SITE~RITE® 8

ULTRASOUND SYSTEM

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:

Imaging Applications	Exam Type (Adult and Pediatric)
Vascular	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)
Vascular Access	Guidance for PICC, CVC, dialysis catheter, port, PIV, midline, arterial line placement, access to fistula and grafts, and general vein and artery access
Interventional	Guidance for biopsy and drainage
Superficial	Assessment of breast, thyroid, parathyroid, testicle, lymph nodes, hernias, musculoskeletal procedures (e.g., joints, ligaments, tendons), soft tissue structures, and surrounding anatomical structures

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

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ULTRASOUND SYSTEM

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

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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

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SITE~RITE®
ULTRASOUND SYSTEM

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
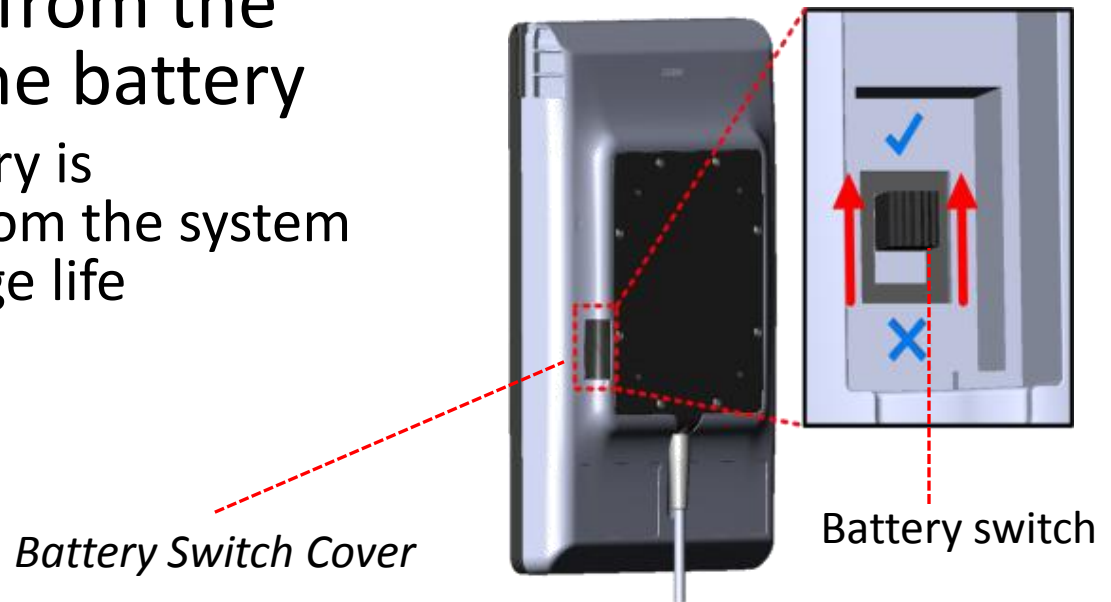
Battery Switch Cover

Battery switch

Site~Rite® 8 Ultrasound System
Overview

Power Button

USB 2.0 (3 ports)

USB 3.0

HDMI video out

Ethernet

Power Connection

Kensington Slot (for security cable)
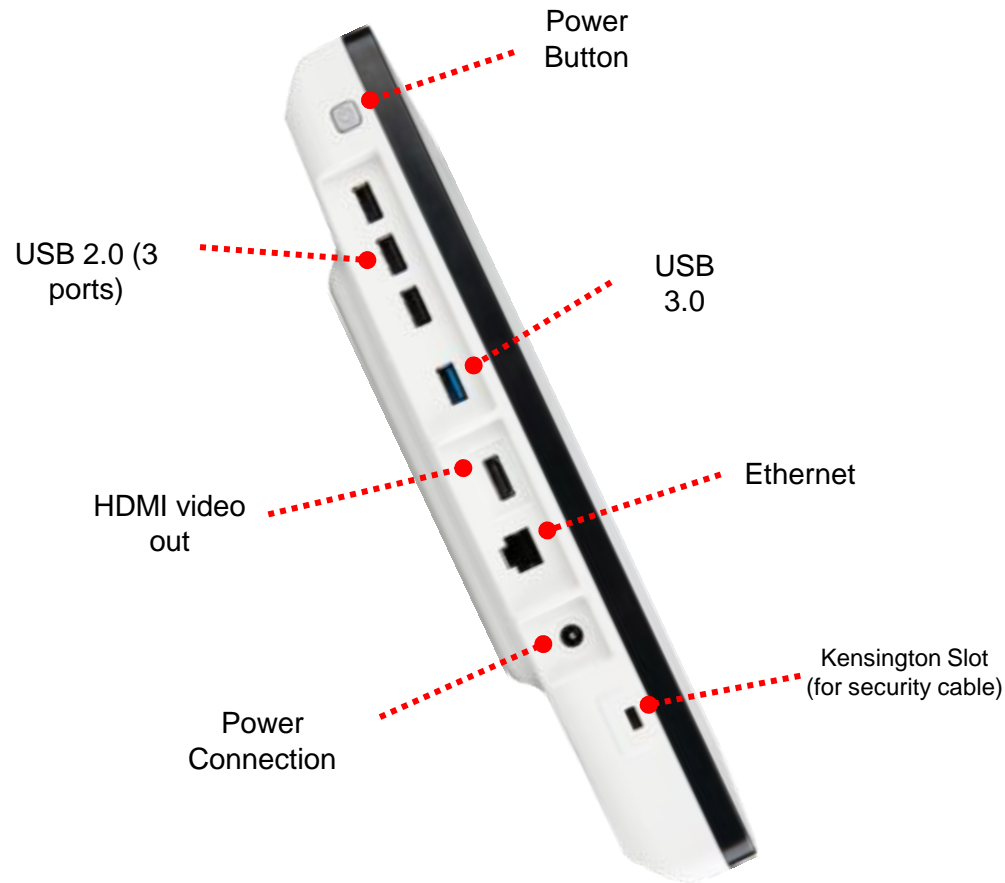
Site~Rite® 8 Ultrasound System
Overview

Linear 32mm Probe

- Site~Rite® 8 Ultrasound Linear Probe Options

Linear 20mm Pinpoint™ GT Technology Probe

Cursor Up: Press to move cursor up.

Cursor Left: Press to move cursor left.

Cursor Right: Press to move cursor right.

OK: Press to select the current control.

Cursor Down: Press to move cursor down.

Cursor Up
Press to move cursor up.

Cursor Left
Press to move cursor left.

Cursor Right
Press to move cursor right.

OK
Press to select the current control.

Cursor Down
Press to move cursor down.

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 · File Management · Date · Catheter Trim Length · Exit Site Marking · Battery Information

09:58:16 · 2015-03-02 · __ cm · __cm · 73%
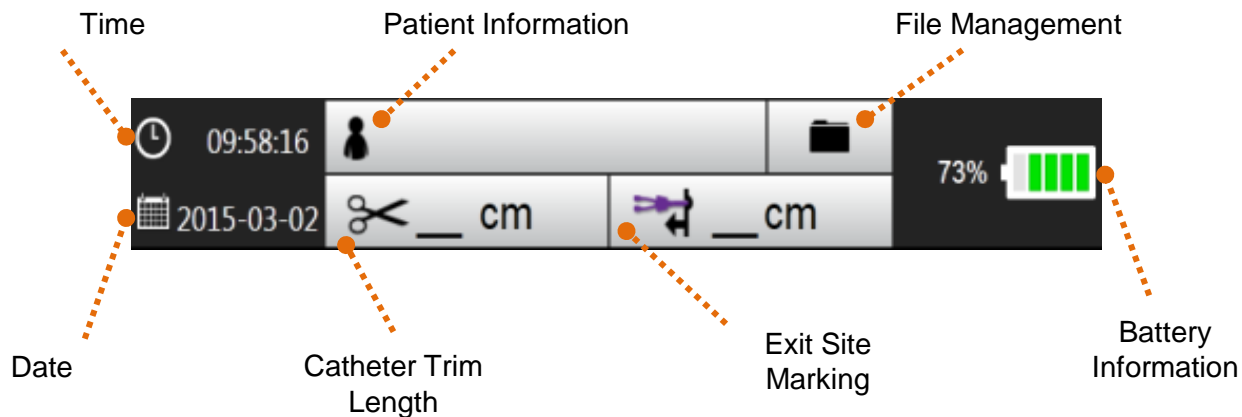
Site~Rite® 8 Ultrasound System
System Overview

PATIENT INFORMATION

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 ![add clinician icon] 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) ![trash icon]

Site~Rite® 8 Ultrasound System
System Overview
PATIENT INFORMATION

- Input the information required per *your procedure protocol* (name, ID, etc.)
  - <u>Note:</u> 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

Site~Rite® 8 Ultrasound System
System Overview

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 N*ame*
2) By default, files are sorted by time of procedure. However, files can also be sorted by selecting *Name, Clinician, Patient ID*, etc.
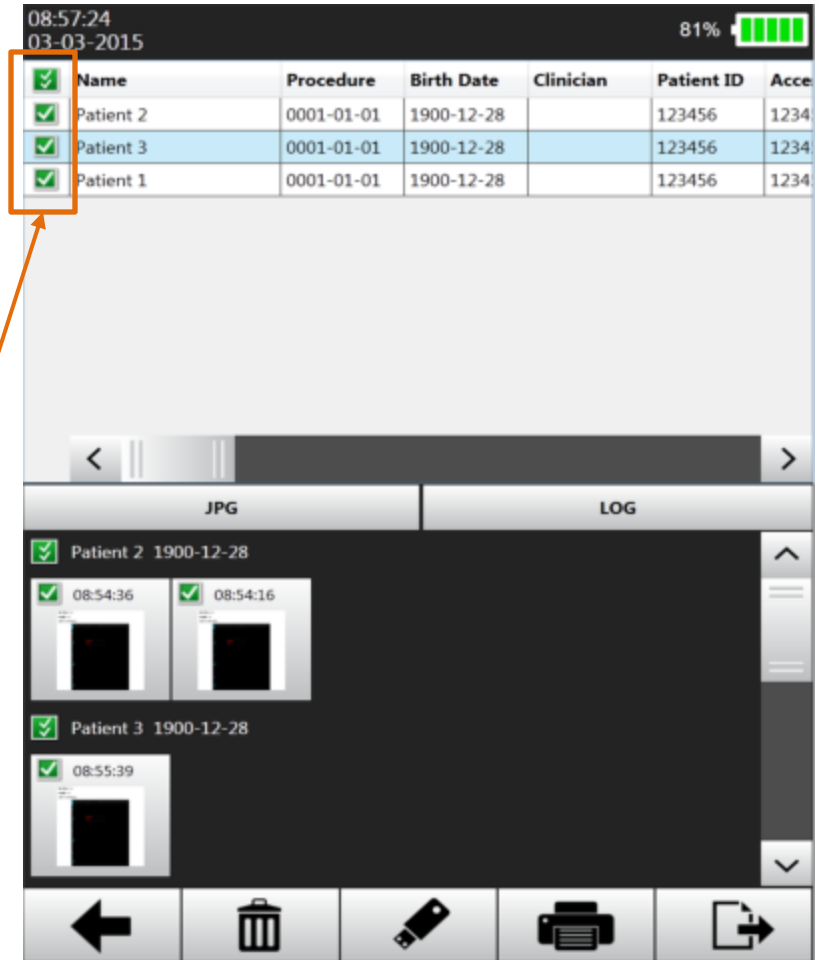
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ULTRASOUND SYSTEM

Site~Rite® 8 Ultrasound System
System Overview

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
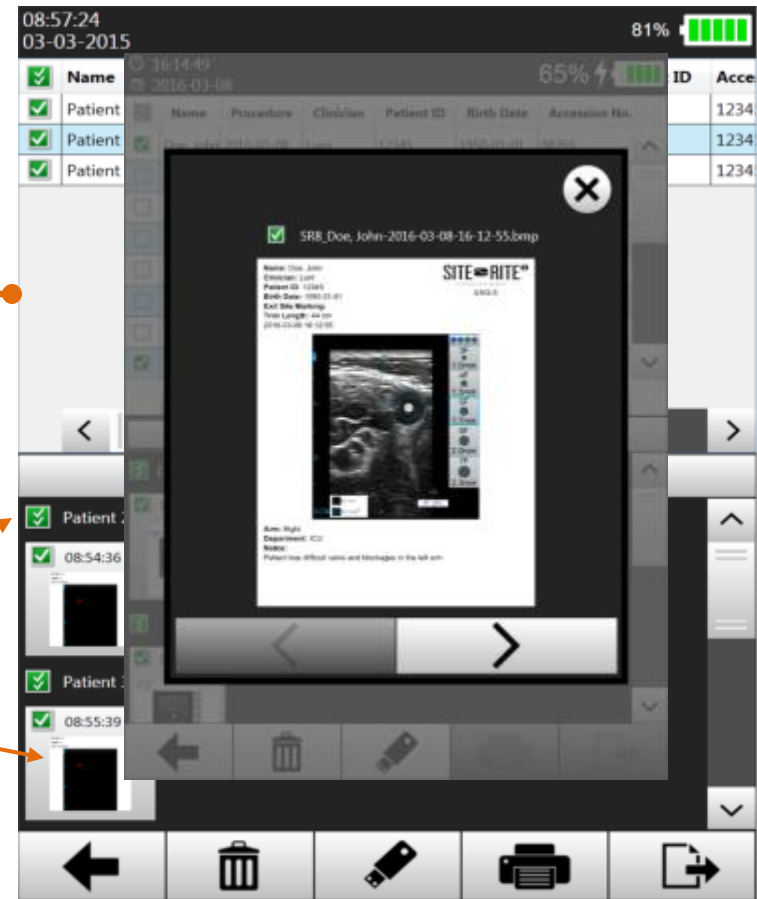
Site~Rite® 8 Ultrasound System
System Overview

CATHETER TRIM LENGTH
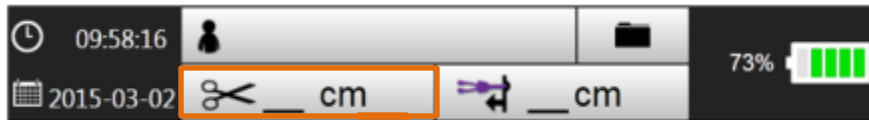
- Select the catheter trim length button to enter the catheter's trim length
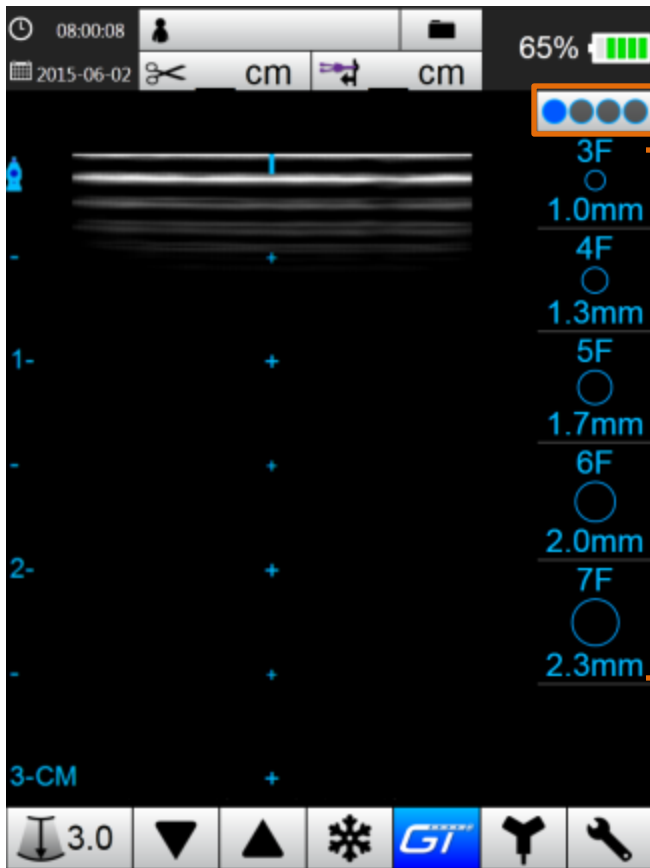
Site~Rite® 8 Ultrasound System
System Overview

EXIT SITE MARKING
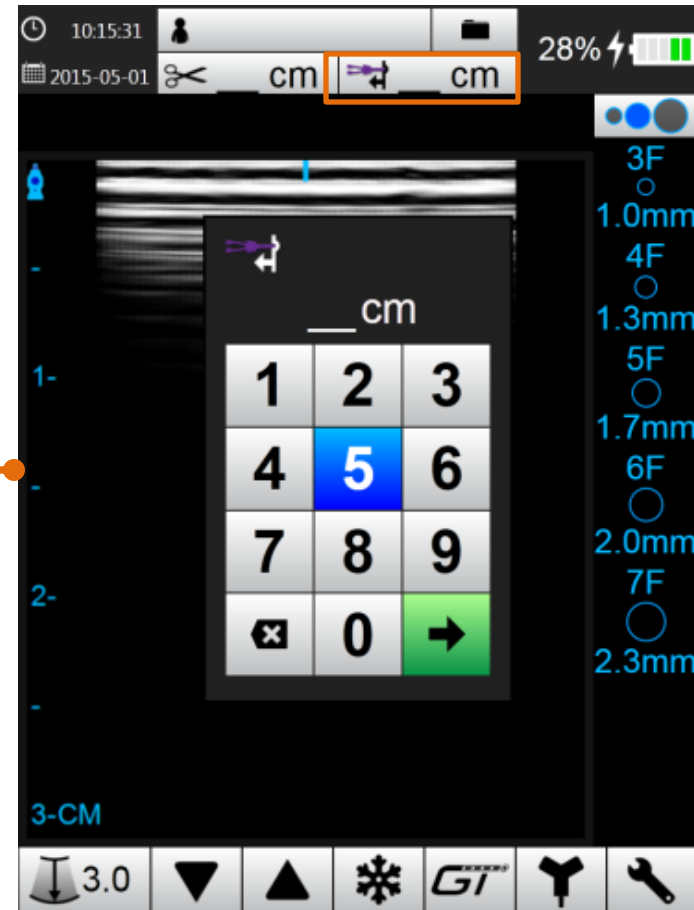
- Select the Exit Site Marking button to enter and note the exit site marking of the catheter (i.e., the length of catheter left outside the patient)
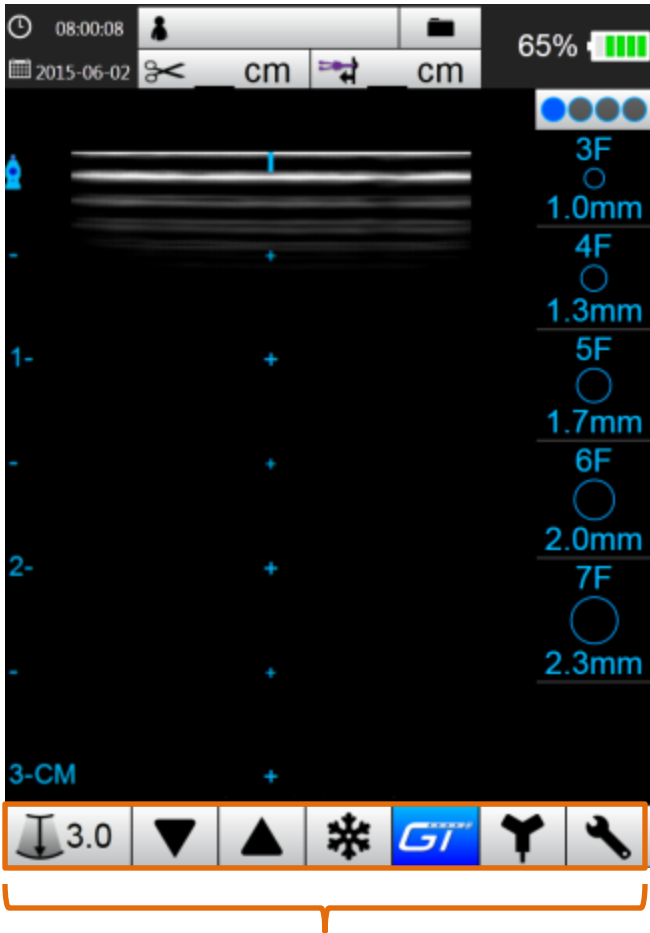
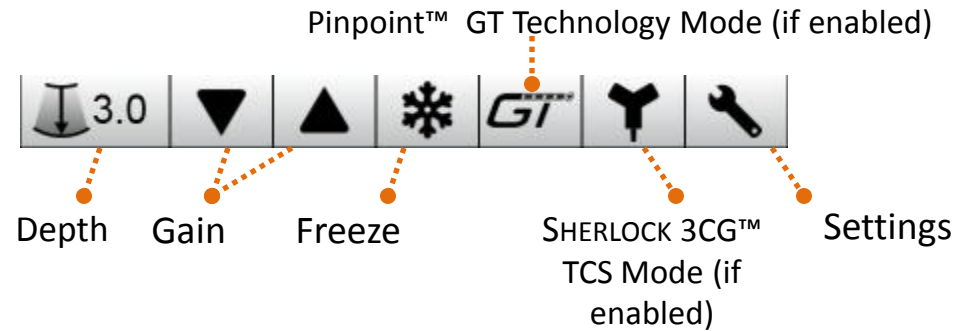# Site~Rite® 8 Ultrasound System
System Overview

- 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™   Settings
                            TCS Mode (if
                            enabled)

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
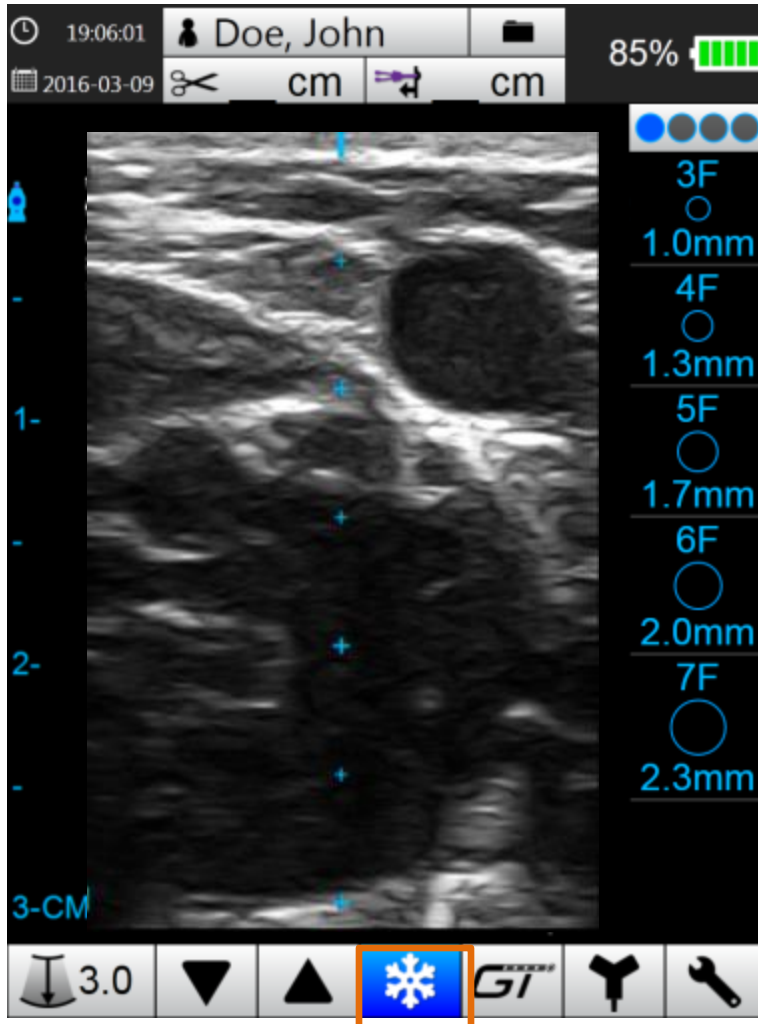
1. To measure the vessel, find and select a vein

2. On the Main Toolbar, select the *Freeze* button to pause the image

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ULTRASOUND SYSTEM

# Site~Rite® 8 Ultrasound System
Measuring Vessels
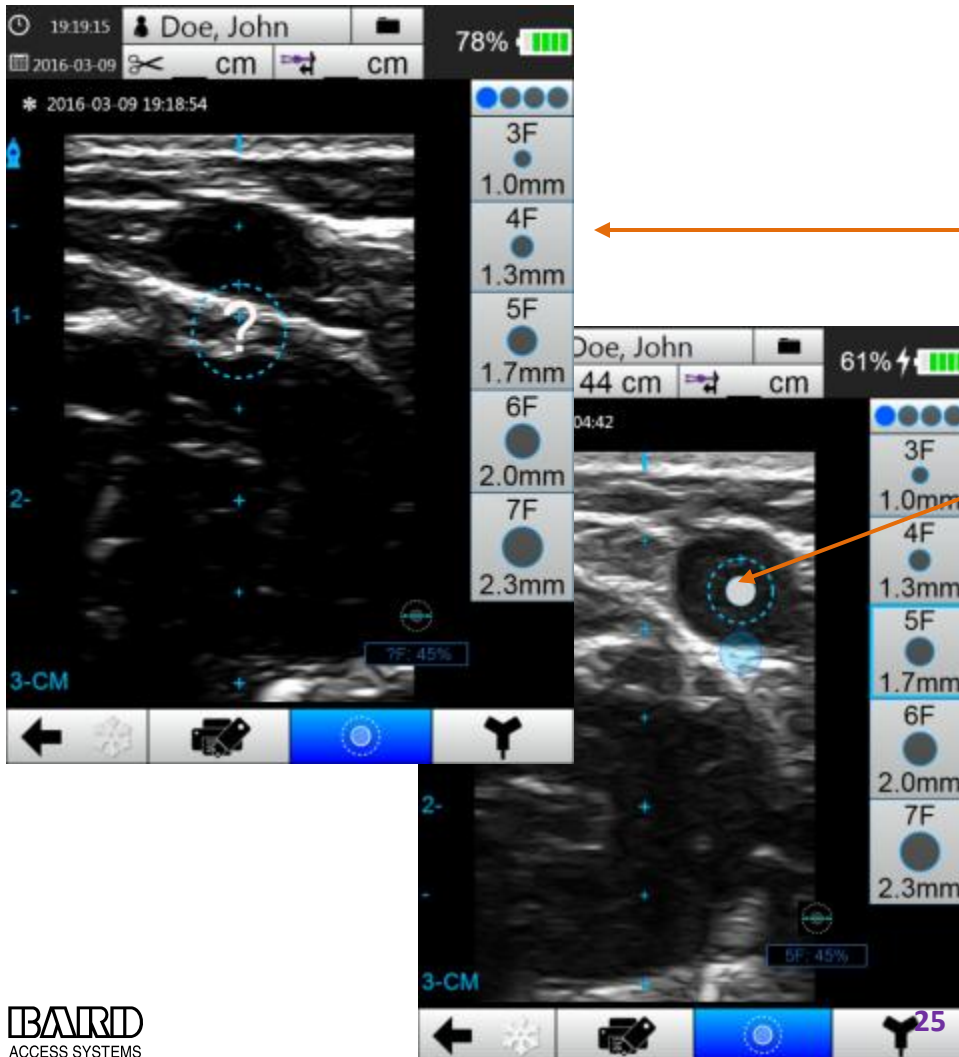
1. Select the measurement tool button [icon] to begin measuring the vessel

2. Next, select the desired catheter size

3. <u>Note:</u> 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
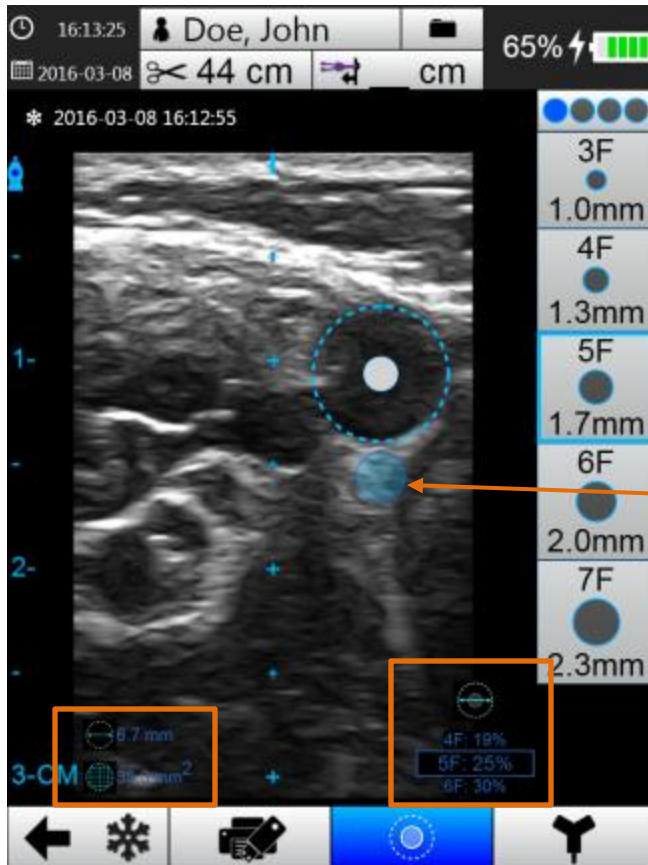
1. Align the top of the dotted circle with the top middle of the vessel (see image below)
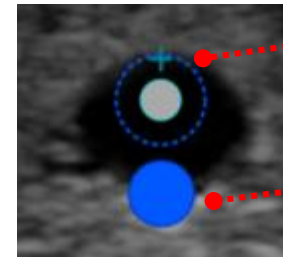
Align with top of vessel

Resizing Marker
Resize circle to approximate vessel size

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

Site~Rite® 8 Ultrasound System
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

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ULTRASOUND SYSTEM
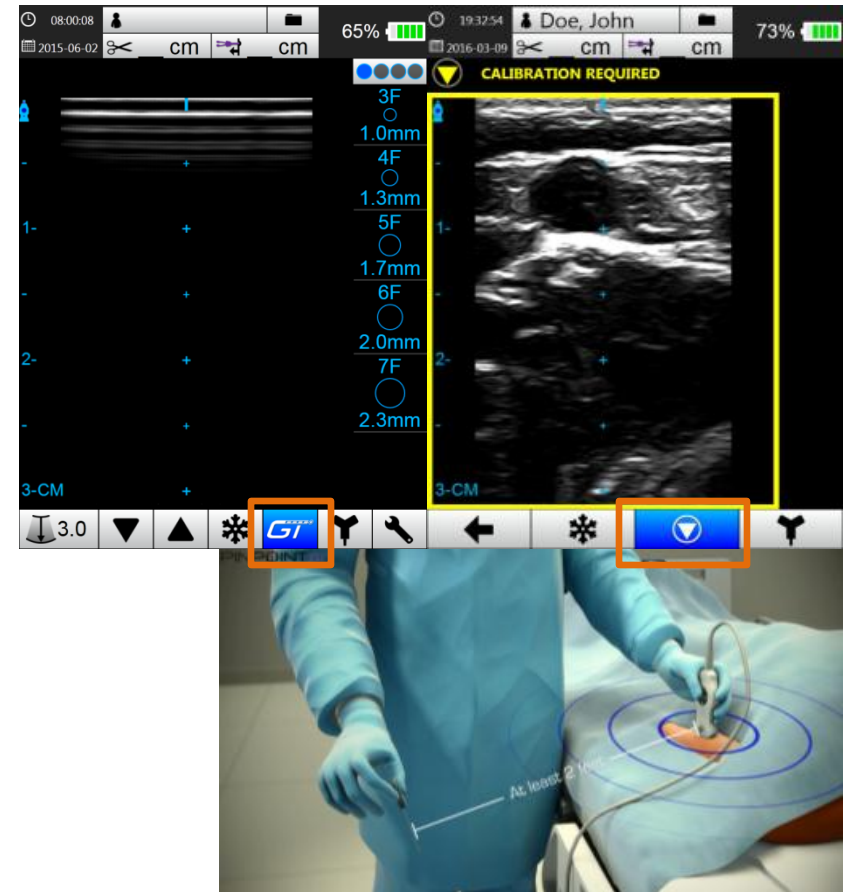
Site~Rite® 8 Ultrasound System
Pinpoint™ GT Technology

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
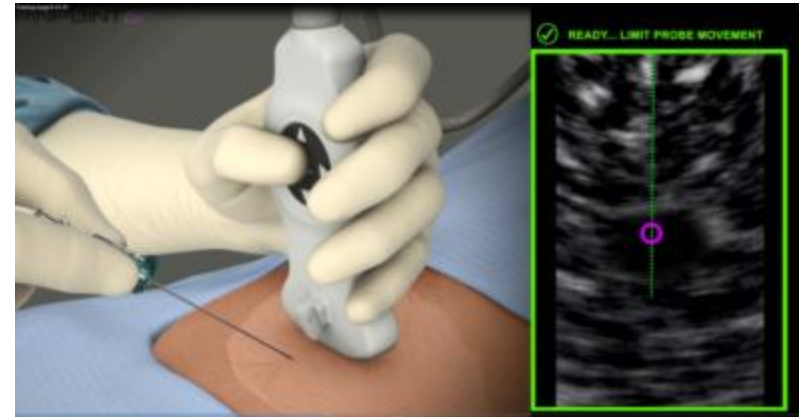
Site~Rite® 8 Ultrasound System
Pinpoint™ GT Technology

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
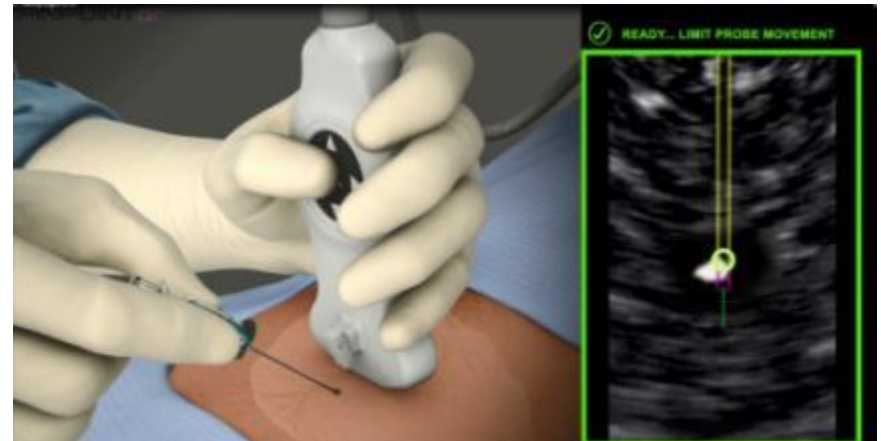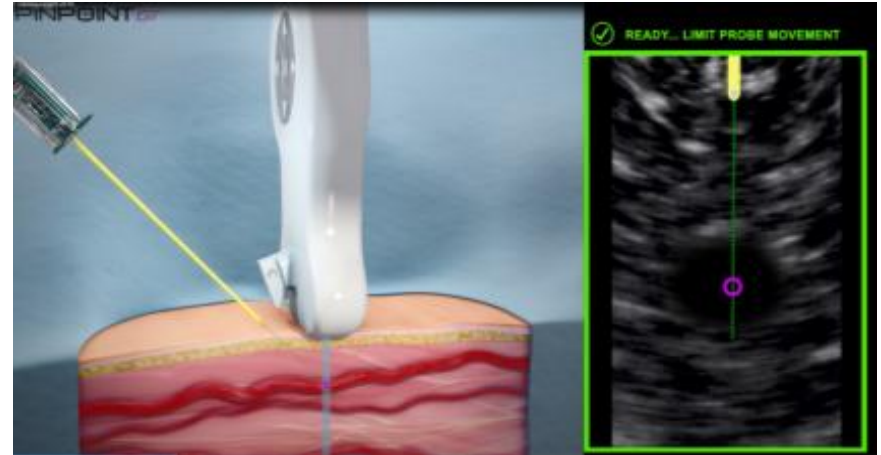
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ULTRASOUND SYSTEM

SHERLOCK 3CG™ Diamond TCS

Site~Rite® 8 Ultrasound System
with Integrated Sherlock 3CG™ Diamond TCS
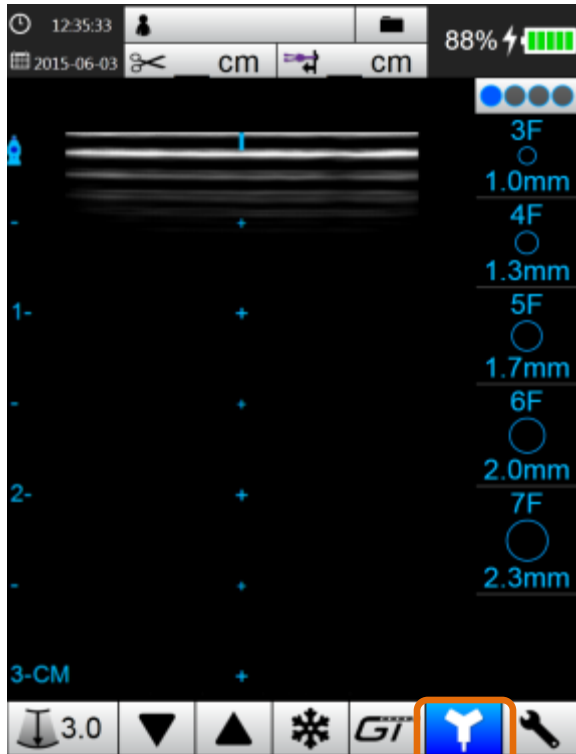
Select the Sherlock 3CG™ TCS Mode Button
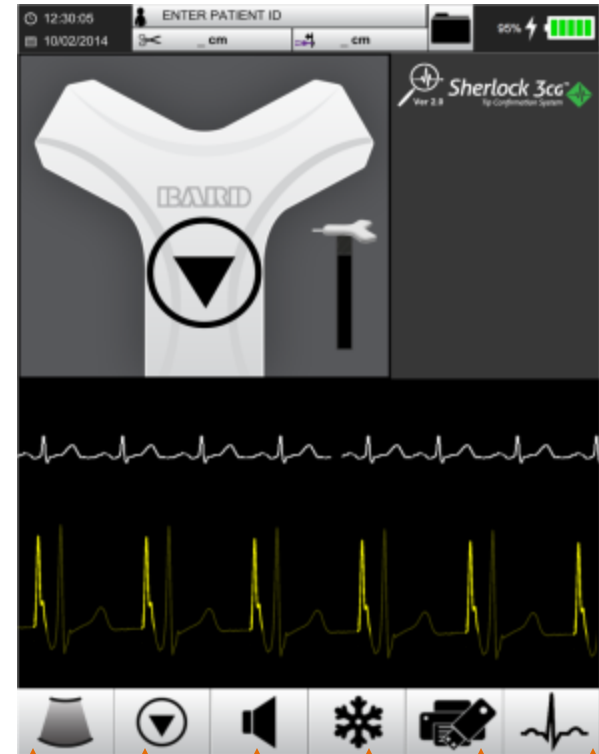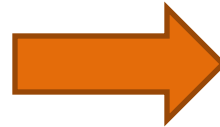
Ultrasound Mode

Calibrate Button

Audio

Freeze

Print/Save

ECG Menu

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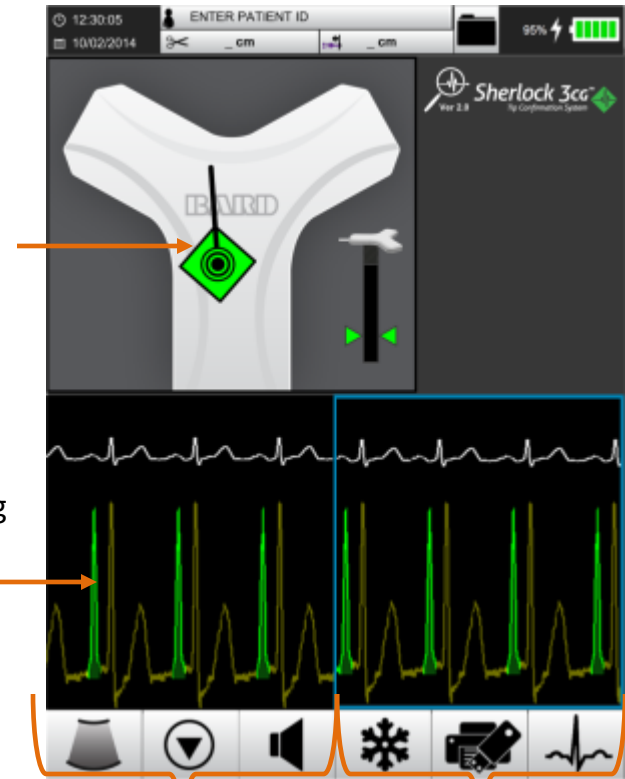## with Integrated SHERLOCK 3CG™ Diamond TCS

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
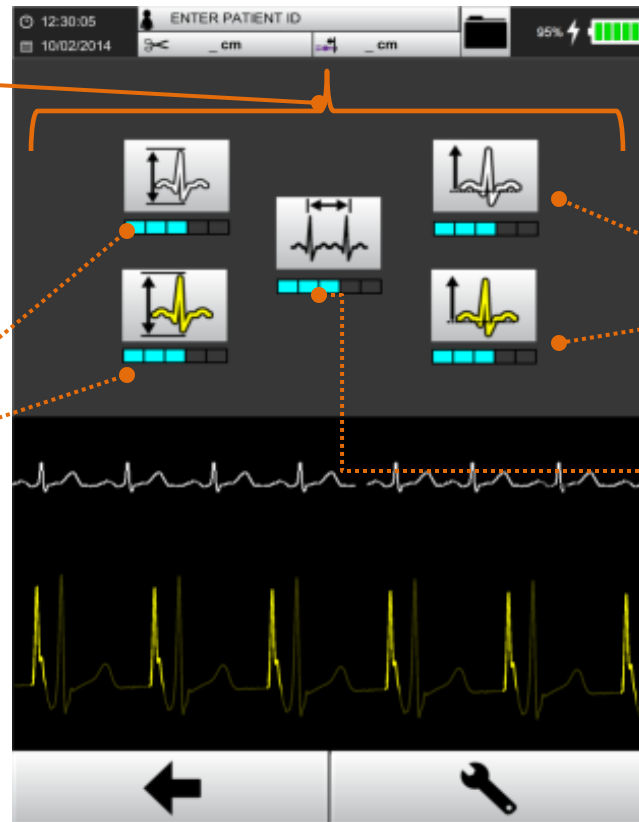## with Integrated Sherlock 3CG™ Diamond TCS

- 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
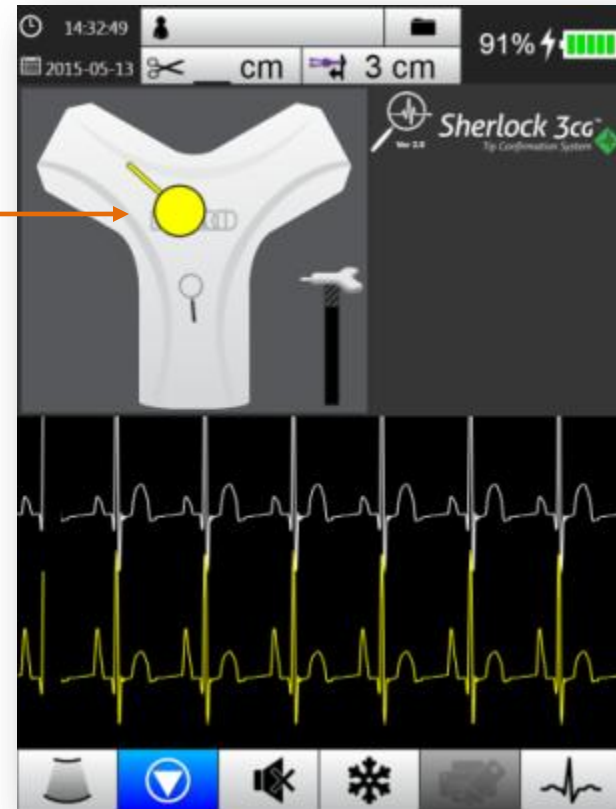
Site~Rite® 8 Ultrasound System
with Integrated Sɪᴛᴇᴇᴋ 3CG™ Diamond TCS

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

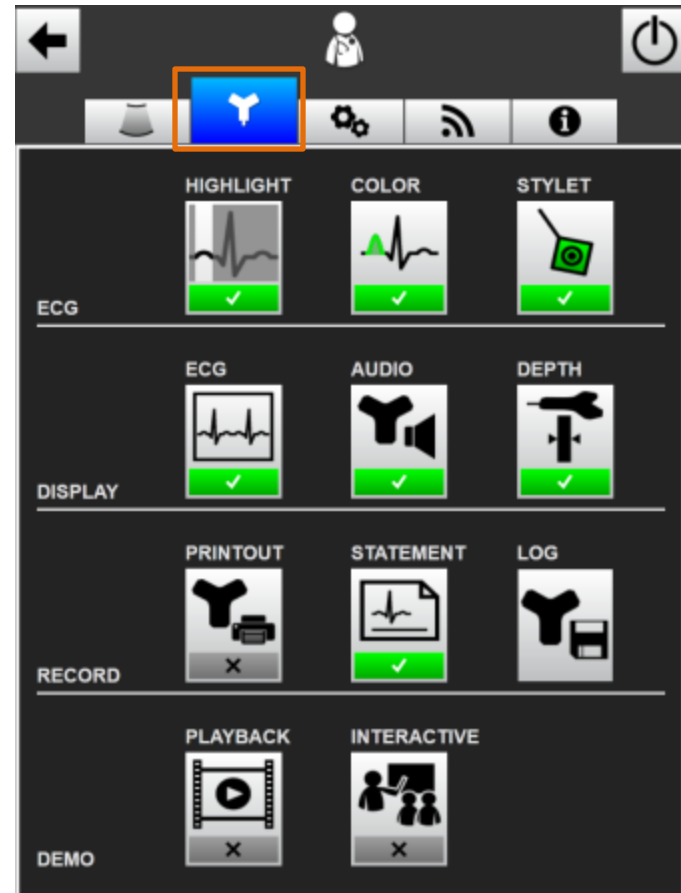**Waveform Scale/Amplitude**

Waveform Level

Speed (Sweep)

Exit   Tools

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

- Select [wrench icon] 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

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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)

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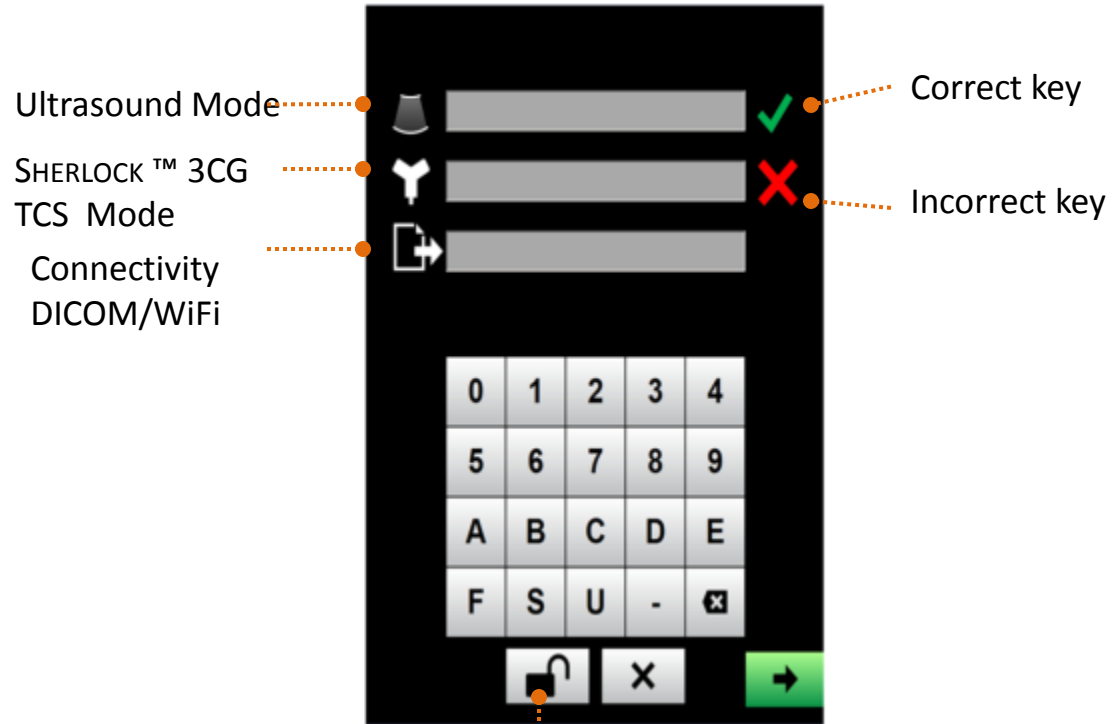
Once code is entered, select the unlock button to activate feature

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SITE~RITE® 8
ULTRASOUND SYSTEM

SECURITY

Site~Rite® 8 Ultrasound System
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

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ACCESSORIES & COMPATIBLE PRODUCTS

8

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
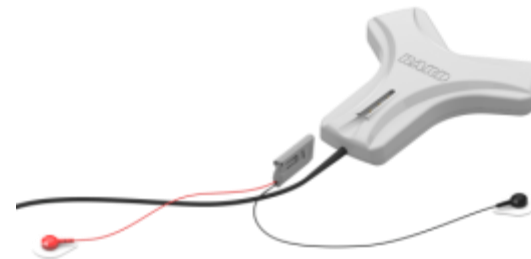## Accessories/Compatible Products

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)
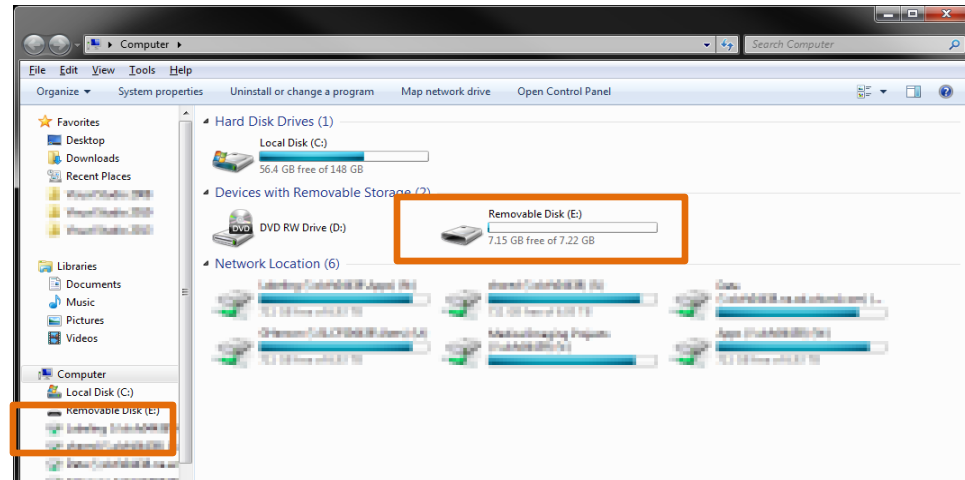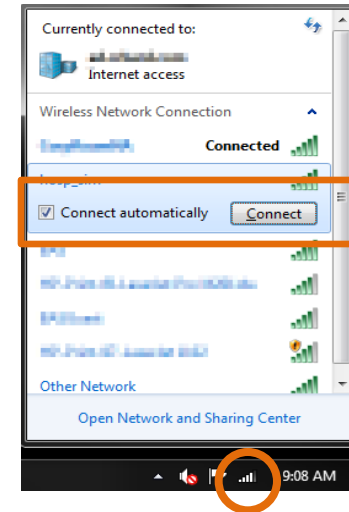
Site~Rite® 8 Ultrasound System
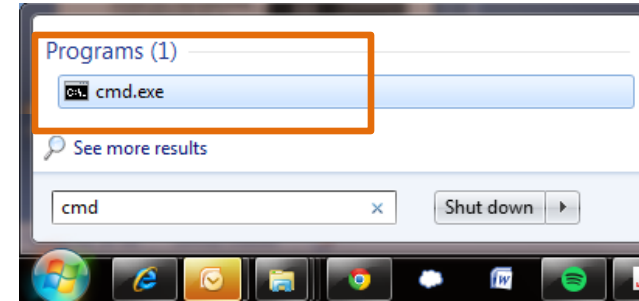## Connectivity

- **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

Step 3: Select the Windows Start icon and type CMD in the text field
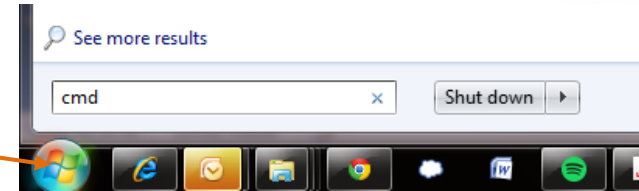
Step 4: select cmd.exe

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:
     - *netsh wlan export profile*
     - Select Enter

<u>Step 5</u>: Type the USB letter

Site~Rite® 8 Ultrasound System
Connectivity

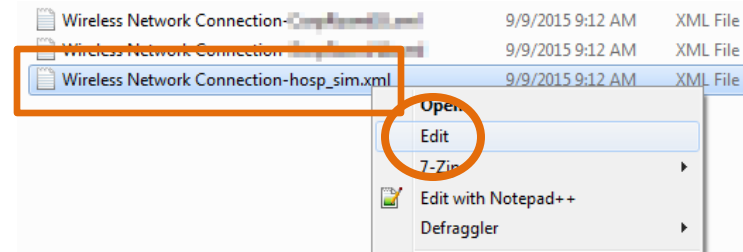- **Setting up WiFi (Secure Network)**
  8. After selecting Enter, the command prompt should show which WiFi profiles were copied to the USB drive.

  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.

Site~Rite® 8 Ultrasound System
Connectivity

- 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.

Before

After

Erase the long number and input the WiFi password between both <keymaterial> values
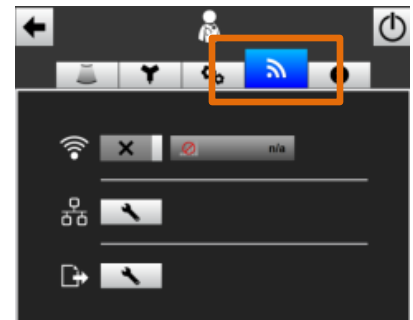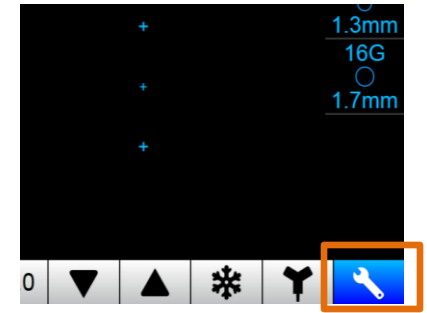
Site~Rite® 8 Ultrasound System
Connectivity

- 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
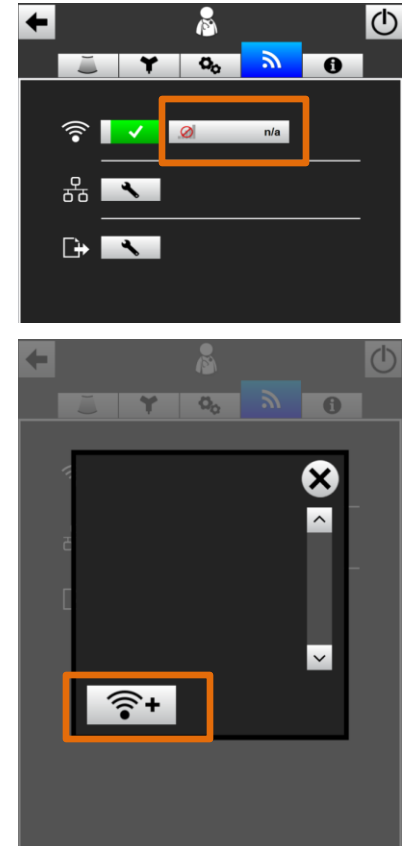
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– Step 4:

  • Select the Select *WiFi Profile* button

– Step 5:

  • Select Add *WiFi Profile* button
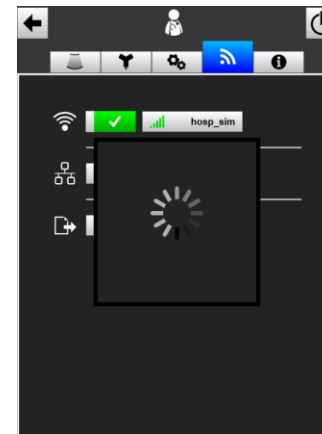
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– Step 6:
  - Wait for the software to detect and import WiFi profile .xml files (from the USB stick)

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

– Step 8:
  - Wait for the connection to complete

– Step 9:
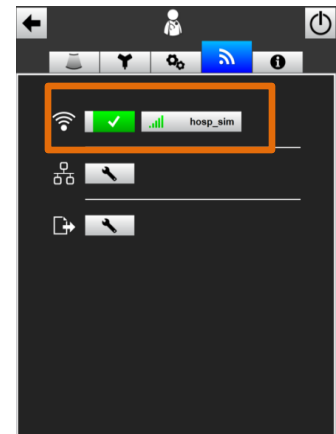 - The WiFi profile should now be connected

Step 8   Step 9

BARD
ACCESS SYSTEMS
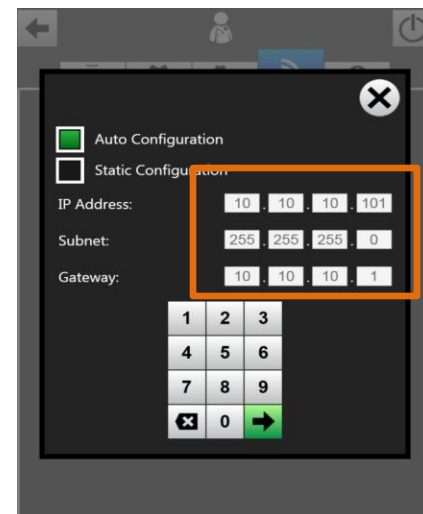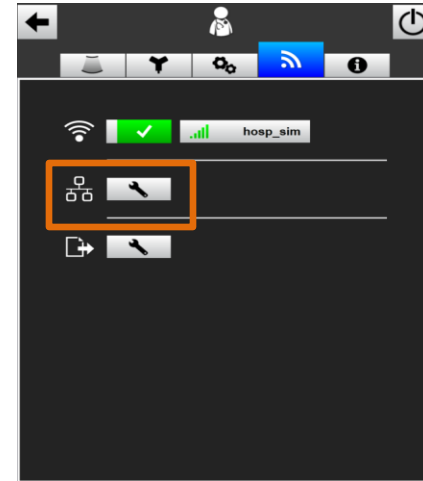
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Connectivity

– 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

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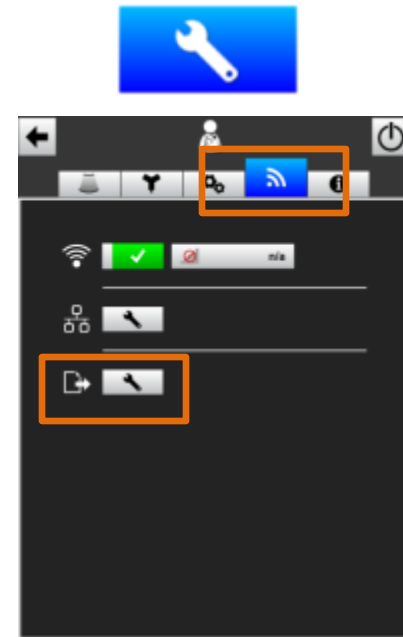
- DICOM Set-up
  - Step 1:
    - To access the DICOM menu, select *Settings*
  - Step 2:
    - Select *Connection Settings* tab
  - Step 3:
    - Select the *DICOM Settings* button

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- 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:
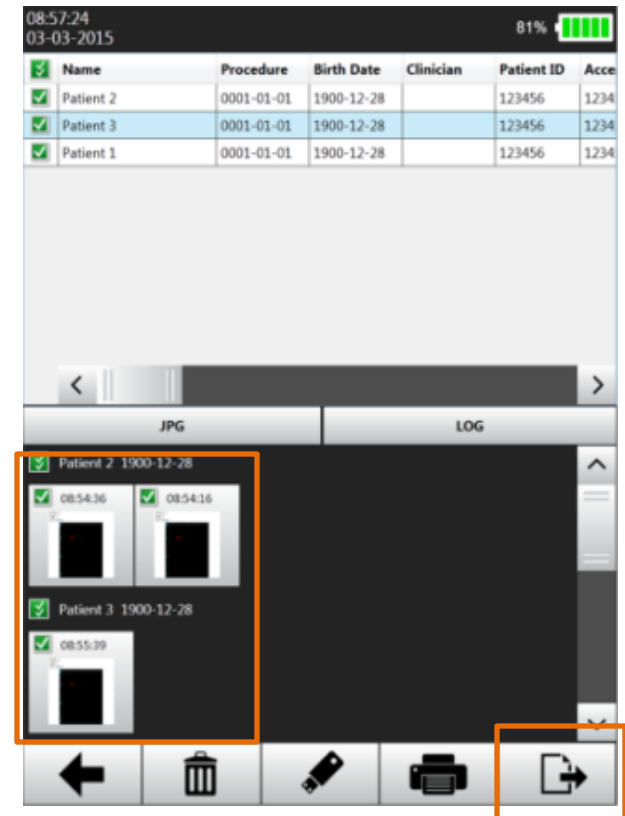   - Select the *Arrow* button to save and exit

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- 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.

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