INSTRUCTIONS FOR USE

Standalone
Instructions for Use

INSTRUCTIONS FOR USE
Keep Dry

Fragile

Manufacturer

CF Type Equipment

Attention, see instructions for use

Storage humidity limitation

Operating humidity limitation

5%
85%

Storage temperature limitation

-18°C

38°C

Operating temperature limitation

Rx Only

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

Do not dispose with ordinary municipal waste
TABLE OF CONTENTS

1 Overview
   1.1 Indications for Use
   1.2 Post Market Clinical Trial
   1.3 Sherlock 3CG* TCS Description
   1.4 System Components
   1.5 Warnings and Precautions

2 Assembling the Sherlock 3CG* TCS
   2.1 Attaching the Sherlock* 3CG TCS Sensor holster to the roll stand
   2.2 Connecting the Sherlock 3CG* TCS Sensor to the Sherlock 3CG* TCS Display

3 Sherlock 3CG* TCS Information
   3.1 Sherlock 3CG* TCS Graphical Interface
   3.2 Sherlock 3CG* TCS Controls and Indicators
   3.3 Settings Icon
      3.3.1 Settings – General
      3.3.2 Settings – Remote
      3.3.3 Settings – Printers
      3.3.4 Settings – File Management
   3.4 Remote Control
   3.5 Sherlock 3CG* TCS Audio Information
   3.6 Parallax

4 Sherlock 3CG* TCS Catheter Guidance
   Step 1: Prepare Device
   Step 2: Position Patient and Perform Ultrasound Pre-scan
   Step 3: Measure Catheter Length
   Step 4: Prepare Sensor
   Step 5: Position Sensor and ECG electrodes
   Step 6: Evaluate External ECG waveform
   Step 7: Perform Initial Magnet Tracking Calibration
   Step 8: Prepare Catheter Sterile Field
   Step 9: Access the Vein
   Step 10: Attach Catheter Stylet to Fin Assembly
   Step 11: Perform Final Magnet Tracking Calibration
   Step 12: Insert Catheter
   Step 13: Catheter Tip Guidance and Positioning
   Step 14: Complete Catheter Placement
   Step 15: Procedural Record

5 Magnetic Navigation Only Mode
   Step 1: Prepare Device
   Step 2: Position Patient and Perform Ultrasound Pre-scan
   Step 3: Measure Catheter Length
   Step 4: Prepare Sensor
   Step 5: Position Sensor
   Step 6: Perform Initial Magnet Tracking Calibration
   Step 7: Prepare Catheter Sterile Field
   Step 8: Access the Vein
   Step 9: Perform Final Magnet Tracking Calibration
   Step 10: Insert Catheter
   Step 11: Catheter Tip Guidance and Positioning

6 Troubleshooting and Error Messages
   6.1 Error Screens
   6.2 ECG Troubleshooting
   6.3 Magnetic navigation troubleshooting

7 Remote Control Installation

8 Sherlock 3CG* TCS Printer Installation
   8.1 Brother* Printer
   8.2 Sony* Printer

9 Cleaning and Disinfection
   9.1 Cleaning Procedure
   9.2 Disinfection Procedure

10 Warranty

11 Service and Repair

12 Technical Specifications
   12.1 Sherlock 3CG* TCS Sensor and Display Operational and Storage Conditions

13 Disposal Information
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 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 PICC 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 the next generation of tip confirmation technology, incorporating both Sherlock* II Tip Location System (TLS) magnetic tip tracking and Sapiens TCS ECG tip confirmation into a single integrated unit. 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 central venous catheters in adult patients. The primary endpoints were to assess the performance of the Sapiens technology with respect to: (1) compatibility with peripherally inserted central catheters (PICCs), tunneled catheters, and ports (2) safety of using an invasive intracardiac electrode, and (3) the accuracy of the Sapiens technology with regard to correct positioning of the catheter tip when compared to postoperative chest x-ray. Three hundred thirty two (332) subjects received a vascular access device in the form of a PICC, port, or tunneled catheter. of the 332 subjects, 114 subjects (34%) received a PICC. Placement of the PICC was deemed acceptable in 99.1% (113/114) of the subjects. No adverse events occurred.

1.3 Sherlock 3CG* 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 [ ] and “Sherlock 3CG* TPS Styler”.

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.

Magnetic Navigation

Permanent magnets are encapsulated within the tip of the Sherlock 3CG* TPS Styler. No magnetic energy is generated by the display or the sensor. The Sherlock 3CG* TCS displays the relative position of the magnet-tipped styler 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 styler, it displays the styler tip location and orientation.
1.4 System Components
The Sherlock 3CG* TCS Standalone and authorized accessories include:
- Sherlock 3CG* TCS Sensor
- Sherlock 3CG* TCS Display
- Remote Control
- Medical Grade Power Supply
- 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
- Remote Control Holder
- Bard Access Systems’ supplied printer
- USB Extension

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 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 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 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 operating system, use the Shutdown button to turn off the Sherlock 3CG* TCS Display.

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 a 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 Sherlock 3CG* TCS Display

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

3.1 Sherlock 3CG* TCS Graphical Interface

Magnet tracking requires calibration.
Sherlock 3CG° Tip Confirmation System

**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.

**OFF SCREEN ICON**
Location of the approaching stylet tip

**DEPTH ICON**
Relative stylet depth under sensor.

**SEARCHING FOR SIGNAL ICON**
Stylet tip had not been detected.

**MAIN SCREEN**
Real-time external and intravascular ECG waveforms.

**REFERENCE SCREEN**
Used for freezing the external and intravascular ECG waveforms to assist in maximum P-Wave identification.

Minimized magnet tracking window.
### 3.2 Sherlock 3CG* TCS Controls and Indicators

#### Front Panel Controls/Indicators

<table>
<thead>
<tr>
<th>Icon</th>
<th>Description</th>
</tr>
</thead>
</table>
| ![Power](image) | **Shutdown**: Select to open the shutdown menu.  
**Caution**: To avoid damage to the operating system, use the Shutdown button to turn off the Sherlock 3CG* TCS Display. |
| ![Setting](image) | **Settings**: Select to open the system settings menu. |
| ![Battery](image) | **Battery Status**: There are 5 charge levels on the battery indicator.  
When the unit is operating on battery power, the battery indicator changes to yellow at 40% and red/blink at 20% of the remaining battery life. When the unit is charging the battery the AC connected indicator will overlay the battery status. |
| ![Freeze](image) | **Freeze**: Select to copy the current ECG waveforms from the Main Screen to the Reference Screen. |
| ![Print](image) | **Print to file**: Select to save and print the current ECG waveforms in the reference screen. (Saves to both the hard-drive and USB external storage device if connected). |
| ![Menu](image) | **Menu**: Select to open/close the ECG menu. |

#### Shutdown Menu Controls

<table>
<thead>
<tr>
<th>Icon</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Sherlock 3CG" /></td>
<td><strong>Sherlock 3CG</strong>: Restarts the Sherlock 3CG* Software Application.</td>
</tr>
<tr>
<td><img src="image" alt="Shutdown" /></td>
<td><strong>Shutdown</strong>: Shuts down the Sherlock 3CG* TCS Display.</td>
</tr>
<tr>
<td><img src="image" alt="Restart" /></td>
<td><strong>Restart</strong>: Restarts the Sherlock 3CG* TCS Display.</td>
</tr>
<tr>
<td><img src="image" alt="Lock" /></td>
<td><strong>Lock</strong>: Locks the password enabled Sherlock 3CG* TCS Display.</td>
</tr>
</tbody>
</table>
**ECG Menu Controls**

<table>
<thead>
<tr>
<th>Icon</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Save" /></td>
<td><strong>Save</strong>: Select to stop and save the ECG waveform recording.</td>
</tr>
</tbody>
</table>
| ![Demo](image) | **Demo**: Select to initiate demonstration mode.  
For training, contact your Bard Access Systems’ Sales Representative. |
| ![Channel](image) | **Channel Selection**: Select either the external (white) or intravascular (yellow) ECG waves for manipulation. |
| ![Scale](image) | **Channel Scale**: Select to adjust the ECG signal amplitude of the external (white) or intravascular (yellow) ECG waveforms on the Main Screen. |
| ![Level](image) | **Channel Level**: Select to adjust the vertical position of the external (white) or intravascular (yellow) ECG waveforms on the Main Screen. |
| ![Speed](image) | **Display Speed**: Select to adjust the speed of the ECG playback. |

**Magnet Tracking Controls**

<table>
<thead>
<tr>
<th>Icon</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Calibrate" /></td>
<td><strong>Calibrate</strong>: Select to calibrate magnet tracking.</td>
</tr>
<tr>
<td><img src="image" alt="Audio" /></td>
<td><strong>Audio</strong>: Select to toggle sound on or off.</td>
</tr>
</tbody>
</table>
3.3 Settings Icon

Select  to open the Sherlock 3CG* TCS Settings Window.

3.3.1 Settings – General

<table>
<thead>
<tr>
<th>Setting</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change Date/Time</td>
<td>Opens Date and Time properties window.</td>
</tr>
<tr>
<td>Change Language</td>
<td>Changes system language settings.</td>
</tr>
<tr>
<td>Restore Defaults</td>
<td>Restores software to factory default settings.</td>
</tr>
<tr>
<td>Log</td>
<td>View and export system error logs.</td>
</tr>
<tr>
<td>Upgrade</td>
<td>Provides system software upgrades when a USB flash drive containing a Sherlock 3CG* TCS compatible installation is inserted.</td>
</tr>
<tr>
<td>About</td>
<td>Indicates system application version information.</td>
</tr>
<tr>
<td>Password</td>
<td>To enable or disable password protection, see figure below.</td>
</tr>
<tr>
<td>Enable Magnet Printing</td>
<td>Enables magnet tracking printing.</td>
</tr>
<tr>
<td>PICC Compatibility</td>
<td>Selects magnet tracking compatibility between Sherlock* TLS and Sherlock 3CG* TPS stylets.</td>
</tr>
<tr>
<td>Close</td>
<td>Closes the General window and Settings menu.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Setting</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enable</td>
<td>Enables the password protection, according to the value entered.</td>
</tr>
<tr>
<td>Disable</td>
<td>Disables the password protection.</td>
</tr>
<tr>
<td>Close</td>
<td>Closes the password window.</td>
</tr>
</tbody>
</table>
3.3.2 Settings – Remote

<table>
<thead>
<tr>
<th>Function</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Add Remote Control</td>
<td>Initiates process to detect and add the remote control for use with the system interface.</td>
</tr>
<tr>
<td>Show Bluetooth Devices</td>
<td>Launches the Bluetooth Devices window.</td>
</tr>
<tr>
<td>Close</td>
<td>Closes the Remote window and Settings menu.</td>
</tr>
</tbody>
</table>

3.3.3 Settings – Printers

<table>
<thead>
<tr>
<th>Function</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Set Current Printer</td>
<td>Sets the selected printer as current.</td>
</tr>
<tr>
<td>Note</td>
<td>Sherlock 3CG* TCS Application will print to the current printer.</td>
</tr>
<tr>
<td>Close</td>
<td>Closes the Printer window and Settings menu.</td>
</tr>
</tbody>
</table>
3.3.4 Settings – File Management

<table>
<thead>
<tr>
<th>Function</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Refresh</td>
<td>Refreshes the file(s) listing in the viewer.</td>
</tr>
<tr>
<td>Hide LOG / Show LOG</td>
<td>Hides/Shows all files with a .log extension from appearing in the viewer.</td>
</tr>
<tr>
<td>Hide/Show Images</td>
<td>Hides/Shows all files with a .jpg extension from appearing in the viewer.</td>
</tr>
<tr>
<td>New Folder</td>
<td>Provides functionality for the user to create and name a new storage folder under the C:\Data archive.</td>
</tr>
<tr>
<td>Delete</td>
<td>Deletes selected files or folders displayed in the viewer and under the C:\Data archive. <strong>Note</strong>: The user is prompted again after initiating this command. Additionally, archives listed under the Refresh button cannot be deleted or moved.</td>
</tr>
<tr>
<td>Copy</td>
<td>Automatically copies selected files or folders to the operating system clipboard.</td>
</tr>
<tr>
<td>Select All</td>
<td>Selects all files displayed in the viewer.</td>
</tr>
<tr>
<td>Paste</td>
<td>Provides functionality for the user to paste to a designated storage location.</td>
</tr>
<tr>
<td>Close</td>
<td>Closes the File Management window and Settings menu.</td>
</tr>
</tbody>
</table>
3.4 Remote Control

Refer to the remote control instructions for use.

3.5 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.
3.6 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

Step 1: Prepare Device
- Connect the sensor to the Sherlock 3CG* TCS Display via USB cord.
- 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’ 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 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 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.
  - 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 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 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’ 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 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 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
- 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 minimize the magnetic navigation window and 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 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 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 approved printer, if connected. A typical printout is shown below.

![Procedural Record Printout](image)

PICC tip location in the SVC confirmed by ECG technology
5 Magnetic Navigation Only Mode

Step 1: Prepare Device
- Connect the sensor to the Sherlock 3CG* TCS Display 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’ 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* 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 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 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’ Ultrasound System Instructions and Bard Access Systems’ catheter Instructions for Use.

Step 10: Perform 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.

Step 11: Insert Catheter
- Refer to Bard Access Systems’ catheter Instructions for Use for catheter insertion.

Step 12: 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.
# 6 Trouble Shooting and Error Messages

## 6.1 Error Screens

<table>
<thead>
<tr>
<th>Error</th>
<th>Cause</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensor Disconnected</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 (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 (800) 443-3385. |
| Magnet 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 (1.5m) 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 (800) 443-3385. |
### 6.2 ECG Troubleshooting

<table>
<thead>
<tr>
<th>Issue</th>
<th>Cause</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sherlock 3CG* TCS display will not power on.</td>
<td>Battery not charged.</td>
<td>Plug unit in and verify battery is properly connected.</td>
</tr>
<tr>
<td>The Sherlock 3CG* TCS display powers on to blank screen</td>
<td>Software is corrupted or display is damaged.</td>
<td>Reboot display. If behavior continues call the technical support hotline (800) 443-3385.</td>
</tr>
<tr>
<td>The Sherlock 3CG* TCS powers on to application toolbar only</td>
<td>Software is corrupted or display is damaged.</td>
<td>Reboot display. If behavior continues call the technical support hotline (800) 443-3385.</td>
</tr>
<tr>
<td>Sherlock 3CG* TCS will not power on or power on but turns off immediately.</td>
<td>Battery not charged.</td>
<td>Press and hold the power button for at least 3 seconds to power on.</td>
</tr>
<tr>
<td>Flat-line ECG signal</td>
<td>No fin connection.</td>
<td>Fully seat fin on the sensor.</td>
</tr>
<tr>
<td></td>
<td>No ECG electrode connection.</td>
<td>Ensure that the area on the skin where the ECG electrodes were placed is oil free and completely dry.</td>
</tr>
<tr>
<td></td>
<td>Damaged ECG electrodes.</td>
<td>Ensure catheter T-lock connections are fully seated. Replace electrodes.</td>
</tr>
<tr>
<td></td>
<td>Air bubble at the catheter tip.</td>
<td>Flush the catheter lumen containing the stylet with saline.</td>
</tr>
<tr>
<td></td>
<td>No stylet-to-fin connection.</td>
<td>Fully seat the stylet connector on the fin. Refer to the Bard Access Systems’ catheter instructions for use.</td>
</tr>
<tr>
<td>Poor ECG signal</td>
<td>Fin and/or stylet connectors not fully seated.</td>
<td>Fully seat fin on sensor. Fully seat stylet connector on fin.</td>
</tr>
<tr>
<td></td>
<td>Poor ECG electrode contact.</td>
<td>Ensure that the area on the skin where the ECG electrodes were placed is oil free and completely dry.</td>
</tr>
<tr>
<td></td>
<td>Patient movement.</td>
<td>Ask the patient to remain still. Ensure the patient is warm and relaxed.</td>
</tr>
<tr>
<td></td>
<td>Extraneous noise.</td>
<td>Avoid touching the stylet or electrodes.</td>
</tr>
<tr>
<td></td>
<td>Damaged ECG electrodes.</td>
<td>Replace electrodes.</td>
</tr>
<tr>
<td></td>
<td>Catheter not locked with saline.</td>
<td>Ensure catheter T-lock connections are fully seated. Flush the catheter lumen containing the stylet with saline.</td>
</tr>
<tr>
<td></td>
<td>The External ECG signal, with black electrode on the patient’s left shoulder (Lead III view) is weak.</td>
<td>Place black electrode on the patient’s right shoulder (Lead II view).</td>
</tr>
<tr>
<td>Wandering ECG baseline</td>
<td>Poor ECG electrode contact.</td>
<td>Ensure that the area on the skin where the ECG electrodes were placed is oil free and completely dry.</td>
</tr>
<tr>
<td></td>
<td>Patient movement.</td>
<td>Ask the patient to remain still. Ensure the patient is warm and relaxed.</td>
</tr>
<tr>
<td></td>
<td>Extraneous noise.</td>
<td>Avoid touching the stylet or electrodes.</td>
</tr>
<tr>
<td></td>
<td>Catheter not locked with saline.</td>
<td>Ensure catheter T-lock connections are fully seated. Flush the catheter lumen containing the stylet with saline.</td>
</tr>
<tr>
<td>Condition</td>
<td>Cause</td>
<td>Solution</td>
</tr>
<tr>
<td>-----------------------------------------</td>
<td>------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------</td>
</tr>
<tr>
<td>ECG signal abnormal</td>
<td>Body ECG leads swapped.</td>
<td>Place ECG leads correctly.</td>
</tr>
<tr>
<td>Absent ECG signal</td>
<td>No distinct P-wave.</td>
<td>Do not rely on ECG guidance for catheter tip confirmation. Refer to Warnings Section.</td>
</tr>
<tr>
<td>Date and time incorrect</td>
<td>Date and time need to be set or reset</td>
<td>Select the date/time and choose the General icon. Select the Change Date and Time icon and follow the prompts.</td>
</tr>
<tr>
<td>Remote control not working</td>
<td>Batteries are low.</td>
<td>Replace batteries with standard AAA batteries.</td>
</tr>
<tr>
<td></td>
<td>Remote Control is not paired with the Display. (If applicable.)</td>
<td>Pair the Remote Control.</td>
</tr>
<tr>
<td></td>
<td>Remote control is not paired through standard installation. (If applicable.)</td>
<td>Select the remote control.</td>
</tr>
<tr>
<td></td>
<td>Incompatible sensor.</td>
<td>Use sensor with product code number 9770131.</td>
</tr>
<tr>
<td></td>
<td>Incorrect PICC stylet is selected.</td>
<td>Select General. Ensure that under PICC compatibility the &quot;ECG Stylet&quot; is highlighted.</td>
</tr>
</tbody>
</table>
### 6.3 Magnetic navigation troubleshooting

| Magnetic navigation does not detect stylet | **Cause:** | Sensor incorrectly oriented.  
Solution: Orient sensor correctly per procedure. |
| Magnetic navigation Stylet icon has erratic behavior | **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). |
| Magnetic navigation Stylet icon disappears, "sweeping magnifying glass" displayed. | **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 [ ] or [ ] |

### If problems continue, call the technical support hotline at (800) 443-3385
7 Remote Control Installation

If the remote control uses a USB receiver, connect the USB receiver to an available USB port. If the remote control does not use a USB receiver, please proceed to the following steps.

1. Turn on the Sherlock 3CG* TCS Display and the Remote Control.

2. Click the Settings icon in the Application Toolbar.

3. Click the Remote button in the system settings menu that appears.

4. Position the remote control within two feet of the Sherlock 3CG* TCS Display. On the left side of the remote control, press and hold the connect button until the blue LED on the remote control starts blinking rapidly.

5. From the Remote window, click the Add Remote Control button.
8 Sherlock 3CG* TCS Printer Installation

8.1 Brother® Printer

1. Connect the USB cable to an available USB port on the Sherlock 3CG* TCS Display.
2. Turn on the display and the Brother® Printer.
3. Select the Settings icon from the Application Toolbar.
4. Select the Printer button in the menu that appears.

![Menu with Printer button highlighted](image1)

5. Select the Brother® Printer icon.

![Printer options](image2)

6. Select the "Set a Current Printer" button.
8.2 Sony® Printer

1. Connect the printer USB cable to an available USB port on the Sherlock 3CG* TCS Display.
2. Ensure the printer is plugged in and powered on and the printer display window reads "READY."
3. Press the wheel on the right of the printer display window.
4. Use the wheel to scroll to the “COMD” option.
5. Press the wheel to enter the COMD menu.
6. Use the wheel to scroll to the “CO:897” option.
7. Press the wheel to apply the CO:897 option.
8. Wait approximately one minute until the printer display window reads “READY” at which point the printer is ready to use with the Sherlock 3CG * TCS display.
9. Select the Settings icon from the Application Toolbar.
10. Select the Printer button from the menu that appears.

11. Select the Sony® printer icon.

12. Select the “Set as Current Printer” button.
9 Cleaning and Disinfection

9.1 Cleaning Procedure
To clean the Sherlock 3CG* TCS:
1. Turn off the system.
2. Dampen a non-abrasive cloth with either warm water or isopropyl alcohol.
3. Gently wipe the dampened cloth over exterior surfaces.

9.2 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.

10 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 Section 1.4 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.
11 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.

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.

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.

12 Technical Specifications

12.1 Sherlock 3CG* TCS Sensor and Display Operational and Storage Conditions
- Operating Temperature: 10˚C to 38˚C (50˚F to 100˚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

13 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.
An issued or revision date for these instructions is included for the user 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: October, 2013

*Bard, Sherlock abd Sherlock 3CG are trademarks and or registered trademarks of C. R. Bard, Inc. All other trademarks are the property of their respective owners.

©2013 C. R. Bard, Inc. All rights reserved.

Manufactured for:
Bard Access Systems, Inc.
605 North 5600 West
Salt Lake City, UT 84116  U.S.A.
(801) 522-5000
Customer Service: (800) 545-0890
Technical/Clinical Support: (800) 443-3385
www.bardaccess.com
www.discoversherlock.com

Bard Limited
Forest House, Brighton Road
Crawley, West Sussex
RH11 9BP UK