Site~Rite® 8 Ultrasound System with Integrated SHERLOCK 3CG™ Diamond TCS

- Select to access SHERLOCK™ Tools Menu

- SHERLOCK™ Tools Menu
  - SHERLOCK 3CG™ Diamond TCS functionality can be adjusted, disabled or saved to clinician to preset
  - Documentation adjustments
  - Initiate demo mode
ADDING SOFTWARE FEATURES
Site~Rite® 8 Ultrasound System

Add Feature Activation Key

• Feature Activation Keys
  – An Activation Key may be required to enable SHERLOCK 3CG™ Diamond TCS or Connectivity on your ultrasound machine
  – After purchase, Activation Keys will be mailed to the customer in a separate envelope
  – Activation keys can also be supplied (or generated electronically) by BAS customer service (1-800-545-0890)
Site~Rite® 8 Ultrasound System
Add Feature Activation Key

• Inputting an Activation Key
  – Select the Settings button on the Main Ultrasound Screen
  – Select the General Settings Tab
  – Select the Add Feature Activation Key button
Site~Rite® 8 Ultrasound System
Add Feature Activation Key

• Inputting the Activation Key
  – Select the appropriate field to input the key
  – Enter the key and select the unlock button
  – Successful activation will be represented by a green check mark
  – Incorrect key will result in a red X
  – Select the green arrow to save changes and exit
• If activation failed, re-enter the activation key. If problem continues, contact Customer Service at 1-800-545-0890

Ultrasound Mode
SHERLOCK™ 3CG
TCS Mode
Connectivity
DICOM/WiFi

Correct key
Incorrect key

Once code is entered, select the unlock button to activate feature
SECURITY
Security

- To password protect the ultrasound system, select Settings, then the General Settings Tab
- Select the Lock button
- Enter any numeric password between 1 and 10 digits
- Select the green arrow to save password and return to settings
- If the password is forgotten, contact BAS field assurance (1-800-296-4146) for a temporary password
ACCESSORIES & COMPATIBLE PRODUCTS
Site~Rite® 8 Ultrasound System
Accessories/Compatible Products

• Medical Equipment Roll Stand
  – Large basket
  – Locking drawer

• Roller Bag Bundle
  – Site~Rite® 8 Ultrasound System Roller Bag (with back pack straps)
  – Kickstand mounting accessory
  – Probe holder accessory
Site~Rite® 8 Ultrasound System
Accessories/Compatible Products

Brother™ Printer

Site~Rite® Keyboard

Site~Rite® Needle Guides* & Site~Rite® Probe Covers

Pinpoint™ GT Technology Practice Packet

With the Integrated SHERLOCK 3CG™ TCS Sensor for use with Integrated SHERLOCK 3CG™ Diamond TCS

*Warning: Pinpoint™ GT Technology is not qualified for use with Site~Rite® Needle Guides. Using Site~Rite® Needle Guides with the Pinpoint™ GT Technology may result in injury to the patient
CONNECTIVITY
Site~Rite® 8 Ultrasound System
Connectivity

- Setting up WiFi (Secure Network)
  - A WiFi profile (from the hospital / facility) must be loaded on the ultrasound system to connect to WiFi – follow the process below to set up a connection

1. Verify (or connect) a Windows™ 7 or 8 PC to the desired WiFi network.

2. Insert an empty USB storage device into the computer, and note the USB storage device’s drive letter under the Computer folder.

Step 1: Connect or confirm connection to desired network

Step 2: Note USB drive letter (in this example it is E)
Site~Rite® 8 Ultrasound System
Connectivity

- Setting up WiFi (Secure Network)
  3. Open a command prompt. To open a command prompt, click on Start and type “cmd” into the Search Programs and Files field.
  4. Select the cmd.exe program when it appears
Site~Rite® 8 Ultrasound System
Connectivity

• Setting up WiFi (Secure Network)
  5. In the Windows command prompt, type the letter of the USB drive followed by a colon (in this example, it is E)
  6. Select Enter
  7. The command prompt should now be in the USB drive. Enter the text:
     o netsh wlan export profile
     o Select Enter
Site~Rite® 8 Ultrasound System
Connectivity

• Setting up WiFi (Secure Network)

8. After selecting Enter, the command prompt should show which WiFi profiles were copied to the USB drive.

9. Return to Computer in Windows Explorer and open the USB folder. Locate the desired profile .xml file on the USB stick. Right-click the file, and choose Edit.
Setting up WiFi (Secure Network)

10. In the text editor that appears, change the text between the `<protected>` values from “true” to “false”

11. Next, change the text between the `<keyMaterial>` values from the encrypted hexadecimal value (erase the long number) to the password used to connect to the WiFi network

12. Save and close file

13. If applicable, open the USB storage device and erase all extra WiFi profiles not intended for the ultrasound system

14. Remove the USB stick.
Site~Rite® 8 Ultrasound System
Connectivity

• Once the WiFi profile is obtained, connect the USB stick to the ultrasound system and follow the prompts below to enable WiFi:
  
  – Step 1:
    • Select the Settings button
  
  – Step 2:
    • In the Settings window, select the WiFi / Connectivity Settings tab
  
  – Step 3:
    • Enable WiFi (if not already enabled). This may take a few minutes
Site~Rite® 8 Ultrasound System
Connectivity

– Step 4:
  • Select the Select WiFi Profile button

– Step 5:
  • Select Add WiFi Profile button
Site~Rite® 8 Ultrasound System
Connectivity

– Step 6:
  • Wait for the software to detect and import WiFi profile .xml files (from the USB stick)

– Step 7:
  • Select the appropriate WiFi network when it becomes available

– Step 8:
  • Wait for the connection to complete

– Step 9:
  • The WiFi profile should now be connected
Site~Rite® 8 Ultrasound System
Connectivity

– Step 10:
  • Verify *connectivity* by confirming the IP address on the system

– Step 11:
  • Select the *Network Settings* button

– Step 12:
  • Confirm the IP address matches the hospital’s network
Site~Rite® 8 Ultrasound System
Connectivity

• DICOM Set-up
  – Step 1:
    • To access the DICOM menu, select *Settings*
  – Step 2:
    • Select *Connection Settings* tab
  – Step 3:
    • Select the *DICOM Settings* button
Site~Rite® 8 Ultrasound System
Connectivity

• DICOM Set-up
  – Step 4:
    • Work with IT or the PACS Department to enter the appropriate client / server / IP information
  – Step 5:
    • Once the appropriate information is entered, select ECHO to test the connection to the PACS server
    • A green checkmark indicates a successful connection. Red X indicates unsuccessful connection
  – Step 6:
    • Select the Arrow button to save and exit
Site~Rite® 8 Ultrasound System

Connectivity

- Using DICOM
  1. To send a file electronically, select the File Management button
  2. Select the Records (touch gray border) to send to PACS (files will be highlighted with a green check mark)
  3. Select the Send to PACS button to send to PACS
Please consult product labels and inserts for any indications, contraindications, hazards, warnings, precautions and directions for use.

Bard, Pinpoint, Sherlock, SHERLOCK 3CG and Site-Rite are trademarks and/or registered trademarks of C. R. Bard, Inc. All other trademarks are the property of their respective owner(s).

©2016 C. R. Bard, Inc. All rights reserved.

0740962 1511R