SYMBOLS

- Consult instructions for use
- Operating Humidity Limitation
- Keep Dry
- Storage Temperature Limitation
- Do not dispose with ordinary municipal waste
- Fragile
- Storage Humidity Limitation
- Operating Temperature Limitation
- CF Type Equipment
- Manufacturer
- Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician
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OVERVIEW

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.

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.

Sherlock 3CG™ Tip Confirmation System (TCS) Description

The Sherlock 3CG™ TCS is designed to aid in PICC tip positioning through magnet tracking and ECG technology. It is designed to operate with Bard Access Systems’ catheter kits labeled “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 cavo-atrial junction. As the catheter advances into the right atrium, the P-wave will decrease in amplitude and may be biphasic or invert.

![Diagram showing changes in P-wave amplitude](image)

**Magnetic Navigation**

Permanent magnets are encapsulated within the tip of the Sherlock 3CG™ TPS Stylet. No magnetic energy is generated by the display 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.
System Components

Authorized accessories include:

- Site™ Rite Vision™ II 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)
- Sherlock 3CG™ TCS Sensor Holster (optional)
- Bard Access Systems' supplied printer (purchased separately)
**WARNINGS**

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.

See the Bard Access Systems’ Site~Rite Vision™ II Ultrasound System IFU for warnings and precautions regarding the use of the Site~Rite Vision™ II Ultrasound System.

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

**Warning:** Do not power the Sherlock 3CG™ TCS in the presence of 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 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 settings without authorization by Bard Access Systems.

**Warning:** If the Site~Rite Vision™ II 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. 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:** 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:** The Sherlock 3CG™ TCS must only be charged with the Medical Grade Power Supply.

**Warning:** Do not remove Sherlock 3CG™ TCS enclosures. To avoid electrical shock, use only the power cord supplied with the system and connect it 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 Bard Access Systems’ cleaning and disinfection procedures. 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.

Caution: To avoid damage to the device operating system, shutdown the device through the Power Control button.
ASSEMBLING THE SHERLOCK 3CG™ TCS

Connecting the Sherlock 3CG™ TCS Sensor to the Site~Rite Vision™ II Ultrasound System

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

When not in use, the Sherlock 3CG™ TCS Sensor can be placed in the holster on the back of the Site~Rite Vision™ II Ultrasound System roll stand.
SHERLOCK 3CG™ TCS INFORMATION

Enabling Ultrasound and Sherlock 3CG™ TCS Layout

From the main ultrasound screen (Ultrasound Mode), the SiteRite Vision™ II Ultrasound System displays ultrasound at the top half of the screen and the Sherlock 3CG™ TCS white external waveform for P-wave pre-assessment at the bottom of the screen. **If your ultrasound screen layout shows ultrasound only (No Sherlock 3CG™ TCS external waveform as shown below), perform the following procedure to enable ultrasound and Sherlock 3CG™ TCS layout:**

1. From the ultrasound screen, go to feature toolbar and select the “settings” icon.
2. In the settings screen, select the ‘Layout’ dropdown menu arrow and select "Ultrasound and S3CG." Then select ‘Apply’.
3. Now the screen layout incorporates ultrasound and Sherlock 3CG™ TCS. In this screen you may assess the presence of the external P-wave.
SHERLOCK 3CG™ TCS GRAPHICAL INTERFACE

Site~Rite Vision™ II Ultrasound System Mode (with Sherlock 3CG™ TCS External ECG)

Ultrasound Imaging

Sherlock 3CG™ TCS Only (TCS Mode)

Calibrate Sensor

Sherlock 3CG™ TCS External ECG
Sherlock 3CG™ TCS Only (TCS Mode) Screen

Calibrate
Audio Mute
Ultrasound Mode

Magnet Tracking Window
Feature Toolbar

Main ECG Display
Reference ECG Display

Real-time external and intravascular ECG waveforms
Used for freezing the external and intravascular ECG waveforms to assist in maximum P-wave identification
Magnet Tracking

- **Stylet Icon**: Location and direction of stylet tip under the sensor. The circle represents the tip of the stylet and the tail represents the body of the stylet.
- **Searching For Signal Icon**: Stylet tip had not been detected.
- **Off Screen Icon**: Location of the approaching stylet tip.
- **Depth Icon**: Relative stylet depth under sensor

Sherlock 3CG™ TCS Controls and Indicators

<table>
<thead>
<tr>
<th>Main Controls</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="ultrasound_icon.png" alt="Ultrasound Mode" /></td>
<td><strong>Ultrasound Mode</strong>: Select to exit the Sherlock 3CG™ TCS Mode (referred to as “TCS Mode”) and enter Ultrasound Mode.</td>
</tr>
<tr>
<td><img src="tcs_mode_icon.png" alt="TCS Mode" /></td>
<td><strong>TCS Mode</strong>: Select to exit Ultrasound Mode and enter TCS Mode.</td>
</tr>
<tr>
<td><img src="calibrate_icon.png" alt="Calibrate Button" /></td>
<td><strong>Calibrate Button</strong>: Select to calibrate magnet navigation in Ultrasound Mode and TCS Mode.</td>
</tr>
<tr>
<td><img src="success_icon.png" alt="Successful Calibration" /></td>
<td><strong>Successful Calibration</strong>: Indicates Sherlock 3CG™ TCS Sensor has been successfully calibrated.</td>
</tr>
<tr>
<td><img src="audio_on_icon.png" alt="Audio On" /></td>
<td><strong>Audio On</strong>: Select to mute the magnet navigation audio.</td>
</tr>
<tr>
<td>Main Controls</td>
<td></td>
</tr>
<tr>
<td>---------------</td>
<td>---</td>
</tr>
<tr>
<td><img src="image" alt="Audio Mute" /></td>
<td><strong>Audio Mute</strong>: Select to turn the magnet navigation audio on.</td>
</tr>
<tr>
<td><img src="image" alt="Freeze" /></td>
<td><strong>Freeze</strong>: Select to copy the current ECG waveforms from the Main Screen to the Reference Screen.</td>
</tr>
<tr>
<td><img src="image" alt="Print" /></td>
<td><strong>Print</strong>: 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.</td>
</tr>
<tr>
<td><img src="image" alt="ECG Settings Menu" /></td>
<td><strong>ECG Settings Menu</strong>: Select to open the ECG Settings Controls (see below)</td>
</tr>
<tr>
<td><img src="image" alt="Channel Select" /></td>
<td><strong>Channel Select</strong>: Select either the external (white) or intravascular (yellow) ECG waves for manipulation.</td>
</tr>
<tr>
<td><img src="image" alt="Scale" /></td>
<td><strong>Scale</strong>: Select to adjust the ECG signal amplitude of the external (white) or intravascular (yellow) ECG waves up or down.</td>
</tr>
<tr>
<td><img src="image" alt="Level Up" /></td>
<td><strong>Level Up</strong>: Select to increase or decrease the vertical position of the external (white) or intravascular (yellow) ECG waves on the Main Screen.</td>
</tr>
<tr>
<td><img src="image" alt="Speed" /></td>
<td><strong>Speed</strong>: Select to adjust the speed of the ECG waveforms on the Main Screen.</td>
</tr>
<tr>
<td><img src="image" alt="Exit Site Marking" /></td>
<td><strong>Exit Site Marking</strong>: Select to open the Exit Site Marking Window.</td>
</tr>
<tr>
<td><img src="image" alt="Save ECG" /></td>
<td><strong>Save ECG</strong>: Select to electronically save the ECG and magnet navigation data to file.</td>
</tr>
<tr>
<td><img src="image" alt="Demo" /></td>
<td><strong>Demo</strong>: Select to initiate demonstration mode.</td>
</tr>
<tr>
<td><img src="image" alt="Interactive Demo Mode" /></td>
<td><strong>Interactive Demo Mode</strong>: Select to demonstrate Sherlock 3CG™ TCS interactively.</td>
</tr>
<tr>
<td><img src="image" alt="Playback Demo Mode" /></td>
<td><strong>Playback Demo Mode</strong>: Select to continuously play a non-interactive demonstration.</td>
</tr>
</tbody>
</table>
Main Controls

<table>
<thead>
<tr>
<th>Icon</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Open Icon" /></td>
<td><strong>Open</strong>: Select to open previously saved ECG and magnet navigation files.</td>
</tr>
<tr>
<td><img src="image" alt="Settings Icon" /></td>
<td><strong>Settings</strong>: Select to bring up PICC Compatibility and Printout menu.</td>
</tr>
</tbody>
</table>

**PICC Compatibility and Print Region Settings**

1. While in TCS Mode, go to the feature menu and select the “Settings” icon.
2. The Sherlock 3CG™ TCS Settings screen will appear.

The Sherlock 3CG™ TCS on Site~Rite Vision™ II 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.

Magnet Printing Enable/Disable will determine if you print out ECG waveform and Magnet Navigation, or ECG only.
**Sherlock 3CG™ TCS Audio Information**

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

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

**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.
SHERLOCK 3CG™ TCS CATHETER CARE GUIDANCE

Step 1: Prepare the device.
- Connect the sensor to the Site~Rite Vision™ II Ultrasound System via USB cord.
- Verify that the external ECG flatline signal is scrolling.
- Verify the battery charge is sufficient for the procedure.
- Enter Patient Information as needed.

Step 2: Position the patient and perform ultrasound pre-scan.
- Refer to the Bard Access Systems’ Site~Rite Vision™ II Ultrasound System Instructions for Use.

Step 3: Measure the catheter length.
- Refer to Bard Access Systems’ Catheter Instructions for Use.

Step 4: Prepare the sensor.
- Slide the Fin Assembly onto 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 the 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 the external ECG waveform.**
- Refer to the Bard Access Systems’ catheter Instructions for Use.

**Step 7: Perform initial magnet-tracking calibration.**
- While still in Ultrasound mode, 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 the 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 Vision™ II Ultrasound System Instructions and Bard Access Systems’ catheter Instructions for Use.

**Step 10: Attach the catheter stylet to the fin assembly.**
- Refer to Bard Access Systems’ catheter Instructions for Use.

**Step 11: Perform the final magnet-tracking calibration.**
- Switch unit to TCS Mode.
- 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 the 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.

**ECG Positioning**

- In patients with a distinct P-wave, the P-wave will increase in amplitude as the catheter approaches the cavo-atrial 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 window.

**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 the 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 directly print and save the ECG and magnet tracking procedural record without previewing.

A typical ECG and Magnet Tracking printout is shown below:

**ECG PRINTOUT**

**MAGNET TRACKING PRINTOUT**

Note: Printout Statement Enable/Disable from Sherlock 3CG™ TCS settings will control whether the following statement is visible on the ECG printout: “PICC tip location in the SVC confirmed by ECG technology”
MAGNETIC-NAVIGATION-ONLY MODE

Step 1: Prepare the device.

- Connect the sensor to the Site~Rite Vision™ II Ultrasound System via USB cord.
- Verify the battery charge is sufficient for the procedure.
- Enter Patient Information as needed.

Step 2: Position the patient and perform the ultrasound pre-scan.

- Refer to the Bard Access Systems’ Site~Rite Vision™ II Ultrasound System Instructions for Use.

Step 3: Measure the catheter length.

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

Step 4: Prepare the sensor.

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

Step 5: Position the 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 the initial magnet-tracking 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 the 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 Vision™ II Ultrasound System Instructions and Bard Access Systems’ catheter Instructions for Use.

Step 9: Perform the final magnet-tracking 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 the 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 measurement as determined in the Bard Access Systems’ Catheter Instructions for Use.

Below is an image of Magnetic tracking only mode.
# TROUBLESHOOTING AND ERROR MESSAGES

## Error Screens

<table>
<thead>
<tr>
<th>Error Screen</th>
<th>Cause</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sensor Disconnected</strong></td>
<td>Sensor not connected to the display</td>
<td>Ensure the sensor is properly connected. Disconnect and reconnect the sensor.</td>
</tr>
<tr>
<td></td>
<td>The display power supply is connected to a noisy electrical outlet.</td>
<td>Disconnect the display power supply from the electrical outlet to run the system on battery power.</td>
</tr>
<tr>
<td></td>
<td>Sensor cannot be detected by the display.</td>
<td>Call the technical support hotline 1(800) 443-3385.</td>
</tr>
</tbody>
</table>
| **Sensor Error** | Interference caused by magnetic field changes or by sensor movement. | 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 1(800) 443-3385. |
| **Magnet Error** | Interference caused by magnetic field changes or by sensor movement. | 1. Turn off and restart the system.  
2. If the error continues, discontinue use and call the technical support hotline 1(800) 443-3385. |
|               | Sensor malfunction. | 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 1(800) 443-3385. |
## ECG Troubleshooting

| Flat-line ECG signal | Cause: No fin connection.  
Solution: Fully seat fin on the sensor.  
Cause: No ECG electrode connection.  
Solution: Ensure that the area on the skin where the ECG electrodes were placed is oil free and completely dry.  
Cause: Damaged ECG electrodes.  
Solution: Ensure catheter T-lock connections are fully seated. Replace electrodes.  
Cause: Air bubble at the catheter tip.  
Solution: Flush the catheter lumen containing the stylet with saline.  
Cause: No stylet-to-fin connection.  
Solution: Fully seat the stylet connector on the fin. Refer to the Bard Access Systems’ catheter instructions for use. |
|---|---|
| Poor ECG signal | Cause: Fin and/or stylet connectors not fully seated.  
Solution: Fully seat fin on sensor. Fully seat stylet connector on fin.  
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.  
Cause: Patient movement.  
Solution: Ask the patient to remain still. Ensure the patient is warm and relaxed.  
Cause: Extraneous noise.  
Solution: Avoid touching the stylet or electrodes.  
Cause: Damaged ECG electrodes.  
Solution: Replace electrodes.  
Cause: Catheter not locked with saline.  
Solution: Ensure catheter T-lock connections are fully seated. Flush the catheter lumen containing the stylet with saline.  
Cause: The External ECG signal, with black electrode on the patient’s left shoulder (Lead III view) is weak.  
Solution: Place black electrode on the patient’s right shoulder (Lead II view). |
| ECG Screen (main/reference screen) is not visible | **Cause**: Incorrect PICC Compatibility is selected.  
**Solution**:  
- In Ultrasound Mode: Select Settings . Select ‘Layout’ dropdown menu and select ‘Ultrasound and S3CG.’ Select ‘Apply.’  
- In TCS Mode: Select Settings , Under ‘PICC Compatibility’ select ‘Magnet and ECG.’ Select ‘Apply.’ |
|-------------------------------------------------|--------------------------------------------------------|
| Absent ECG signal | **Cause**: Sensor / sensor cables damaged.  
**Solution**: Call technical hotline at 1(800)443-3385 to replace sensor and/or cables.  
**Cause**: Sensor disconnected.  
**Solution**: Ensure the sensor is properly connected.  
**Cause**: Sensor is not communicating with display.  
**Solution**: Reboot the display. |
| ECG signal abnormal | **Cause**: Body ECG leads swapped.  
**Solution**: Place ECG leads correctly.  
**Cause**: No distinct P-wave.  
**Solution**: Do not rely on ECG guidance for catheter tip confirmation. Refer to Warnings Section. |
| Wandering ECG baseline | **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.  
**Cause**: Patient movement.  
**Solution**: Ask the patient to remain still. Ensure the patient is warm and relaxed.  
**Cause**: Extrinsic noise.  
**Solution**: Avoid touching the stylet or electrodes.  
**Cause**: Catheter not locked with saline.  
**Solution**: Ensure catheter T-lock connections are fully seated. Flush the catheter lumen containing the stylet with saline. |
## Magnetic Navigation Troubleshooting

| Magnetic navigation does not detect stylet | **Cause**: Sensor incorrectly oriented.  
**Solution**: Orient sensor correctly per procedure.  
**Cause**: Stylet outside sensor depth range (3 to 11 cm).  
**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).  
**Cause**: Too much time has passed since calibration. Magnetic fields have changed.  
**Solution**: Pull catheter tip back at least 12 inches (30 cm) from the sensor, recalibrate and re-advance catheter.  
**Cause**: Stylet did not advance under the sensor.  
**Solution**: Pull catheter back and re-advance.  
**Cause**: Stylet not at the catheter tip.  
**Solution**: Ensure stylet tip is within 1 cm of distal end of catheter. Adjust as necessary.  
**Cause**: Incompatible catheter.  
**Solution**: Verify that the Bard Access Systems’ catheter kit has a ![icon] or ![icon].  
**Cause**: Stylet magnet trimmed off.  
**Solution**: Replace catheter with a new Bard Access Systems’ catheter from a kit labeled ![icon] or ![icon]. |
| Magnetic navigation Stylet icon has erratic behavior | **Cause:** Stylet at edge of sensor’s depth range (3 to 11 cm).  
**Solution:**  
1. Pull catheter back until stylet icon is stable.  
2. Verify catheter is moving in the correct direction and continue placement. |
| --- | --- |
|  | **Cause:** Magnetic interference.  
**Solution:** Pull catheter tip back at least 12 inches (30 cm) from the sensor, recalibrate, and re-advance catheter. |
|  | **Cause:** Too much time has passed since calibration. Magnetic fields have changed.  
**Solution:** Pull catheter tip back at least 12 inches (30 cm) from the sensor, recalibrate and re-advance catheter. |
| Magnetic navigation Stylet icon disappears, "sweeping magnifying glass" displayed. | **Cause:** Stylet is out of sensor’s depth range (3 to 11 cm).  
**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. |
|  | **Cause:** Magnetic interference.  
**Solution:** Pull catheter tip back at least 12 inches (30 cm) from the sensor, recalibrate, and re-advance catheter. |
|  | **Cause:** Too much time has passed since calibration. Magnetic fields have changed.  
**Solution:** Pull catheter tip back at least 12 inches (30 cm) from the sensor, recalibrate and re-advance catheter. |

If problems continue, call the technical support hotline at 1(800) 443-3385.
CLEANING AND DISINFECTION

Cleaning Procedure

To clean the Sherlock 3CG™ TCS:

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.

Disinfection Procedure

For a list of disinfectants approved for use on the Sensor, Display and Remote Control 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.
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:

- Opening or servicing the 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 System Component Section for complete components.
- Installation of unauthorized software.
- Modification of system 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.
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 1(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.

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

- Opening or servicing the 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 System Component Section for complete components.
- Installation of unauthorized software.
- Modification of system settings without authorization by Bard Access Systems.

**Warning:** Only Bard Access Systems’ authorized service 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.
TECHNICAL SPECIFICATIONS

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

Operating Temperature: 10˚C to 40˚C (50˚F to 104˚F)

Storage Temperature: -18˚C to 40˚C (0˚F to 104˚F)

Operating Humidity: 5% to 85% non-condensing

Storage Humidity: 5% to 95% non-condensing

DISPOSAL INFORMATION

Cleaning Procedures

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.
An issued or revision date for these instructions is included for the user’s information. In the event that two years have lapsed between the issued revision date and use of the product, contact Bard Access Systems, Inc. to see if any additional product information is available.

Revision date: December 2013

Manufacturer:
Bard Access Systems, Inc.
605 North 5600 West
Salt Lake City, UT 84116
U.S.A.
Customer Service: 1-800-545-0890
Technical/Clinical Support: 1-800-443-3385
Fax: 1-801-522-4948
www.bardaccess.com
www.discoversherlock.com

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