



Instructions for Use

For use with
Site~Rite® 8 Ultrasound System

BAIRD

Table of Contents

Section		Section	
1 Overview	3	5 Magnet Navigation Only Mode	17
1.1 Indications for Use		Step 1: Prepare Device	
1.2 Post Market Clinical Trial		Step 2: Position Patient and Perform Ultrasound Pre-scan	
1.3 Sherlock 3CG™ TCS Description		Step 3: Measure Catheter Length	
1.4 System Components		Step 4: Prepare Sensor	
1.5 Warnings and Precautions		Step 5: Position Sensor	
2 Assembling the Sherlock 3CG™ TCS	6	Step 6: Perform Initial Magnet Navigation Calibration	
2.1 Attaching the Sherlock 3CG™ TCS Sensor Holster to the Roll Stand		Step 7: Prepare Catheter Sterile Field	
2.2 Connecting the Sherlock 3CG™ TCS Sensor to the Site~Rite® 8 Ultrasound System		Step 8: Access the Vein	
3 Sherlock 3CG™ TCS Information	6	Step 9: Perform Final Magnet Navigation Calibration	
3.1 Switching Between Ultrasound and TCS		Step 10: Insert Catheter	
3.2 Sherlock 3CG™ TCS Graphical Interface		Step 11: Catheter Tip Guidance and Positioning	
3.3 Sherlock 3CG™ TCS Controls and Indicators		6 Trouble Shooting and Error Messages	19
3.4 Sherlock 3CG™ TCS Audio Information		6.1 Error Screens	
3.5 Parallax		6.2 ECG Troubleshooting	
4 Sherlock 3CG™ TCS Catheter Guidance	14	6.3 Magnetic Navigation Troubleshooting	
4.1 Verifying Catheter Compatibility		7 Magnetic Navigation Printing	23
4.2 Catheter Placement		8 Cleaning and Disinfection	24
Step 1: Prepare Device		8.1 Cleaning Procedure	
Step 2: Position Patient and Perform Ultrasound Pre-scan		8.2 Disinfection Procedure	
Step 3: Measure Catheter Length		9 Warranty	24
Step 4: Prepare Sensor		10 Service and Repair	25
Step 5: Position Sensor and ECG electrodes		11 Technical Specifications	25
Step 6: Evaluate External ECG waveform		11.1 Sherlock 3CG™ TCS Sensor and Display Operational and Storage Conditions	
Step 7: Perform Initial Magnet Navigation Calibration		12 Disposal Information	25
Step 8: Prepare Catheter Sterile Field			
Step 9: Access the Vein			
Step 10: Attach Catheter Stylet to Fin Assembly			
Step 11: Perform Final Magnet Navigation Calibration			
Step 12: Insert Catheter			
Step 13: Catheter Tip Guidance and Positioning			
Step 14: Complete Catheter Placement			
Step 15: Procedural Record			



1 Overview

1.1 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 P wave 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.

1.2 Post Market Clinical Trial

The Sherlock 3CG™ Tip Confirmation System (TCS) is Bard's next generation, fully integrated magnetic navigation and ECG-based peripherally inserted central catheter (PICC) tip confirmation technology, which represents the next evolution of the Sherlock™ II Tip Location System and the previously-marketed Sapiens Tip Confirmation System. The Sapiens TCS Post-Market Clinical trial was a prospective, single arm, single center study designed to assess the efficacy of the ECG method for correctly positioning the tip of catheters in adult patients. The primary endpoints were to assess the performance of the Sapiens technology with respect to: (1) the accuracy of the Sapiens technology with regard to correct positioning of the catheter tip when compared to postoperative chest x-ray, (2) safety of using an invasive intracardiac electrode, and (3) compatibility with peripherally inserted central catheters. One hundred fourteen (114) subjects received a PICC. Final PICC tip location was confirmed at the cavoatrial junction or within +/- 1 cm in 99.1% (113/114) of the subjects. No adverse events were reported.

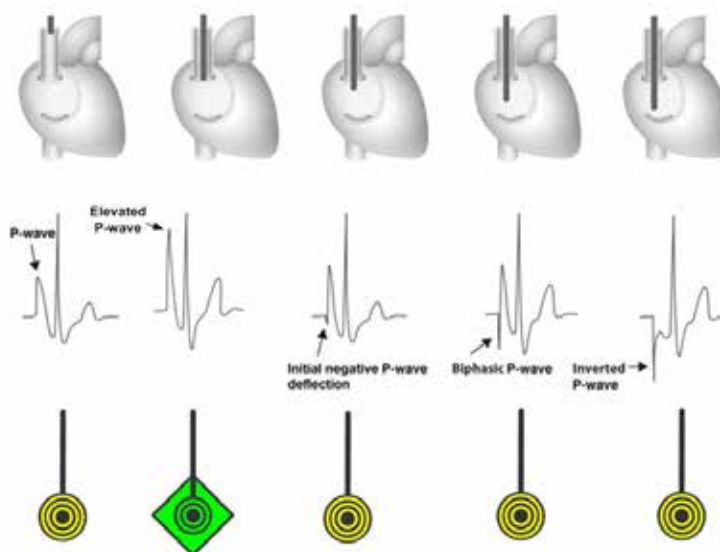
1.3 Sherlock 3CG™ TCS Description

The Sherlock 3CG™ TCS is designed to aid in PICC tip positioning through magnet navigation and ECG technology. It is designed to operate with Bard Access Systems' catheter kits labeled [] and "Sherlock 3CG™ TPS Stylet".

Note: When used in conjunction with catheter kits labeled [] the device provides magnetic navigation information but does not allow positioning through ECG technology.

ECG Positioning

The Sherlock 3CG™ TCS displays an ECG signal detected by the intravascular and body electrodes, which can be used for catheter tip positioning. In patients with a distinct P-wave, the P-wave will increase in amplitude as the catheter approaches the top of the cavoatrial junction. As the catheter advances into the right atrium, the P-wave will decrease in amplitude and may be biphasic or invert. In addition to the ECG signal, the magnet tracking stylet icon is augmented with the shape and color changes shown below.



Note: In instances where the P-wave is not present, not identifiable, or intermittent the stylet icon will remain a yellow circle.

Magnetic Navigation

Permanent magnets are encapsulated within the tip of the Sherlock 3CG™ TPS Stylet. No magnetic energy is generated by the Site~Rite® 8 Ultrasound System or the sensor. The Sherlock 3CG™ TCS displays the relative position of the magnet-tipped stylet to the sensor. It does this in two steps:






1. Sherlock 3CG™ TCS takes a background measurement of the ambient magnetic field during the calibration cycle.
2. Sherlock 3CG™ TCS senses changes in the magnetic field. When the Sherlock 3CG™ TCS detects the stylet, it displays the stylet tip location and orientation.

1.4 System Components

Ultrasound probe:



Authorized accessories include:

- Site~Rite® 8 Ultrasound System
- Sherlock 3CG™ TCS Sensor
- Sherlock 3CG™ TPS Stylet (included with specially marked central venous catheter kits) []
- Sherlock™ TLS Stylet (included with specially marked central venous catheter kits) []
- Fin Assembly (included with specially marked central venous catheter kits) []
- Sherlock™ Sensor Holder (ordered separately or with specially marked central venous catheter kits) [] or [].
- Bard Access Systems' supplied printer (purchased separately).

1.5 Warnings and Precautions

This section specifies warnings and precautions specific to the functionality of the Sherlock 3CG™ TCS.

- See the Bard Access Systems' catheter Instructions for Use (IFU) for possible complications associated with peripherally inserted central catheter (PICC) placements and ECG positioning.

Warnings

- Warning:** This product should only be operated by qualified medical personnel.
- Warning:** Do not power the Sherlock 3CG™ TCS in the presence of noncontained flammable anesthetic gases. Explosion may result.
- Warning:** Do not attempt to sterilize the sensor. Damage to the equipment may occur.
- Warning:** The following actions void the warranty of the Sherlock 3CG™ TCS and may result in injury or equipment damage.
 - Opening or servicing the Site~Rite® 8 Ultrasound System with Sherlock 3CG™ TCS by anyone other than Bard Access Systems' authorized service personnel.
 - Removing system labels by anyone other than Bard Access Systems' authorized service personnel.
 - Connecting the sensor or applied patient components to any unauthorized system or accessory. Refer to Section 1.4 for complete components.
 - Installation of unauthorized software.
 - Modification of system software settings without authorization by Bard Access Systems.



- Warning:** If the Site~Rite® 8 Ultrasound System with Sherlock 3CG™ TCS is visibly damaged, discontinue use immediately. Use of the damaged system may result in injury or equipment damage.
- Warning:** Do not submerge the sensor in liquid or allow fluid to enter the connectors. Damage to the equipment may occur.
- Warning:** Sherlock 3CG™ TCS is not intended to diagnose or treat disease.
- Warning:** Only Bard Access Systems' authorized service personnel should attempt to service this equipment. 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.
- Warning:** Do not rely on ECG signal detection for catheter tip positioning when interpretation of the external or intravascular ECG P-wave is difficult.
For example, when:
- P-wave is not present
 - P-wave is not identifiable
 - P-wave is intermittent
- These conditions may be a result of heart rhythm abnormalities, atrial fibrillation, atrial flutter, severe tachycardia or presence of cardiac rhythm devices. In these cases, rely on magnetic navigation and external measurement for tip positioning and use chest x-ray or fluoroscopy to confirm catheter tip location, as indicated by institutional guidelines and clinical judgment.
- Warning:** Do not rely on ECG signal detection for catheter tip positioning when there are no observable changes in the intravascular P-wave. In this case, rely on magnetic navigation and external measurement for tip positioning and use chest X-ray or fluoroscopy to confirm catheter tip location, as indicated by institutional guidelines and clinical judgment.
- Warning:** Do not place and/or use the Sherlock 3CG™ TCS 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. The magnetic and the RF fields associated with the MRI environment may interfere with the display of ECG waveforms. Consult the MRI manufacturer for more information.
- Warning:** Do not remove Sherlock 3CG™ TCS enclosures. To avoid electrical shock, use only the power cord supplied with the system and connect only to properly grounded wall outlets. Only Bard Access Systems qualified personnel should service the system
- Warning:** Ensure all connecting cables and connections are electrically insulated and do not come into contact with other electrical cables or metal surfaces.
- Warning:** Ensure that the patient does not directly or indirectly contact non-insulated metal surfaces.
- Warning:** Place skin electrodes carefully at locations indicated in these Instructions for Use and ensure good skin-electrode contact. Failure to do so may cause unstable ECG waveforms and/or ECG waveforms that are not described in these Instructions for Use. In such a case, rely on magnetic navigation and external measurement for tip positioning and use chest X-ray or fluoroscopy to confirm catheter tip location, as indicated by the institutional guidelines and clinical judgment.

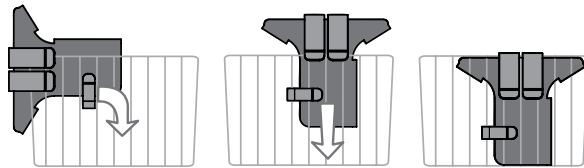
Precautions

- Caution:** Federal (U.S.A) law restricts this device to sale by or on the order of a physician.
- Caution:** Do not pull the cables to disconnect from the system. Pulling the cable may damage the cable or cable connection.
- Caution:** Excessive twisting or bending of the sensor cable may cause system failure.
- Caution:** Use only cleaning and disinfection products approved by Bard Access Systems. Failure to do so may damage the device.
- Caution:** Do not use excessive force when connecting or disconnecting the Fin Assembly to or from the sensor or equipment damage may occur.
- Caution:** When the sensor is not in use, store in the holster, roll stand basket or other secure location to avoid damage.
- Caution:** Do not allow any ferromagnetic objects, e.g., wired undergarments, metal instruments, watches, jewelry, electronics, metal bedrails, etc. to be within 12 in (30 cm) of the sensor once the calibration process is complete. These items may interfere with the sensor's ability to accurately locate the Sherlock™ Stylet tip.
- 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 ft (1.5 m).
- Caution:** Electrodes should be applied only to intact, clean skin (e.g., not over open wounds, lesions, infected or inflamed areas).
- Caution:** Placement of red electrode outside of the correct region may result in reduced ECG performance. See Section 4.
- Caution:** Discontinue electrode use immediately, if skin irritation occurs.

2 Assembling the Sherlock 3CG™ TCS

2.1 Attaching the Sherlock 3CG™ TCS Sensor Holster to the Roll Stand

The Sherlock 3CG™ TCS Sensor can be placed in the holster when not in use. To attach the sensor holster to the roll stand see illustrations below.



Caution: When the sensor is not in use, store in the holster, roll stand basket or other secure location to avoid damage.


2.2 Connecting the Sherlock 3CG™ TCS Sensor to the Site~Rite® 8 Ultrasound System



The Sherlock 3CG™ TCS Sensor connects to the USB port on the display.

3 Sherlock 3CG™ TCS Information

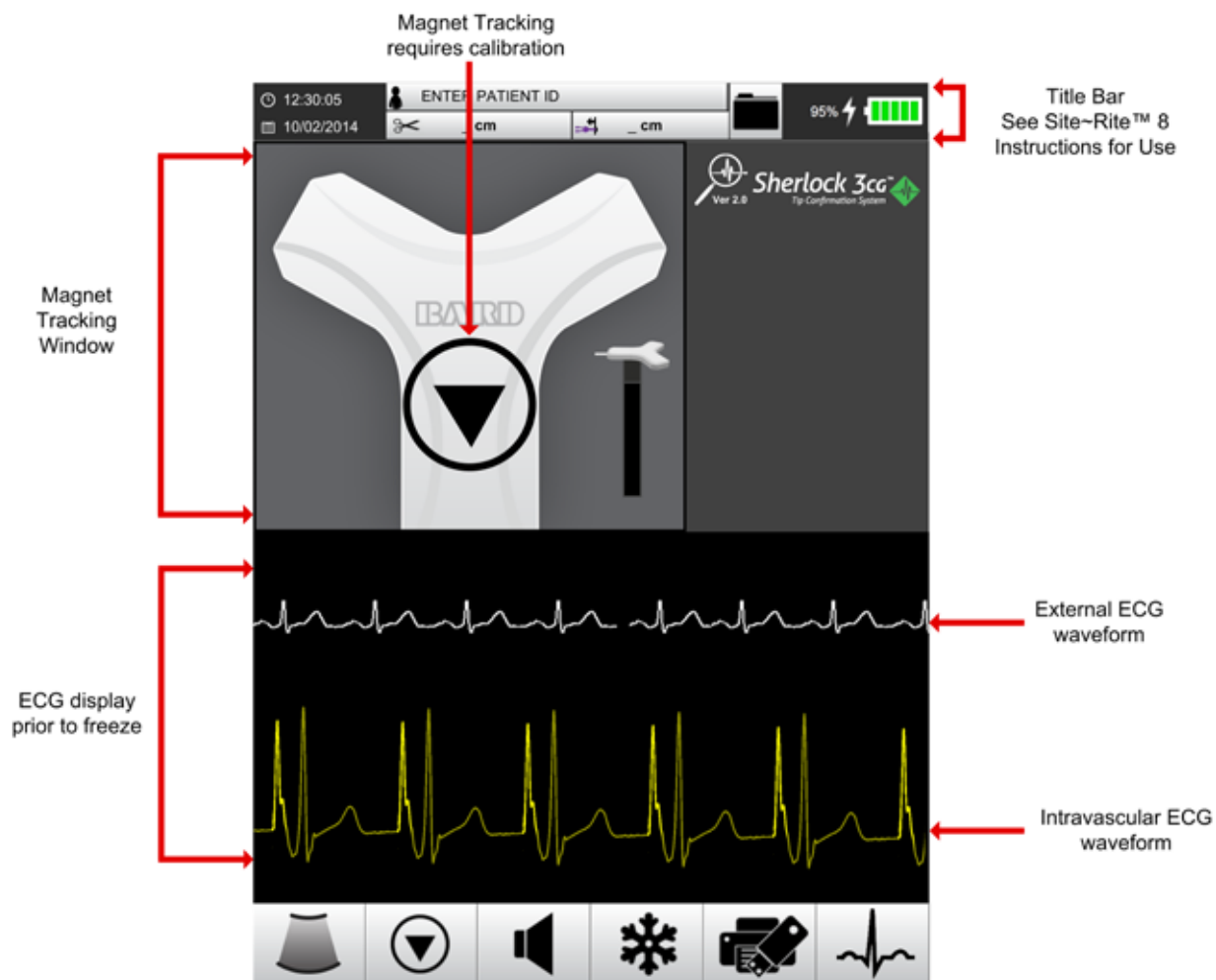
3.1 Switching Between Ultrasound and TCS

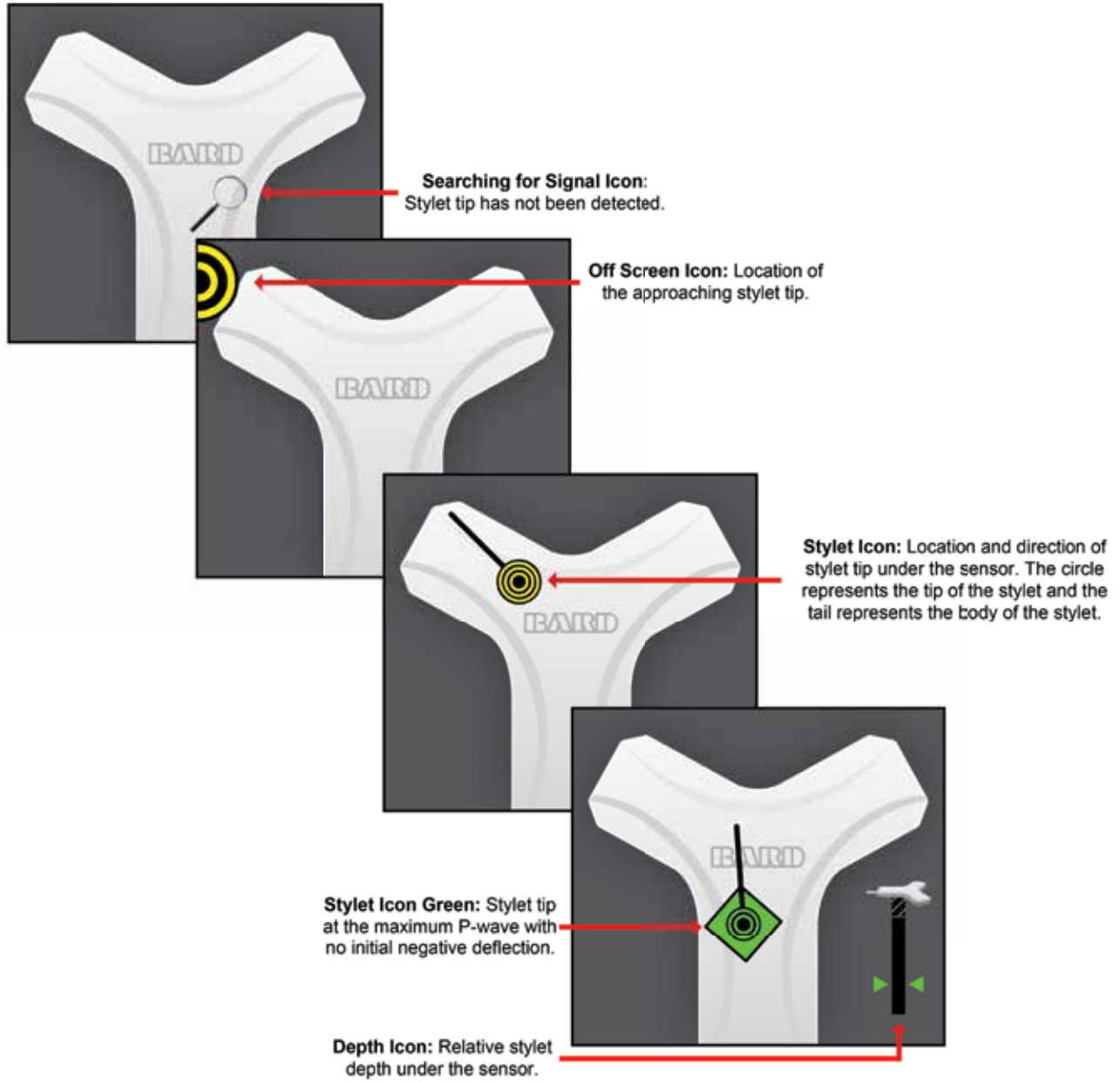
To switch from Ultrasound mode to TCS mode select the TCS icon [] via the touchscreen or the buttons on the probe.

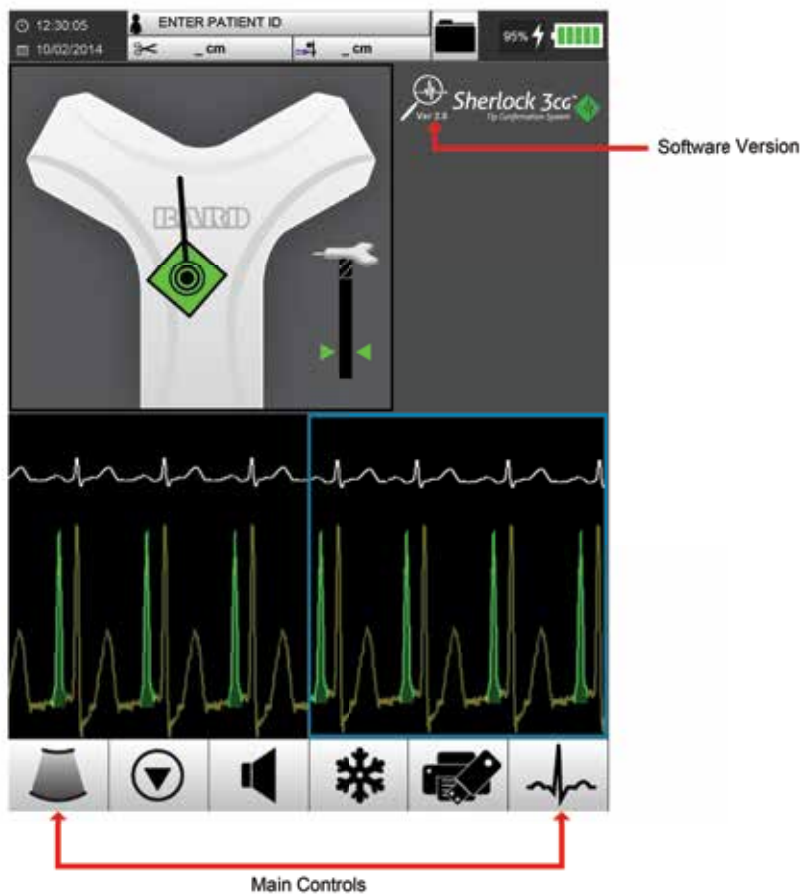
To switch from TCS Mode to Ultrasound Mode, select the ULTRASOUND icon [] via the touchscreen or the buttons on the probe.

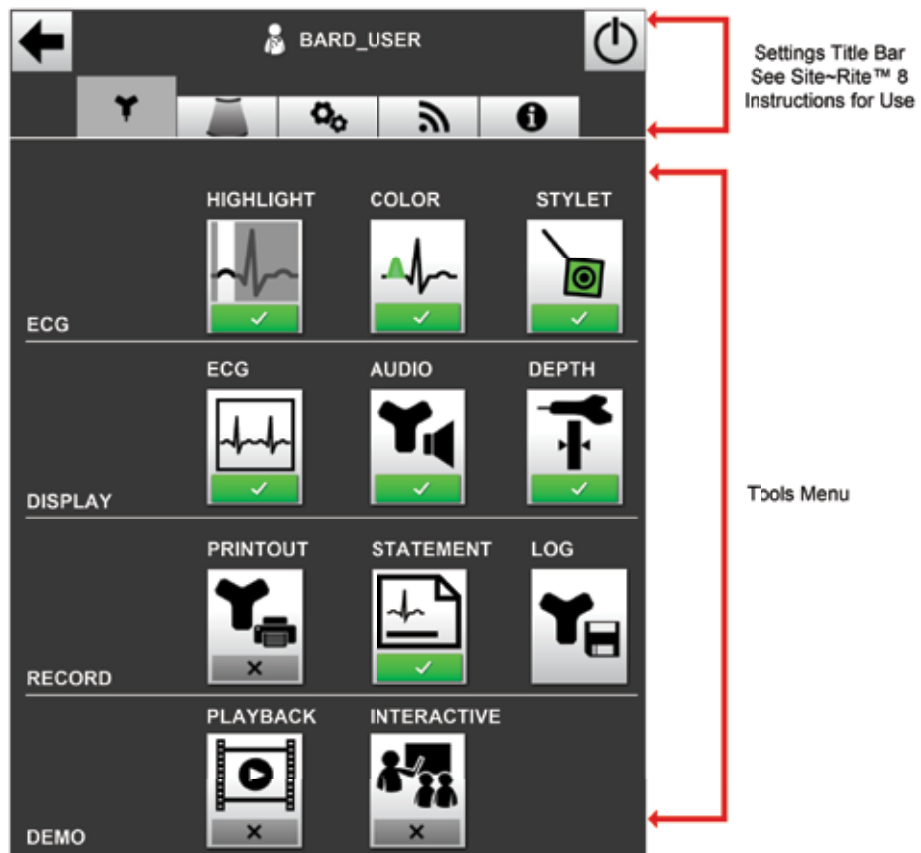
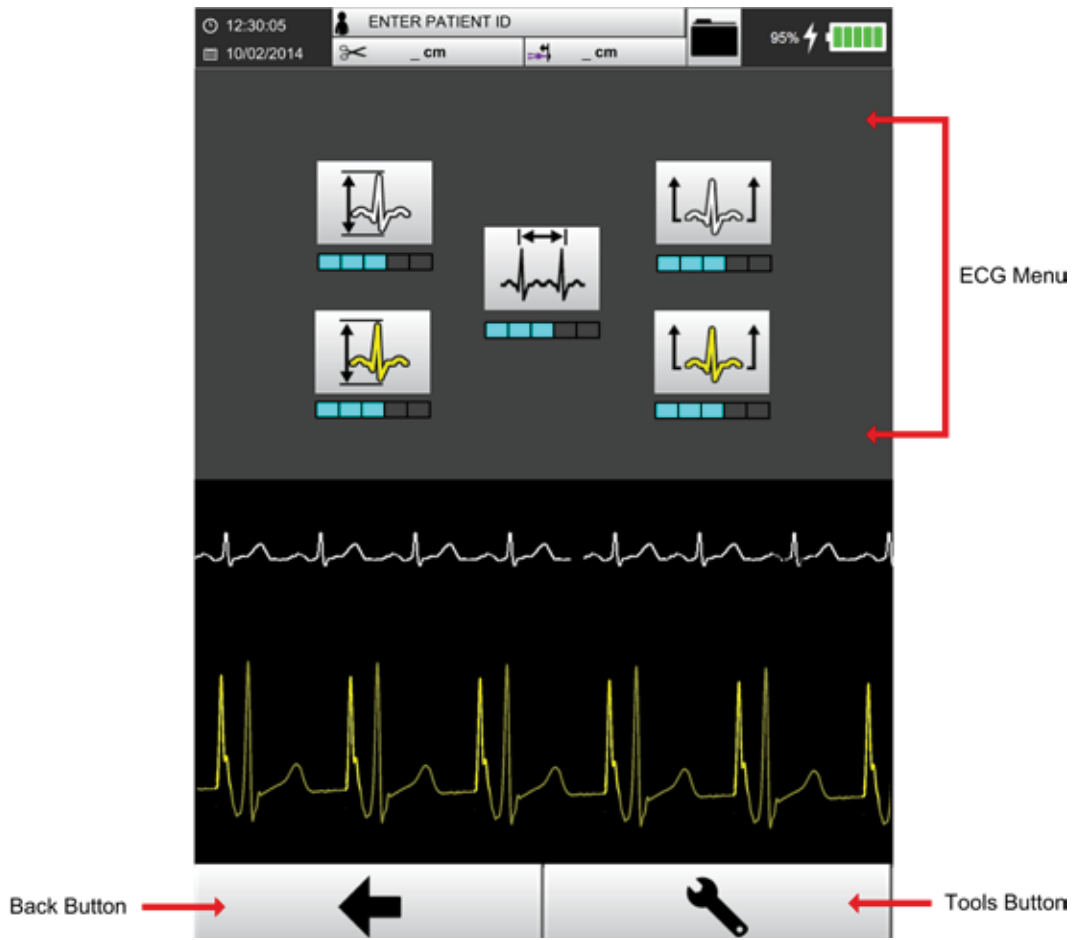


3.2 Sherlock 3CG™ TCS Graphical Interface











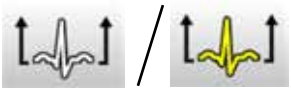







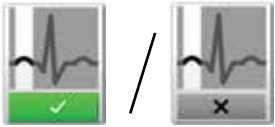














3.3 Sherlock 3CG™ TCS Controls and Indicators

Main Controls	
	Ultrasound Mode: Select to exit the TCS Mode and enter Ultrasound Mode.
	Calibrate Button: Select to calibrate magnet navigation.
	Audio On: Select to mute the magnet navigation audio.
	Audio Mute: Select to turn the magnet navigation audio on.
	Freeze: Select to copy the current ECG waveforms from the Main Screen to the Reference Screen.
	Print: Select to Print and Save the ECG and magnet navigation data. Data will be printed to paper and saved to a file on an external USB storage device.
	ECG Menu: Select to open the ECG Menu.

ECG Menu	
	Scale: Select to adjust the ECG signal amplitude of the external (white) or intravascular (yellow) ECG waveforms on the Main Screen.
	Level Up: Select to increase the vertical position of the external (white) or intravascular (yellow) ECG waveforms on the Main Screen.
	Speed: Select to adjust the speed of the ECG waveforms on the Main Screen.
	Exit: Select to close the ECG Menu.

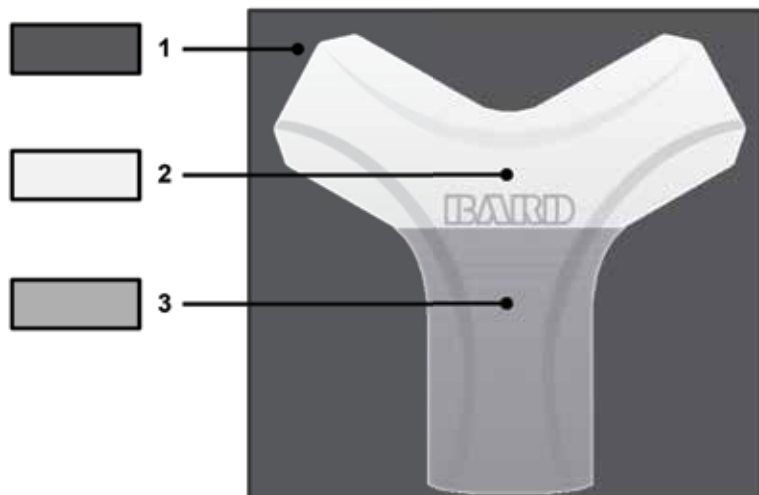
	<p>Tools: Select to open the Tools Menu.</p>
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Tools Menu	
	<p>P-wave Highlighting: Select to enable or disable highlighting the P-wave on the ECG signals.</p>
	<p>ECG Color: Select to enable or disable the intravascular (yellow) ECG waveform changing color based on ECG changes.</p>
	<p>Stylet Color: Select to enable or disable the stylet icon changing color and shape based on ECG changes.</p>
	<p>Depth Gauge: Select to enable or disable the depth gauge.</p>
	<p>ECG Toggle: Select to toggle between ECG & Magnet and Magnet Only Navigation . Magnet Navigation Only mode is compatible with PICCs labeled with []. ECG and Magnet Navigation mode is compatible with PICCs labeled with [].</p>
	<p>Magnet Navigation Audio: Select to enable or disable the initial state of magnet navigation audio.</p>
	<p>Confirmation Statement Printing: Select to enable or disable the confirmation statement printing on the ECG printout.</p>
	<p>Magnet Navigation Printout: Select to enable or disable the magnet navigation printout.</p>
	<p>Log: Select to stop and save the ECG recording.</p>
	<p>Demonstration: Select to initiate playback / interactive demonstration mode respectively. For training, contact your Bard Access Systems' Sales Representatives.</p>
	<p>Exit: Select to close the Tools Menu.</p>

3.4 Sherlock 3CG™ TCS Audio Information

When the audio is on, there are three possible tones:

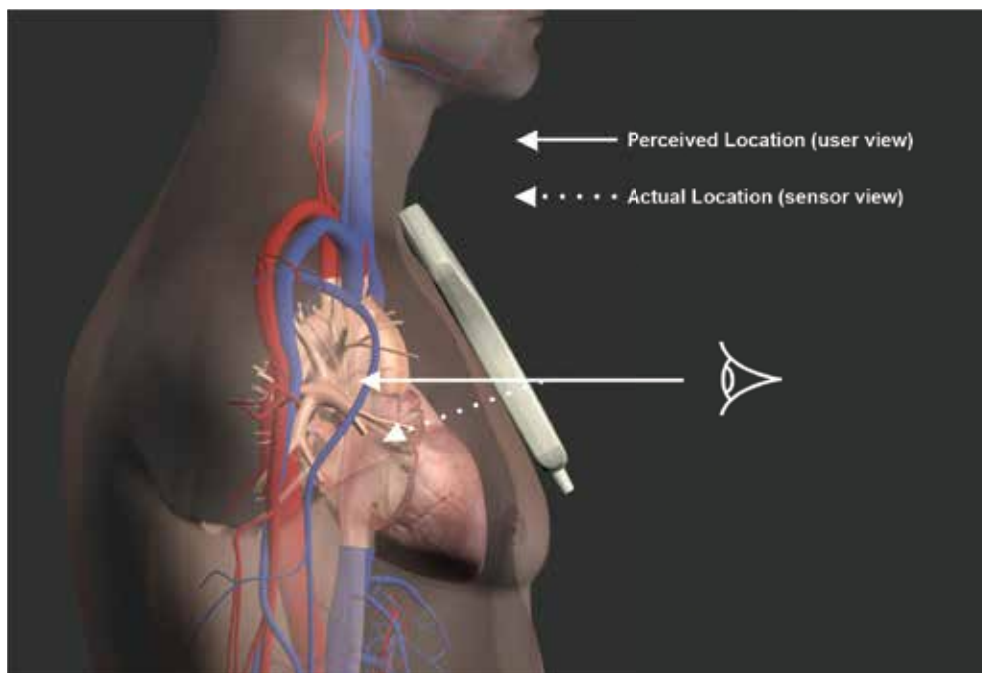
- Tone 1: The stylet tip is detected and the tip is not under the sensor.
- Tone 2: The stylet tip is under the sensor and is at or above the Bard logo.
- Tone 3: The stylet tip is under the sensor and below the Bard logo.



Note: Audio signals are only applicable to the magnetic navigation capability of the device.

3.5 Parallax

When a patient's chest is not flat, the sensor will rest at an angle, causing an effect known as parallax. Parallax is the difference in the apparent location of an object from two different points of view. The difference between the point of view of the sensor and the user can be several centimeters.







Note: Parallax should only be considered in relation to magnetic navigation.

4 Sherlock 3CG™ TCS Catheter Guidance

4.1 Verifying Catheter Compatibility

The Sherlock 3CG™ TCS on Site~Rite® 8 Ultrasound System is compatible with the following PICCs as described below:

- The PICCs indicated with [] are compatible for ECG and Magnet Navigation [].
- The PICCs indicated with [] are only compatible for Magnet Navigation [].

4.2 Catheter Placement

Step 1: Prepare Device

- Connect the sensor to the Site~Rite® 8 Ultrasound System via USB cable.
- Verify that the ECG flatline signal is scrolling.
- Verify the battery charge is sufficient for the procedure.
- Enter Patient Information as needed.

Step 2: Position Patient and Perform Ultrasound Pre-scan

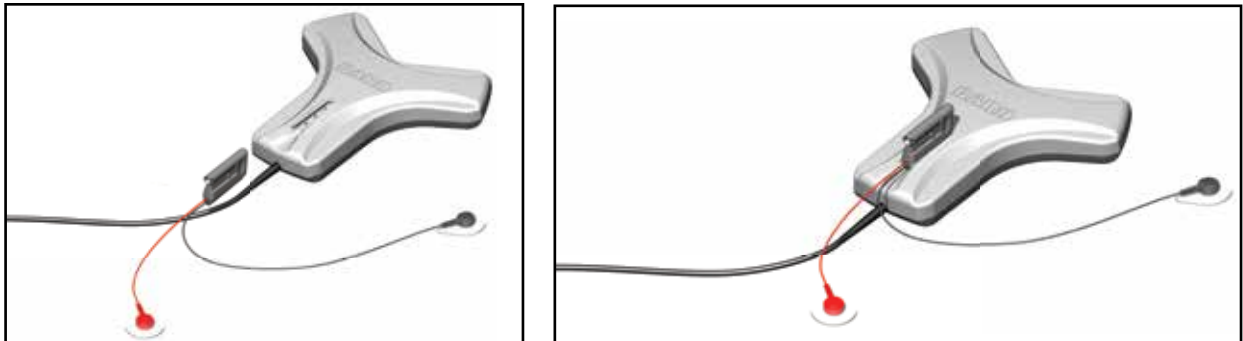
- Refer to the Bard Access Systems' Site~Rite® 8 Ultrasound System Instructions for Use.

Step 3: Measure Catheter Length

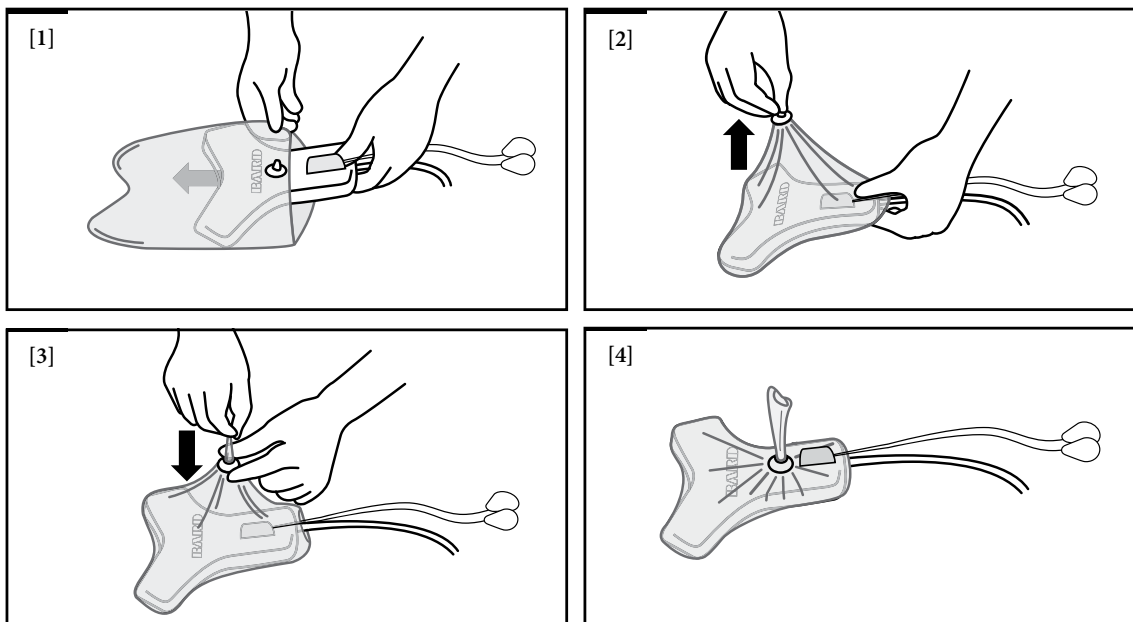
- Refer to Bard Access Systems' Catheter Instructions for Use.

Step 4: Prepare Sensor

- Slide the Fin Assembly on to the sensor until fully seated.



- Place sensor in the sensor holder with the fin and ECG electrodes remaining outside the holder and tighten the cinch ring.



Step 5: Position Sensor and ECG electrodes

- Remove the adhesive backing from the sensor holder and place the sensor directly on the patient's skin with the adhesive side down. Place the sensor as flat as possible for best results.

Note: The sensor should be positioned the same for left or right side placements.

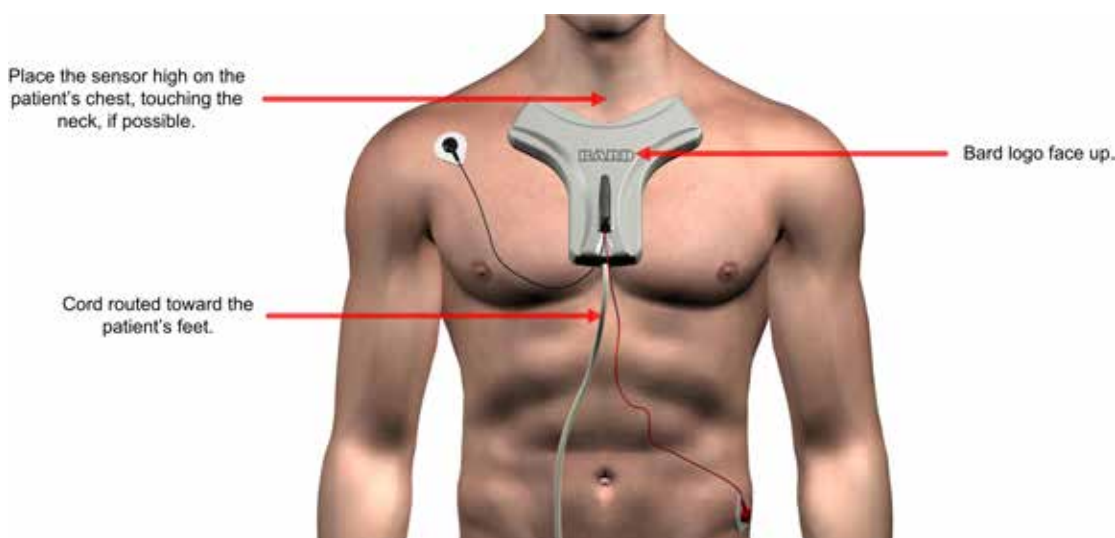
- Prepare and attach external ECG electrodes per the following steps:

- Ensure electrode locations are oil-free and completely dry.

Caution: Electrodes should be applied only to intact, clean skin (e.g., not over open wounds, lesions, infected or inflamed areas).

- Attach electrodes to all lead wires.
- Remove backing and press electrodes firmly onto skin at the specified locations.
 - Place **black** electrode on patient's lower **right** shoulder.
 - Place **red** lead on patient's lower **left** side, inferior to the umbilicus and laterally along the mid-axillary line.

Caution: Placement of red electrode outside of this region may result in reduced ECG performance.



Warning: Place skin electrodes carefully at locations indicated in these Instructions for Use and ensure good skin-electrode contact. Failure to do so may cause unstable ECG waveforms and/or ECG waveforms that are not described in these Instructions for Use. In such a case, rely on magnetic navigation and external measurement for tip positioning and use chest X-ray or fluoroscopy to confirm catheter tip location, as indicated by the institutional guidelines and clinical judgment.

Caution: Discontinue electrode use immediately, if skin irritation occurs.


Tips:

- Prior to securing the sensor holder to the patient, it may be necessary to clean the skin and remove excess hair.
- Do not move the sensor after it is secure. Best results will be achieved if the patient remains still and the sensor is not placed on open wounds, over bandages, drapes, gowns or other coverings.

Step 6: Evaluate External ECG waveform

- Refer to the Bard Access Systems' catheter Instructions for Use.

Step 7: Perform Initial Magnet Navigation Calibration

- Calibrate the Sherlock 3CG™ TCS by selecting CALIBRATE [] prior to setting up the sterile field to ensure there is no environmental interference.

Tip: If calibration fails, remove any items that may be causing magnetic interference (e.g., active motor driven equipment, monitor leads, cell phones, name tags, jewelry, etc.).

Step 8: Prepare Catheter Sterile Field

- Refer to the Bard Access Systems' catheter Instructions for Use.


Step 9: Access the Vein

- Refer to the Bard Access Systems' Site~Rite® 8 Ultrasound System Instructions and Bard Access Systems' catheter Instructions for Use.

Step 10: Attach Catheter Stylet to Fin Assembly

- Refer to Bard Access Systems' catheter Instructions for Use.

Step 11: Perform Final Magnet Navigation Calibration

- Ensure the catheter tip is at least 12 inches (30 cm) away from the sensor before calibrating.
- Select CALIBRATE [] immediately prior to catheter insertion.
- Once calibration is complete, ask the patient to remain still and do not reposition the patient.
- Refer to Bard Access Systems' catheter instructions for use for catheter insertion.


Step 12: Insert Catheter

- Refer to Bard Access Systems' catheter Instructions for Use for catheter insertion.

Step 13: Catheter Tip Guidance and Positioning

- Refer to Bard Access Systems' catheter Instructions for Use for catheter insertion.
- Initially a searching magnifying glass will indicate that the stylet tip is outside the sensor range.
- Use a slow steady motion while advancing the catheter.

Magnetic Navigation and Catheter Tip Navigation

- As the stylet tip approaches the sensor, an icon appears at the edge of the screen indicating the approach of the stylet tip.
- When the stylet is under the sensor, the stylet and depth icons will display the location, orientation, and depth of the stylet in relation to the sensor.
- Advance the catheter slowly to achieve optimal performance (1 cm per second). There may be a slight delay from the time the catheter is moved until the stylet icon moves on the display. Advancing the catheter too quickly may result in erratic movements of the stylet icon on the display.
- Insert the catheter until the magnetic navigation shows the stylet moving consistently downward.
- Continue to slowly advance catheter until the catheter is inserted to the external measurement as determined in the Bard Access Systems' catheter instructions for use.
- Select [] to freeze / save the current ECG waveforms in the reference screen.

Note: select the minimized magnetic navigation window to return to a maximized state

ECG Positioning

- In patients with a distinct P-wave, the P-wave will increase in amplitude as the catheter approaches the cavoatrial junction. As the catheter advances into the right atrium, the P-wave will decrease in amplitude and may become biphasic or inverted.

Note: If the intravascular ECG waveform is not displayed, flush the catheter with saline. If the problem continues, check the stylet-to-fin connection.

- To freeze and compare ECG waveforms select [] to copy ECG waveforms in the reference screen.


Note: Pause to let the rhythm settle before freezing the reference ECG waveforms.


- For final catheter positioning, refer to Bard Access Systems' catheter instructions for use.

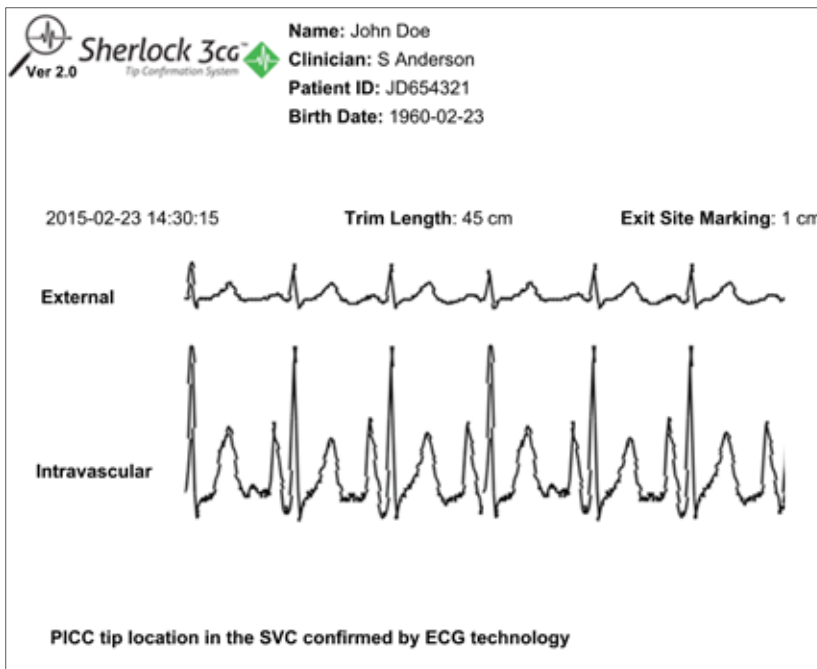
Step 14: Complete Catheter Placement

- Complete catheter insertion, securement and remaining procedure according to the catheter Instructions for Use and facility protocol.

Step 15: Procedural Record

- Select [] to print / save a procedural record.

Note: Selecting [] will send the procedural record to a storage device and/or an approved printer, if connected. A typical printout is shown below.



5 Magnet Navigation Only Mode

Step 1: Prepare Device

- Connect the sensor to the Site~Rite® 8 Ultrasound System via USB cord.
- Verify the battery charge is sufficient for the procedure.
- Enter patient Information as needed.

Step 2: Position Patient and Perform Ultrasound Pre-scan

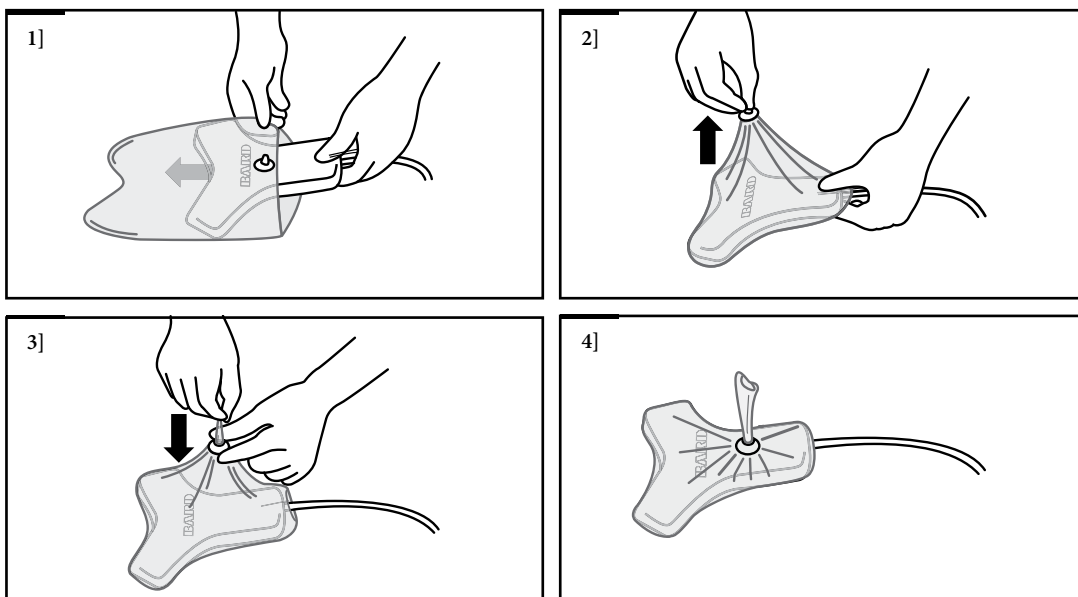
- Refer to the Bard access Systems' Site~Rite® 8 Ultrasound System Instructions for Use.

Step 3: Measure Catheter Length

- Refer to Bard Access Systems' Catheter Instructions for Use.

Step 4: Prepare Sensor

- Place the Sherlock 3CG™ TCS Sensor in the sensor holder and tighten the cinch ring.

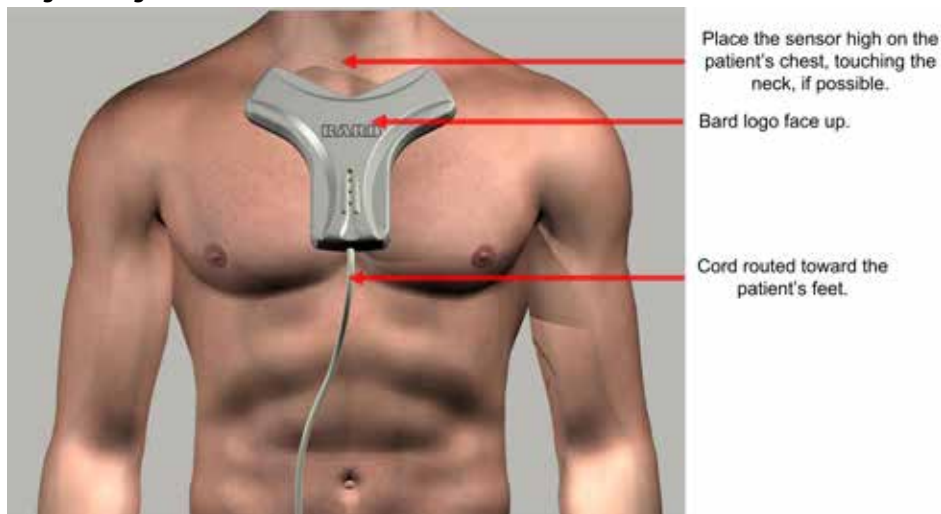


Step 5: Position Sensor

- Remove the adhesive backing from the sensor holder and place the sensor directly on the patient's skin with the adhesive side down. Place the sensor as flat as possible for best results.

Note: The sensor should be positioned the same for left or right side placements.

Step 6: Perform Initial Magnet Navigation Calibration



- Calibrate the Sherlock 3CG™ TCS by selecting CALIBRATE [] prior to setting up the sterile field to ensure there is no environmental interference.

Tip: If calibration fails, remove any items that may be causing magnetic interference (e.g. active motor driven equipment, monitor leads, cell phones, name tags, jewelry, etc.).

Step 7: Prepare Catheter Sterile Field

Refer to the Bard Access Systems' catheter Instructions for Use.

Step 8: Access the Vein

- Refer to the Bard Access Systems' Site~Rite® 8 Ultrasound System Instructions for Use and Bard Access Systems' catheter Instructions for Use.

Step 9: Perform Final Magnet Navigation Calibration

- Ensure the catheter tip is at least 12 inches (30 cm) away from the sensor before calibrating.
- Select CALIBRATE [] immediately prior to catheter insertion.
- Once calibration is complete, ask the patient to remain still and do not reposition the patient.
- Refer to Bard Access Systems' catheter Instructions for Use for catheter insertion.

Step 10: Insert Catheter

- Refer to Bard Access Systems' catheter Instructions for Use for catheter insertion.

Step 11: Catheter Tip Guidance and Positioning

- Refer to Bard Access Systems' catheter Instructions for Use for catheter insertion.
- Initially a searching magnifying glass will indicate that the stylet tip is outside the sensor range.
- Use a slow steady motion while advancing the catheter.

Magnetic Navigation

- As the stylet tip approaches the sensor, an icon appears at the edge of the screen indicating the approach of the stylet tip.
- When the stylet is under the sensor, the stylet and depth icons will display the location, orientation, and depth of the stylet in relation to the sensor.
- Advance the catheter slowly to achieve optimal performance (1 cm per second). There may be a slight delay from the time the catheter is moved until the stylet icon moves on the display. Advancing the catheter too quickly may result in erratic movements of the stylet icon on the display.
- Insert the catheter until the magnetic navigation shows the stylet moving consistently downward.
- Continue to slowly advance catheter until the catheter is inserted to the external measurements as determined in the Bard Access Systems' catheter instructions for use.






- Below is an image of Magnetic Navigation only mode.



6 Trouble Shooting and Error Messages

6.1 Error Screens

<p>Sensor Disconnected</p> 	<p>Cause: Sensor not connected to the display. Solution: Ensure the sensor is properly connected. Disconnect and reconnect the sensor.</p> <p>Cause: The display power supply is connected to a noisy electrical outlet. Solution: Disconnect the display power supply from the electrical outlet to run the system on battery power.</p> <p>Cause: Sensor cannot be detected by the display Solution: Call the technical support hotline at (800) 443-3385.</p>
<p>Sensor Error</p> 	<p>Cause: Interference caused by magnetic field changes or by sensor movement. Solution: 1. Move all metal objects at least 12 inches (30 cm) away from the sensor. 2. Lower bed rails. 3. Move all active electronic devices at least 5 feet (1.5 m) away. 4. Do not move the sensor and ask the patient to remain still. 5. Calibrate. 6. If the error continues, discontinue use and call the technical support hotline at (800) 443-3385.</p> <p>Cause: Sensor malfunction. Solution: 1. Turn off and restart the system. 2. If the error continues, discontinue use and call the technical support hotline at (800) 443-3385</p>

<p>Magnet Error</p> 	<p>Cause: Interference caused by magnetic field changes or by sensor movement.</p> <p>Solution:</p> <ol style="list-style-type: none"> 1. Move all metal objects at least 12 inches (30 cm) away from the sensor. 2. Lower bed rails. 3. Move all active electronic devices at least 5 feet (1.5m) away. 4. Do not move the sensor and ask the patient to remain still. 5. Ensure catheter tip is at least 12 inches (30 cm) away from the sensor. 6. Calibrate. 7. If the error continues, discontinue use and call the technical support hotline at (800) 443-3385.
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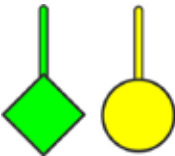




6.2 ECG Troubleshooting

<p>Flat-line ECG signal</p>	<p>Cause: No fin connection.</p> <p>Solution: Fully seat fin on the sensor.</p>
	<p>Cause: No ECG electrode connection.</p> <p>Solution: Ensure that the area on the skin where the ECG electrodes were placed is oil free and completely dry.</p>
	<p>Cause: Damaged ECG electrodes.</p> <p>Solution: Ensure catheter T-lock connections are fully seated. Replace electrodes.</p>
	<p>Cause: Air bubble at the catheter tip.</p> <p>Solution: Flush the catheter lumen containing the stylet with saline.</p>
	<p>Cause: No stylet-to-fin connection.</p> <p>Solution: Fully seat the stylet connector on the fin. Refer to the Bard Access Systems' catheter instructions for use.</p>
<p>Poor ECG signal</p>	<p>Cause: Fin and/or stylet connectors not fully seated.</p> <p>Solution: Fully seat fin on sensor. Fully seat stylet connector on fin.</p>
	<p>Cause: Poor ECG electrode contact.</p> <p>Solution: Ensure that the area on the skin where the ECG electrodes were placed is oil free and completely dry.</p>
	<p>Cause: Patient movement.</p> <p>Solution: Ask the patient to remain still. Ensure the patient is warm and relaxed.</p>
	<p>Cause: Extraneous noise.</p> <p>Solution: Unplug the Site~Rite® 8 Ultrasound System from AC power.</p> <p>Solution: Make Sure the Ultrasound probe is not in close proximity to the sensor and/or lead wires.</p>
	<p>Cause: Damaged ECG electrodes.</p> <p>Solution: Replace electrodes.</p>
	<p>Cause: Catheter not locked with saline.</p> <p>Solution: Ensure catheter T-lock connections are fully seated. Flush the catheter lumen containing the stylet with saline.</p>
	<p>Cause: The External ECG signal, with black electrode on the patient's left shoulder (Lead III view) is weak.</p> <p>Solution: Place black electrode on the patient's right shoulder (Lead II view)</p>



Wandering ECG baseline	<p>Cause: Poor ECG electrode contact. Solution: Ensure that the area on the skin where the ECG electrodes were placed is oil free and completely dry.</p>
	<p>Cause: Patient movement. Solution: Ask the patient to remain still. Ensure the patient is warm and relaxed.</p>
	<p>Cause: Extraneous noise. Solution: Avoid touching the stylet or electrodes.</p>
	<p>Cause: Catheter not locked with saline. Solution: Ensure catheter T-lock connections are fully seated. Flush the catheter lumen containing the stylet with saline.</p>
ECG signal abnormal	<p>Cause: Body ECG leads swapped. Solution: Place ECG leads correctly.</p>
	<p>Cause: No distinct P-wave. Solution: Do not rely on ECG guidance for catheter tip confirmation. Refer to Warnings Section.</p>
P-wave highlight is offset from the P-wave	<p>Cause: Poor ECG signal. Solution: See Poor ECG signal troubleshooting.</p>
ECG/Stylet icon does not turn green with an elevated P-wave	<p>Cause: Poor ECG signal. Solution: See Poor ECG signal troubleshooting.</p>
	<p>Cause: System cannot identify elevated P-wave. Solution: Rely on institutional guidelines and clinical judgment.</p>
ECG/Stylet icon does not remain green consistently with an elevated P-wave	<p>Cause: Poor ECG signal. Solution: See Poor ECG signal troubleshooting.</p>
	<p>Cause: System cannot identify elevated P-wave. Solution: Rely on institutional guidelines and clinical judgment.</p>
Absent ECG signal	<p>Cause: Sensor / sensor cables damaged. Solution: Call technical hotline at (800) 443-3385 to replace sensor and/or cables.</p>
	<p>Cause: Sensor disconnected. Solution: Ensure the sensor is properly connected.</p>
	<p>Cause: Sensor is not communicating with display. Solution: Reboot the display.</p>
ECG Screen (main/reference screen) is not visible	<p>Cause: Incompatible sensor. Solution: Use appropriate sensor. Contact customer service (800) 545-0890.</p>
	<p>Cause: Incorrect PICC compatibility is selected. Solution: Make sure to have [] selected from the menu when using a catheter kit labeled [].</p>



6.3 Magnetic Navigation Troubleshooting

<p>Magnetic navigation does not detect stylet.</p>  <p>Note: Depth icons will not be present.</p>	<p>Cause: Sensor incorrectly oriented.</p> <p>Solution: Orient sensor correctly per procedure.</p>
	<p>Cause: Stylet outside sensor depth range (3 to 11 cm).</p> <p>Solution: - If the vein is deep, ensure that the top of the sensor on the insertion side is touching the patient's skin (e.g. by using tape). - If the vein is shallow, lift the sensor away from the skin (e.g., by using a folded blanket).</p>
	<p>Cause: Too much time has passed since calibration. Magnetic fields have changed.</p> <p>Solution: Pull catheter tip back at least 12 inches (30 cm) from the sensor, recalibrate and re-advance catheter.</p>
	<p>Cause: Stylet did not advance under the sensor.</p> <p>Solution: Pull catheter back and re-advance.</p>
	<p>Cause: Stylet not at the catheter tip.</p> <p>Solution: Ensure stylet tip is within 1 cm of distal end of catheter. Adjust as necessary.</p>
	<p>Cause: Incompatible catheter.</p> <p>Solution: Verify that the Bard Access Systems' catheter kit has a  icon or  icon.</p>
	<p>Cause: Stylet magnet trimmed off.</p> <p>Solution: Replace catheter with a new Bard Access Systems' catheter from a kit labeled  or .</p>
	<p>Cause: Stylet is out of sensor's depth range (3 to 11 cm)</p> <p>Solution: 1. Pull catheter back until stylet icon is stable. 2. Verify catheter is moving in the correct direction and continue placement using ECG guidance and catheter measurement.</p>
<p>Magnetic navigation Stylet icon has erratic behavior.</p>	<p>Cause: Stylet at edge of sensor's depth range (3 to 11 cm).</p> <p>Solution: 1. Pull catheter back until stylet icon is stable. 2. Verify catheter is moving in the correct direction and continue placement.</p>
	<p>Cause: Magnetic interference.</p> <p>Solution: Pull catheter tip back at least 12 inches (30 cm) from the sensor, recalibrate, and re-advance catheter.</p>
	<p>Cause: Too much time has passed since calibration. Magnetic fields have changed.</p> <p>Solution: Pull catheter tip back at least 12 inches (30 cm) from the sensor, recalibrate and re-advance catheter.</p>
<p>Magnetic navigation Stylet icon disappears, "sweeping magnifying glass" displayed.</p>	<p>Cause: Stylet is out of sensor's depth range (3 to 11 cm).</p> <p>Solution: 1. Pull catheter back until stylet icon is stable. 2. Verify catheter is moving in the correct direction and continue placement using ECG guidance and catheter measurement.</p>
	<p>Cause: Magnetic interference.</p> <p>Solution: Pull catheter tip back at least 12 inches (30 cm) from the sensor, recalibrate, and re-advance catheter.</p>
	<p>Cause: Too much time has passed since calibration. Magnetic fields have changed.</p> <p>Solution: Pull catheter tip back at least 12 inches (30 cm) from the sensor, recalibrate and re-advance catheter.</p>

If problems continue, call the technical support hotline at (800) 443-3385.





7 Magnetic Navigation Printing


Select [] to open Menu. Select [] to open Settings.

- Under the menu, navigate down until the MAGNET PRINTOUT DISABLED [] button is highlighted.

- Select the MAGNET PRINTOUT DISABLED [] button

- After being selected the MAGNET PRINTOUT DISABLED button will toggle to the MAGNET PRINTOUT ENABLED [] button.

- Close Settings by selecting the EXIT [] button.

Note: Selecting [] after Magnet Navigation Only Mode will send the procedural record to a storage device and/or an approved printer, if connected.

A typical Magnet Navigation Only printout is shown below.

Name: John Doe
Clinician: S Anderson
Patient ID: JD654321
Birth Date: 1960-02-23
Exit Site Marking: 1 cm
Trim Length: 45 cm
 2015-02-23 14:30:15





Notes:

8 Cleaning and Disinfection

Caution: Use only cleaning and disinfecting products approved by Bard Access Systems. Failure to do so may damage the device.

8.1 Cleaning Procedure

To clean the Sherlock 3CG™ TCS Sensor:

1. Turn off the system.
2. Dampen a nonabrasive cloth with either warm water or isopropyl alcohol.
3. Gently wipe the dampened cloth over exterior surfaces.

8.2 Disinfection Procedure

For a list of disinfectants approved for use on the Sensor and Display, contact Bard Access Systems, Inc.

Warning: Do not submerge the sensor or allow fluid to enter the connector. Damage to the equipment may occur.

Warning: Do not attempt to sterilize the sensor. Damage to the equipment may occur.

9 Warranty

The manufacturer, 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 year from the date of purchase. If this product proves to be so defective, purchaser may return the same to Bard Access Systems, Inc. for repair, replacement or credit at Bard Access Systems Inc.'s option in accordance with Bard Access Systems Inc.'s Return Goods Policy found in the current price list. The warranty on the repaired or replaced unit continues from the purchase date of the original unit. This warranty does not cover damages resulting from misuse, abuse, modification, or alteration of this product or the repair of this product by anyone other than an authorized Bard Access Systems, Inc. representative.

Without limitation, the following actions void the warranty of the Sherlock 3CG™ TCS Sensor:

Warning: The following actions void the warranty of the Sherlock 3CG™ TCS Sensor and may result in injury or equipment damage.

- Opening or servicing the Sherlock 3CG™ TCS Sensor by anyone other than Bard Access Systems' authorized service personnel.
- Removing system labels by anyone other than Bard Access Systems' authorized service personnel.
- Connecting the sensor or applied patient components to any unauthorized system or accessory. Refer to Section 1.4 for complete components.
- Installation of unauthorized software.
- Modification of system software settings without authorization by Bard Access Systems.

TO THE EXTENT ALLOWABLE BY APPLICABLE LAW, 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.

IN NO EVENT WILL BARD ACCESS SYSTEMS, INC. BE LIABLE TO YOU FOR ANY INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM YOUR HANDLING OR USE OF THIS PRODUCT EVEN IF BARD ACCESS SYSTEMS, INC. HAS BEEN ADVISED OF THE POSSIBILITY OR LIKELIHOOD OF SUCH DAMAGES. IN NO EVENT WILL BARD ACCESS SYSTEMS, INC.'S LIABILITY UNDER THIS WARRANTY WITH RESPECT TO THIS PRODUCT EXCEED THE PURCHASE PRICE PAID TO BARD ACCESS SYSTEMS, INC. FOR SUCH PRODUCT.

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.



10 Service and Repair

There is no periodic or preventative maintenance required for the Sherlock 3CG™ TCS.

For servicing information or to return your Sherlock 3CG™ TCS for repair, please contact Bard Access Systems' technical support hotline at (800) 443-3385.

Warning: Only qualified personnel should attempt to service this equipment. The Sherlock 3CG™ TCS contains static sensitive components and circuits.

Failure to observe proper static control procedures may result in damage to the system.

Warning: Opening or servicing the Sherlock 3CG™ TCS Sensor by anyone other than Bard Access Systems' authorized service personnel will void the warranty and may result in injury or equipment damage.

11 Technical Specifications

11.1 Sherlock 3CG™ TCS Sensor and Display Operational and Storage Conditions

Operating Temperature: 15°C to 38°C (59°F to 100°F)

Storage Temperature: 10°C to 38°C (50°F to 100°F)




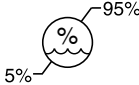

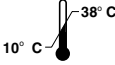


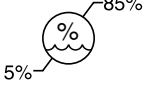

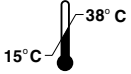



Operating Humidity: 5% to 85% non-condensing

Storage Humidity: 5% to 95% non-condensing

12 Disposal Information

To return the Sherlock 3CG™ TCS for end of life recycling, please contact your nearest Bard sales or distributor office in the country of purchase.


Sherlock 3CG Tip Confirmation System — Symbols

	Manufacturer		Type CF Applied Part
	Date of manufacture		Storage Humidity Limitation
	Quantity		Storage Temperature Limitation
	Consult instructions for use		Do not dispose with ordinary municipal waste
	Operating Humidity Limitation		Fragile, handle with care
	Operating Temperature Limitation		Keep Dry
	Catalog number	Rx Only	Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.
	Serial number		

An issued or revision date for these instructions is included for the users information. In the event two years have elapsed between this date and product use, the user should contact Bard Access Systems, Inc. to see if additional product information is available.
Revision date: July, 2015

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(801) 522-5000

Customer Service: (800) 545-0890
Technical/Clinical Support: (800) 443-3385
www.bardaccess.com
www.discoversherlock.com



BARID

ACCESS SYSTEMS



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