Sherlock 3CG+™

Tip Confirmation System

For use with Site~Rite 8
Ultrasound System™

Instructions for Use

Manufacturer

Consult instructions for use

Rx Only

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

Serial Number

Date of Manufacture

Direct Current

Fragile, handle with care

Keep Dry

Type CF applied part

Do not dispose with ordinary municipal waste

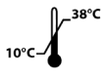
The Green Dot

Catalog Number

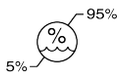
Caution

Class II Electrical Equipment

Operate Indoors Only



Storage temperature limitation



Storage humidity parameters

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1 Overview

1.1 Indications for Use

The Sherlock 3CG+™ Tip Confirmation System (TCS) is indicated for navigation and positioning of central venous access devices (CVADs) of at least 2 Fr in size. The Sherlock 3CG+™ TCS provides real-time catheter tip location information by using catheter navigation technology along with the patient's cardiac electrical activity and is indicated for use as an alternative method to chest X-ray and fluoroscopy for CVAD tip placement confirmation of approaches from the superior vena cava.

In adult patients and in adolescents (greater than 12 through 21 years of age), the Sherlock 3CG+™ TCS can be used with CVADs such as peripherally inserted central catheters (PICCs), central venous catheters (CVCs), implantable ports, and hemodialysis catheters; in children (greater than 2 to 12 years of age), in infants (greater than 1 month to 2 years of age), and in neonates (from birth to 1 month of age), the Sherlock 3CG+™ TCS can be used with PICCs and with centrally inserted central catheters (CICCs). In each specific age group, the CVAD type and size must be chosen and the CVAD must be used according to the CVAD's indications and instructions for use.

Limiting but not contraindicated situations for this method 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 catheter 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 electrocardiogram (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 CVAD tip positioning through real-time navigation and ECG technology. It is designed to operate with

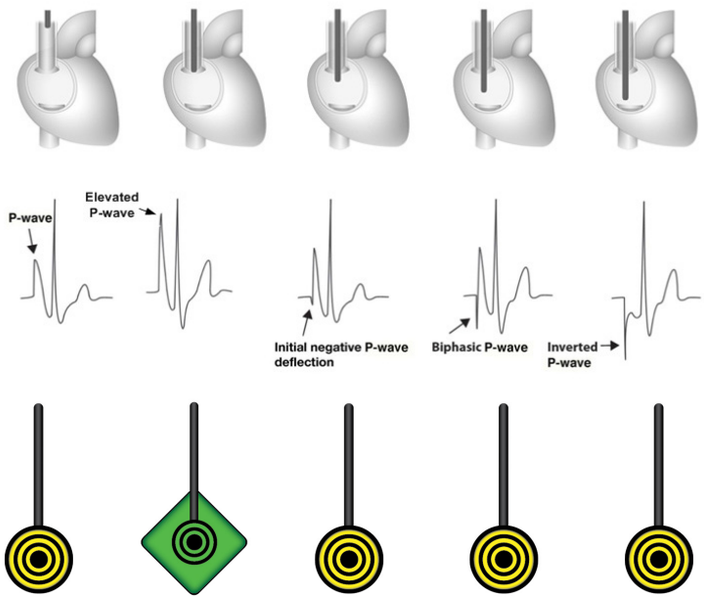
Bard Access Systems' catheter kits labeled [] and "Sherlock 3CG™ TPS Stylet".

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

Note: When used in conjunction with catheters smaller than 3 Fr, the system provides ECG information only with an electrically conductive stylet.

ECG Confirmation

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.



Warning: The Sherlock 3CG+™ TCS should be used for placements that approach the top of the cavo-atrial junction through the superior vena cava (SVC). The Sherlock 3CG+™ TCS should not be used for placements starting inferior to the cavo-atrial junction as this may result in ECG waveforms that are not described in the Instructions for Use.

Note: When magnet tracking is utilized, in addition to the ECG signal, the magnet tracking stylet icon is augmented with the identified shape and color changes.

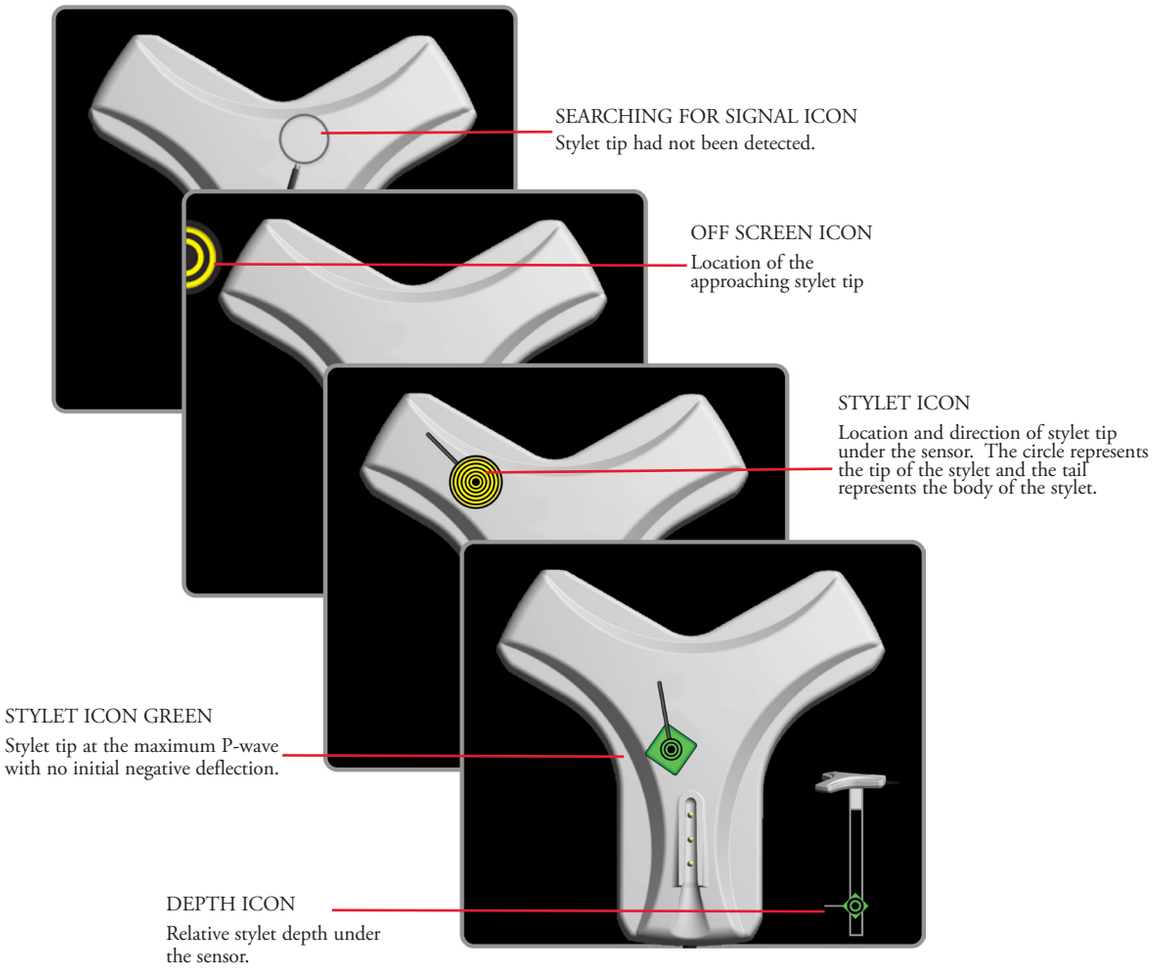
Note: In instances where the P-wave is not present, not identifiable, or intermittent the stylet icon will remain a yellow circle.

Real-Time Navigation

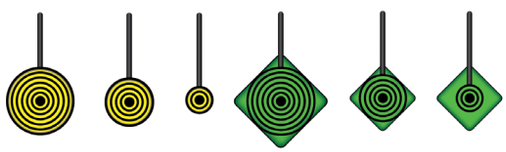
Magnetic Navigation

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.



The relative stylet depth under the sensor is displayed in two ways: The Depth Icon depicted above and the Stylet Icon rings depicted below.



ECG Navigation (when enabled)

In patients with a distinct R-peak, the Sherlock 3CG+™ TCS displays a blue ECG navigation signal that displays the relative position of the catheter tip in the vasculature.

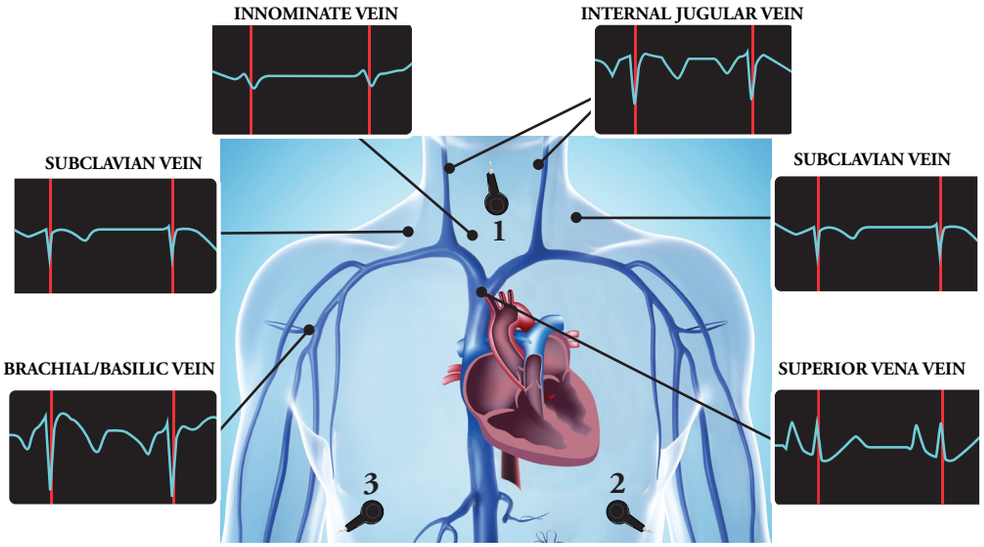
• Advancing catheter in the correct direction the R-peak will initially appear negative, will become flat in proximity to the blue electrode, and then becomes positive when you enter the superior vena cava.

• Advancing catheter in wrong direction the R-peak will remain negative

Note: Do not rely on ECG Navigation, for determining gross malposition of the catheter, when interpretation of the ECG R-wave is difficult. For example, when:

- R-wave is not present
- R-wave is not identifiable
- R-wave is intermittent

These conditions may be a result of heart rhythm abnormalities, or the presence of cardiac rhythm devices.



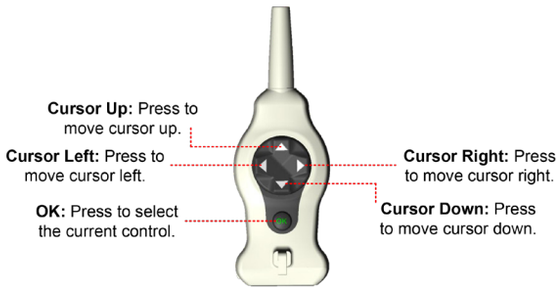
Note: When using the fin assembly for ECG navigation, place the black electrode at location 1. Place the red electrode at location 2.

Note: When using the Nautilus Delta™ ECG cable with the blue, red, and green electrodes, place the blue electrode at location. 1. Place the red electrode at location 2 and place the green electrode at location 3.

Note: When using the Nautilus Delta™ ECG cable with the blue, black, and green electrodes, place the blue electrode at location 1. Place the green electrode at location 2 and place the black electrode at location 3.

1.4 System Components

Ultrasound probe:



The following are components to the Sherlock 3CG+™ TCS:

a) Display

b) Sherlock 3CG+™ TCS Mobile Medical Application running on the display

c) One of the following sensors:

Sherlock 3CG™ TCS Sensor

Sherlock 3CG™ TPS Sensor (Magnet Only)

Sherlock™ II TLS Sensor (Magnet Only)

Nautilus Delta™ TCS Patient Module (ECG Only)

Sherlock 3CG™ TCS Small Sensor

The following are accessories, ancillary devices, or spare parts to the Sherlock 3CG+™ TCS:

a) Sherlock 3CG™ TPS Stylet

b) Nautilus Delta™ E Electrical Adaptor

c) Fin assembly

d) Sensor Holster

e) Sherlock™ Sensor Holder

1.5 Contraindications

There are no contraindications specific to the Sherlock 3CG+™ TCS.

1.6 Warnings and Precautions

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

- See the catheter's Instructions for Use (IFU) for possible complications associated with central venous access device (CVAD) placements and ECG positioning.

Warnings

Warning: Before using the Sherlock 3CG+™ TCS for the first time, be sure to read and understand all of the information in the Instructions for Use.

Warning: This device should only be operated by qualified medical personnel trained in central venous catheter placement procedures and in assessing the ECG information provided by the Sherlock 3CG+™ TCS.

Warning: Unstable ECG waveforms may be detected because of patient's movements or manipulation by the user. In such a situation the use of an additional method, according to your institutional guidelines is required to confirm catheter tip location.

Warning: Read and follow the Instructions for Use provided with the Electrical Adaptor when using it with the Sherlock 3CG+™ TCS.

Warning: The Sherlock 3CG+™ TCS is not intended to be used as monitoring equipment.

Warning: The Sherlock 3CG+™ TCS is not intended to be used as life-supporting equipment.

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

Warning: In certain patients, unstable ECG waveforms may be detected because of the manipulation of the Electrical Adaptor by the operator. Verify that the connection between the Electrical Adaptor and the central venous catheter and the connection between the Electrical Adaptor are free from contact with any other material and do not touch the Electrical Adaptor and any of its connections. If the problem persists, the use of an additional method for catheter tip location confirmation, according to your institutional guidelines is required to confirm catheter tip location.

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: In order to prevent the unauthorized access to patient information stored on the internal storage device of the display running the Sherlock 3CG+™ TCS Mobile Medical Application, setting up password protection on the display is recommended. To set up password protection on the display, follow the instructions provided in this document.

Warning: When using the saline technique, ensure that the catheter lumen is constantly filled with saline, such that electrical conductivity through the catheter is ensured from the proximal to the distal end of the vascular access device.

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. This does not apply to changing the battery in the display.
- 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 or ECG 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 when magnet tracking is utilized, 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. When ECG Navigation is utilized, in any situation in which you cannot unambiguously identify the specific ECG waveforms for different locations in the vasculature as described in the Instructions for Use, rely on 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 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, if utilized, 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.

Warning: The Sherlock 3CG+™ TCS should be used for placements that approach the top of the cavo-atrial junction through the superior vena cava (SVC). The Sherlock 3CG+™ TCS should not be used for placements starting inferior to the cavo-atrial junction as this may result in ECG waveforms that are not described in the Instructions for Use.

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: Assess placement of patient applied parts as to not interfere with surgical site or sterile field.

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: When magnet tracking is utilized, do not allow any ferromagnetic objects, e.g. wired undergarments, metal instruments, watches, jewelry, electronics, metal bed rails, 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 display.

Caution: The Sherlock 3CG+™ TCS complies with IEC 60601-1-2 for electromagnetic compatibility (EMC) for medical electrical equipment. This standard is designed to provide reasonable protection against harmful interference in a typical medical installation. However, because of the proliferation of radiofrequency transmitting equipment and other sources of electrical noise in healthcare and other environments, it is possible that high levels of such interference due to close proximity or strength of a source might disrupt the performance of this device. Medical electrical equipment needs special precautions regarding EMC, and all equipment must be installed and put into service according to the EMC information specified in the instructions for use.

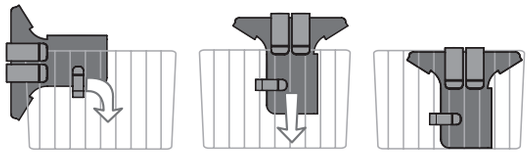
Caution: The Sherlock 3CG+™ TCS may interfere with wireless devices if not installed and used in accordance with the instructions for use. However, there is no guarantee that interference will not occur in a particular installation.

Caution: Portable and mobile RF communications equipment may interfere with the display of ECG waveforms by the Sherlock 3CG+™ TCS.

2 Assembling the Sherlock 3CG+™ TCS

2.1 Attaching the sensor holster to the roll stand

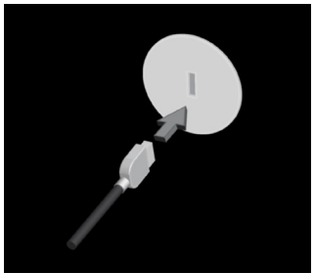
The sensor can be placed in the holster when not in use. To attach the holster to a roll stand see illustrations below.



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

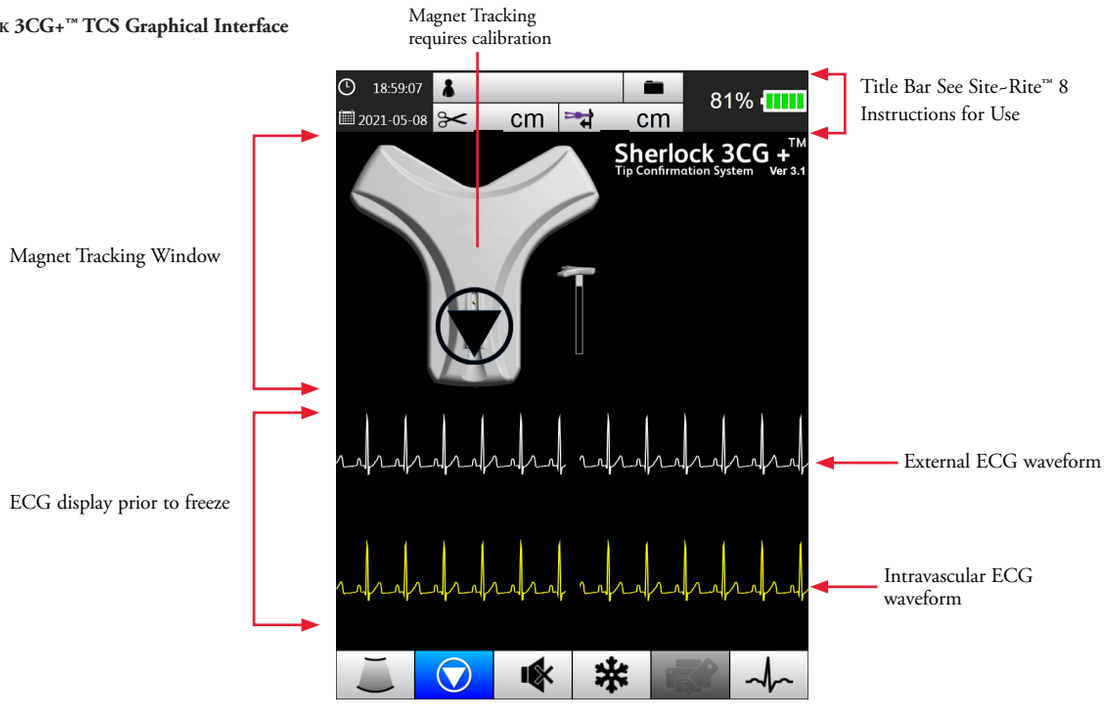
2.2 Connecting the sensor to the display

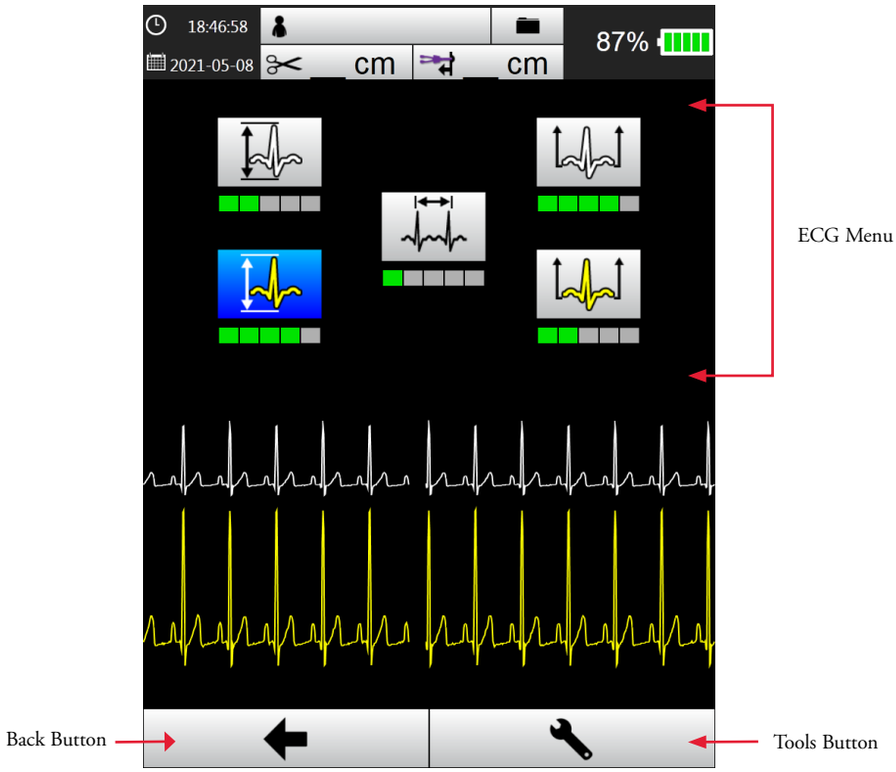
The sensor connects to the USB port on the display.

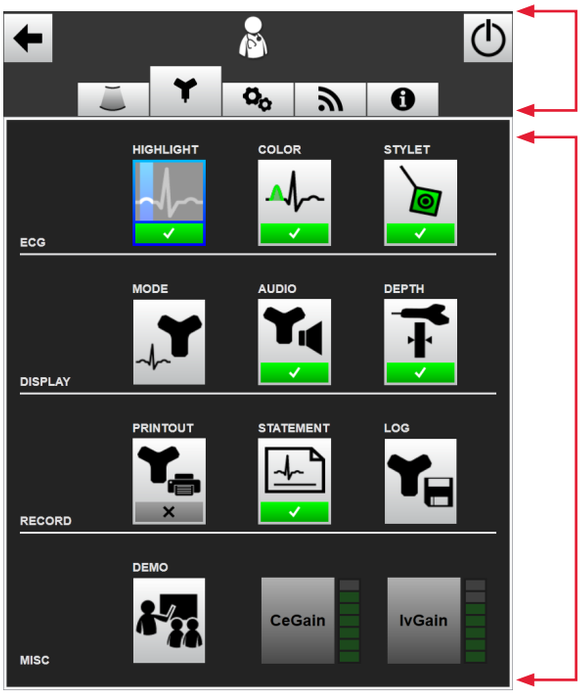


3 Sherlock 3CG+™ TCS Information

3.1 Sherlock 3CG+™ TCS Graphical Interface

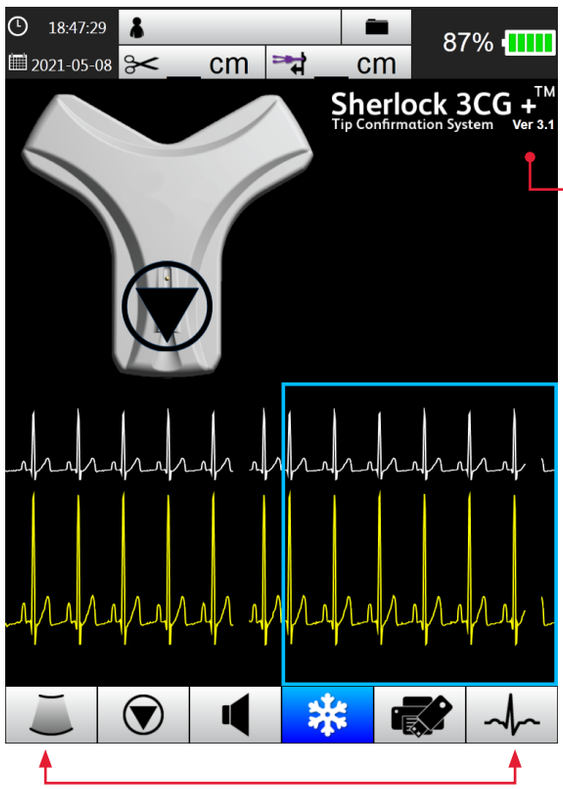






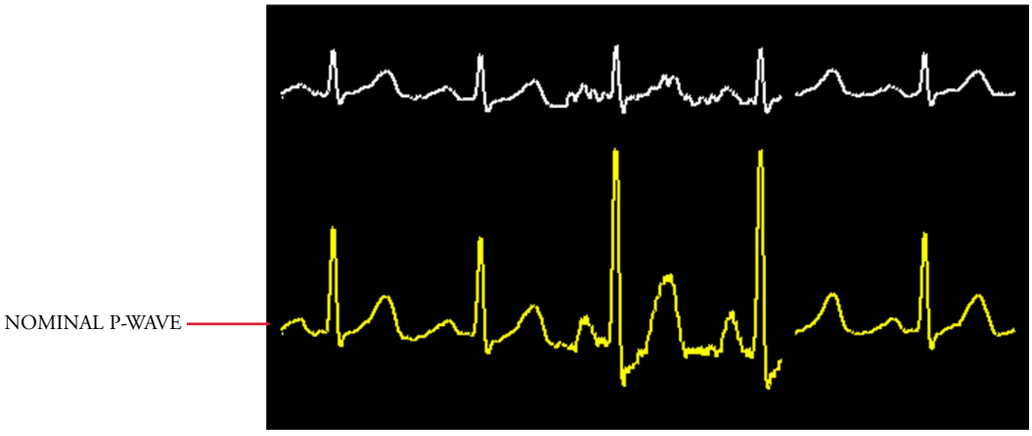
Settings Title Bar See Site-Rite™ 8 Instructions for Use

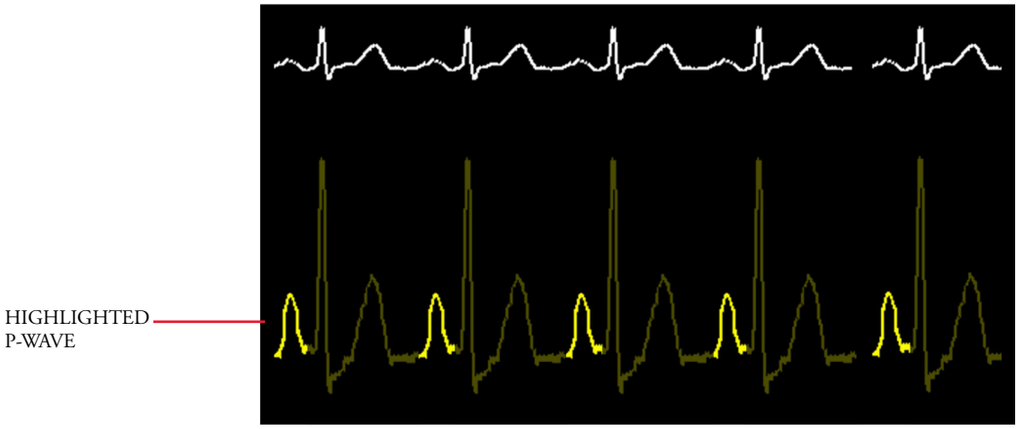
Tools Menu

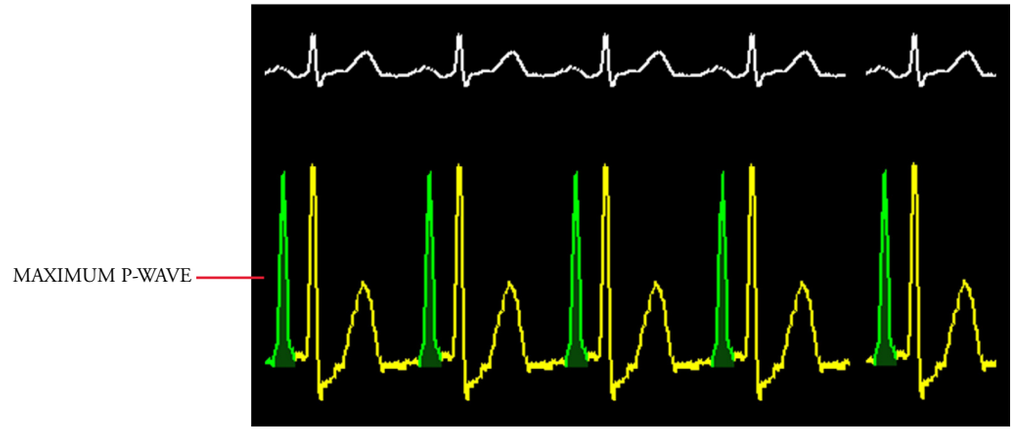


Software Version

Main Controls

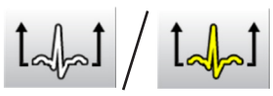
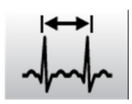

NOMINAL P-WAVE


HIGHLIGHTED
P-WAVE


MAXIMUM P-WAVE

3.2 SHERLOCK 3CG+™ TCS Controls and Indicators

Main Controls and Indicators	
	**Ultrasound Mode:** Select to exit the TCS Mode and enter Ultrasound Mode.
	**Freeze:** Select to copy the current ECG waveforms from the Main Screen to the Reference Screen.
	**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:** Select to open/close the ECG menu.
	**Calibrate:** Select to calibrate magnet navigation
	**Audio:** Select to toggle sound on or off.
	**ECG Navigation:** Select to enable or disable ECG Navigation via R-Peak.
	**R-Peak:** Select to turn off and on R-Peak identifier.

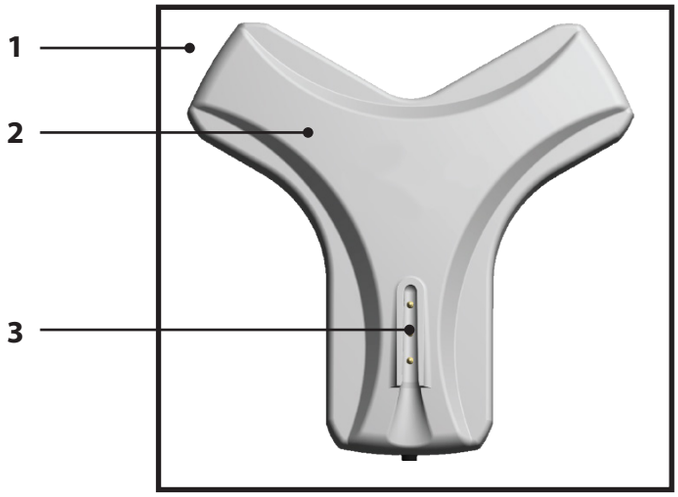
ECG Menu Controls	
	**Tools:** Select to open the tools menu.
	**Channel Scale:** Select to adjust the ECG signal amplitude of the external (white), intravascular (yellow) or navigation (blue) ECG waveforms on the Main Screen.
	**Channel Level:** Select to adjust the vertical position of the external (white), intravascular (yellow) or navigation (blue) ECG waveforms on the Main Screen.
	**Display Speed:** Select to adjust the speed of the ECG playback.
	**Exit:** Select to close the ECG Menu.

Tools Menu Controls	
	**P-wave Highlighting:** Select to enable or disable highlighting the P-wave on the ECG signals.
	**ECG Color:** Select to enable or disable the intravascular (yellow) ECG waveforms changing color to green and yellow in sync with the stylet icon.
	**Stylet Color:** Select to enable or disable the stylet icon changing color and shape based on ECG changes.
	**Depth Gauge:** Select to enable or disable the depth gauge.
	**Confirmation Statement Printing:** Select to enable or disable the confirmation statement printing on the ECG printout.
	**Demonstration:** Select to open demonstration menu. For training, contact your sales representatives.
	**Magnet Navigation Audio:** Select to enable or disable magnet navigation audio as the default setting.
	**ECG Only:** Select to view only the ECG display, magnet navigation will be disabled.
	**Magnet Navigation Only:** Select to view only magnet navigation, the ECG display will be disabled.
	**ECG and Magnet Navigation:** Select to enable the ECG display and magnet navigation.
	**ivGain:** Select to toggle through each of the ivGain levels.
	**ceGain:** Select to toggle through each of the ceGain levels.
	**Exit:** Select to close the Menu Window.

3.3 Sherlock 3CG+™ TCS Audio Information

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

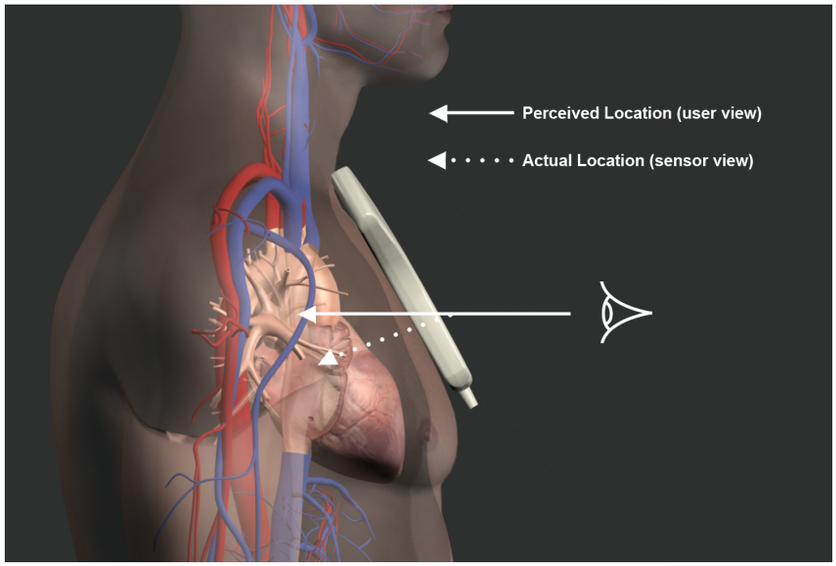
- Tone 1: stylet tip detected and the tip is not under the sensor.
- Tone 2: stylet tip is under the top half of the sensor. See image below.
- Tone 3: stylet tip is under the bottom half of the sensor. See image below.



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

3.4 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, when utilized.

4 Magnet and ECG Catheter Guidance

Step 1: Prepare Device

- Connect the sensor to the 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 ultrasound system Instructions for Use.

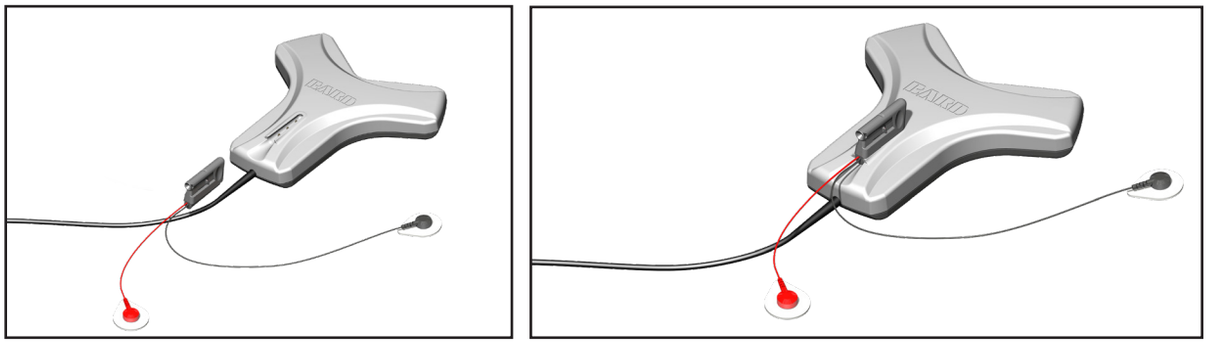
  Warning: The Sherlock 3CG+™ TCS should be used for placements that approach the top of the cavo-atrial junction through the superior vena cava (SVC). The Sherlock 3CG+™ TCS should not be used for placements starting inferior to the cavo-atrial junction as this may result in ECG waveforms that are not described in the Instructions for Use.

Step 3: Measure Catheter Length (if applicable)

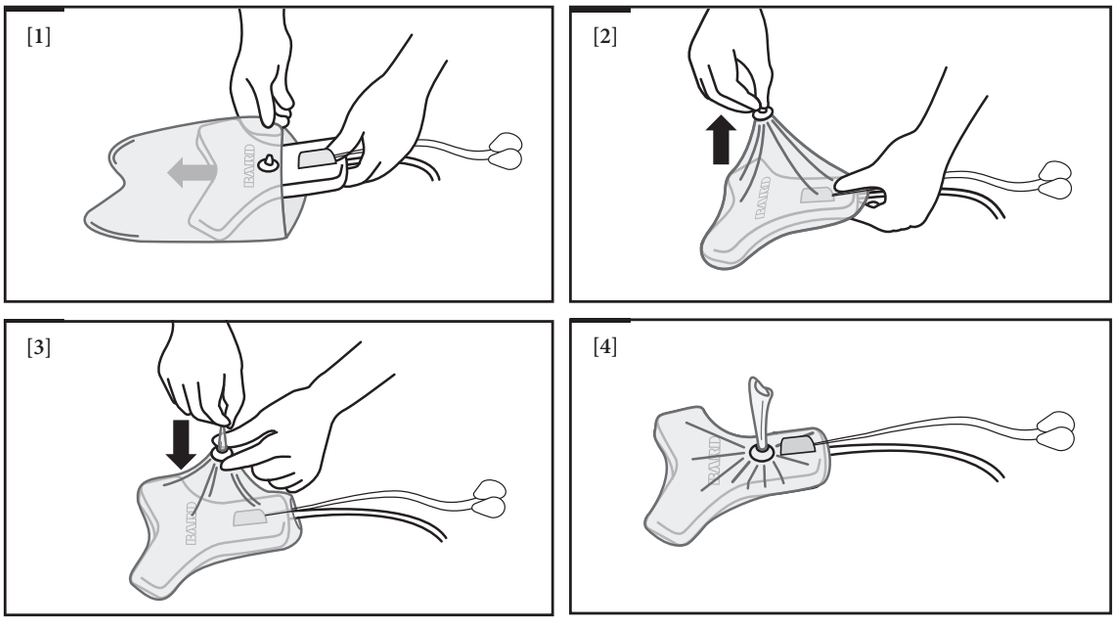
- Refer to catheter Instructions for Use.

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.

Caution: Assess placement of patient applied parts as to not interfere with surgical site or sterile field.

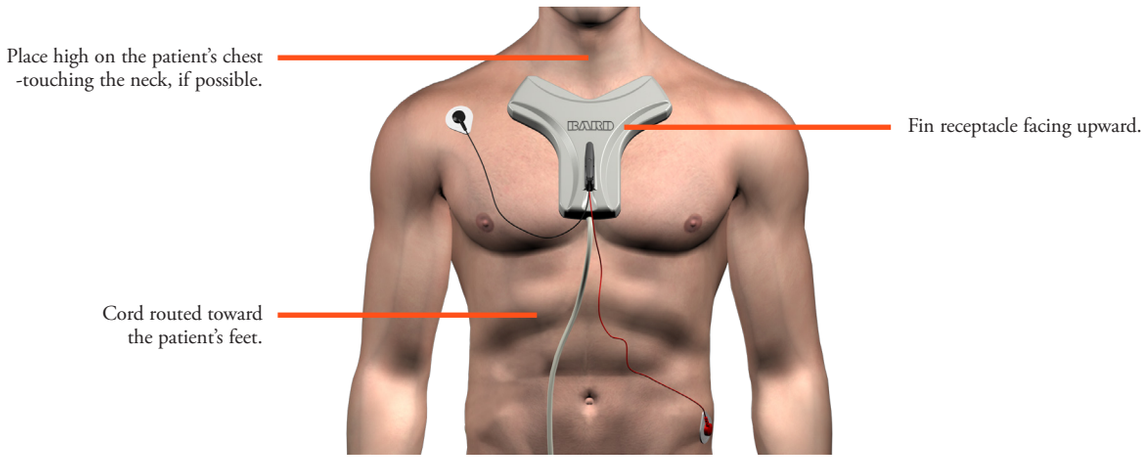
Note: The sensor should be positioned the same for left or right side placements.

- 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 the black electrode on the patients lower right shoulder
  - Place red electrode on the patient's lower left abdomen, 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, if utilized, 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 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 catheter Instructions for Use.

Step 9: Access the Vein

- Refer to the ultrasound system Instructions for Use and catheter Instructions for Use.

Step 10: Attach Catheter Stylet to Fin Assembly

- Refer to 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 catheter Instructions for Use for catheter insertion.

Step 12: Insert Catheter

- Refer to catheter Instructions for Use for catheter insertion.

Step 13: Catheter Tip Guidance and Positioning

- Refer to 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 catheter Instructions for Use.
- Select Freeze 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 Confirmation

- 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 Freeze 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 catheter Instructions for Use.

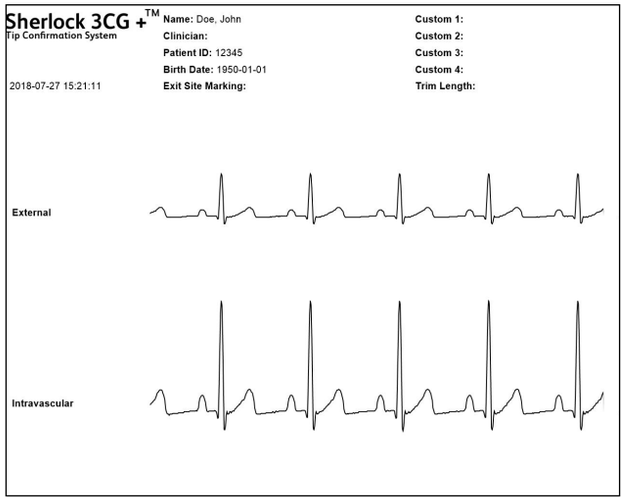
Step 14: Complete Catheter Placement

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

Step 15: Procedural Record

- Select Print to print / save a procedural record.

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



5 Magnet Only Catheter Guidance

Step 1: Prepare Device

- Connect the sensor to the 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

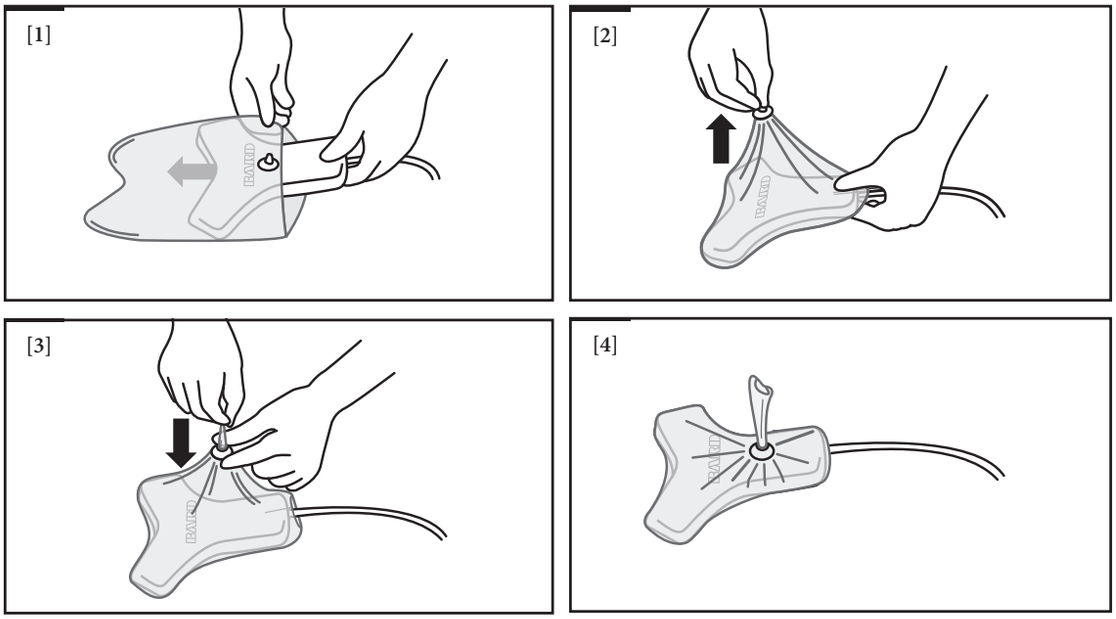
- Refer to the ultrasound system Instructions for Use.

Step 3: Measure Catheter Length

- Refer to catheter Instructions for Use.

Step 4: Prepare Sensor

-Place the sensor in the sensor holder and tighten the cinch ring.

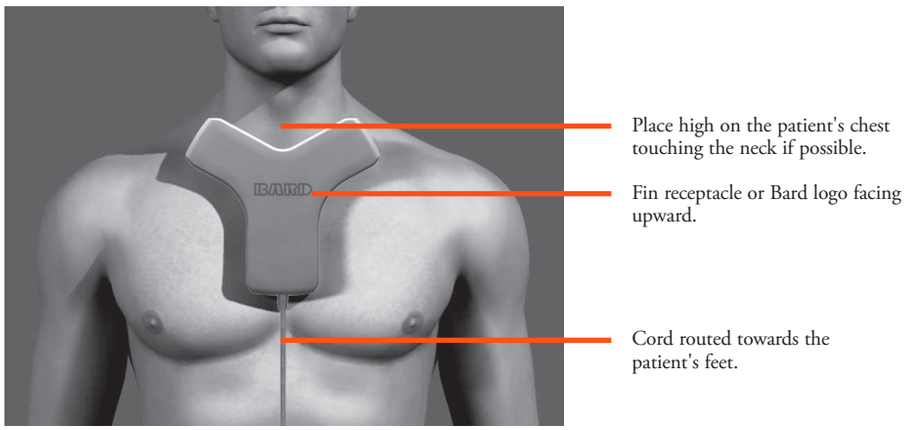


Step 5: Position Sensor

- 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.

Caution: Assess placement of patient applied parts as to not interfere with surgical site or sterile field.

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 7: Prepare Catheter Sterile Field

Refer to the catheter Instructions for Use.

Step 8: Access the Vein

- Refer to the ultrasound system Instructions for Use and catheter Instructions for Use.

Step 9: 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 catheter Instructions for Use for catheter insertion.

Step 10: Insert Catheter

- Refer to catheter Instructions for Use for catheter insertion.

Step 11: Catheter Tip Guidance and Positioning

- Refer to 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 catheter Instructions for Use.

- Below is an image of magnet tracking only mode

.

6. ECG Only Catheter Guidance

Step 1: Prepare Device

- Connect the sensor to the 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 ultrasound system Instructions for Use.

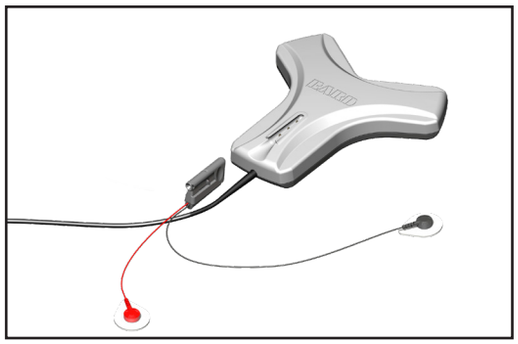
  Warning: The Sherlock 3CG+™ TCS should be used for placements that approach the top of the cavo-atrial junction through the superior vena cava (SVC). The Sherlock 3CG+™ TCS should not be used for placements starting inferior to the cavo-atrial junction as this may result in ECG waveforms that are not described in the Instructions for Use.

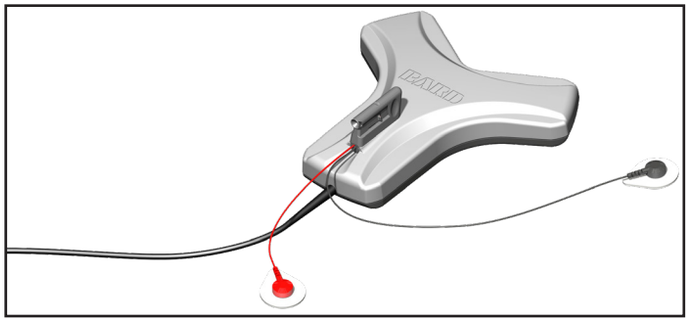
Step 3: Measure Catheter Length (if applicable)

- Refer to catheter Instructions for Use.

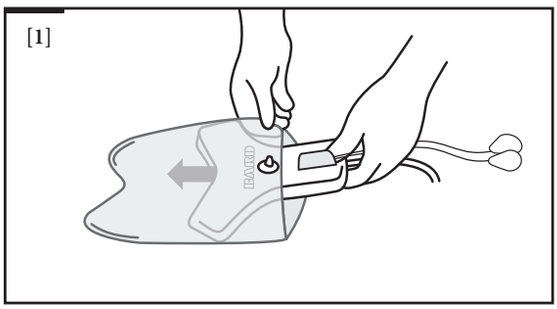
Step 4: Prepare Sensor

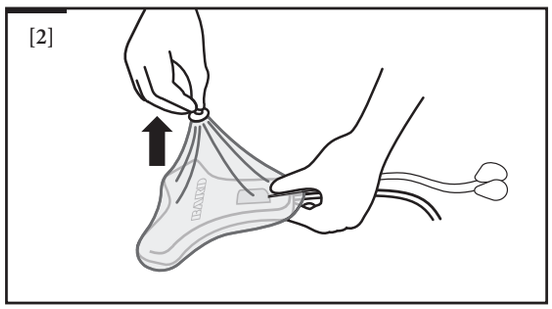
- Slide the Fin Assembly onto the sensor until fully seated.

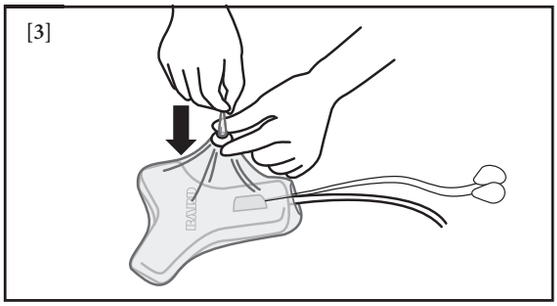


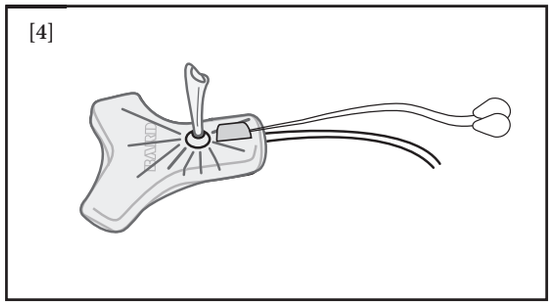


- Place the sensor in the sensor holder and tighten the cinch ring









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.

Caution: Assess placement of patient applied parts as to not interfere with surgical site or sterile field.

- 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 the patient's skin below the jugular notch over the manubrium of sternum.

    • Place red lead on the 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, if utilized, 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 catheter Instructions for Use.

Step 7: Prepare Catheter Sterile Field

- Refer to the catheter Instructions for Use.

Step 8: Access the Vein

- Refer to the ultrasound system Instructions for Use and catheter Instructions for Use.

Step 9: Attach Catheter Stylet to Fin Assembly

- Refer to catheter Instructions for Use.

Step 10: Insert Catheter

- Refer to catheter Instructions for Use for catheter insertion.

Step 11: Catheter Tip Guidance and Positioning

- Refer to catheter Instructions for Use for catheter insertion.

- Use a slow steady motion while advancing the catheter.

ECG Navigation (Blue ECG Signal if enabled)

In patients with a distinct R-peak, the R-peak will first present as a large negative amplitude when entering the vasculature, moving to a flatline as it approaches the blue ECG lead, and becoming positive in amplitude as the catheter enters the superior vena cava (reference Section 1.3). As the catheter advances to the cavo-atrial junction, clinicians should refer to the ECG Confirmation instructions below.

Note: Do not rely on ECG Navigation for determining gross malposition of the catheter when interpretation of the ECG R-wave is difficult. For example, when:

- R-wave is not present
- R-wave is not identifiable
- R-wave is intermittent

These conditions may be a result of heart rhythm abnormalities or the presence of cardiac rhythm devices.

ECG Confirmation

- 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 Freeze 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 catheter Instructions for Use.

Note: While the navigation (blue) ECG signal is enabled, the P-wave highlighting and the ECG color change are disabled. Enable the intravascular (yellow) ECG signal to enable the P-wave highlighting and ECG color settings.

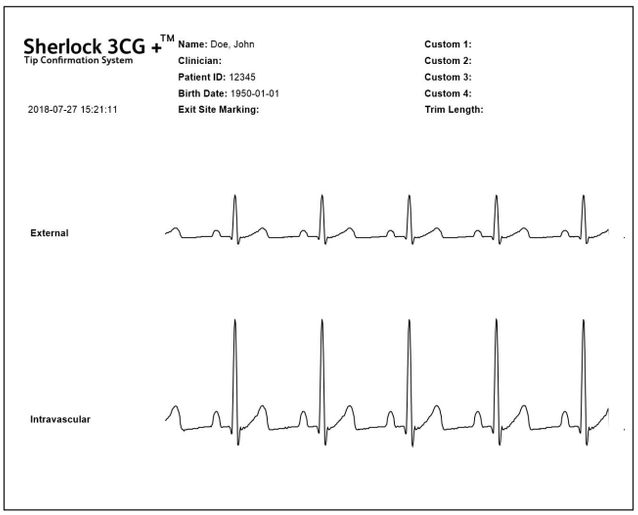
Step 12: Complete Catheter Placement

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

Step 13: Procedural Record

- Select Print to print / save a procedural record.

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



7 Trouble Shooting and Error Messages

7.1 Error Screens

Sensor Disconnected 	Cause: Sensor not connected to the display. Solution: Ensure the sensor is properly connected. Disconnect and reconnect the sensor.
	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.
	Cause: Sensor cannot be detected by the display. Solution: Call the technical support hotline (800) 443-3385.
Sensor Error 	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 (800) 443-3385.
	Cause: Sensor malfunction. Solution: 1. Turn off and restart the system. 2. If the error continues, discontinue use and call the technical support hotline (800) 443-3385.
Magnet Error 	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 (1.5m) 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.

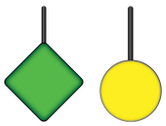
7.2 ECG Troubleshooting

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 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).
	Cause:	Noise from AC outlet.
	Solution:	Disconnect the power supply from the AC outlet.
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:	Extraneous 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.
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.
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.
In ECG navigation, blue R-wave inverts too soon in procedure	Cause:	Black electrode is not positioned at below the jugular notch over the manubrium of the sternum.
	Solution:	For ECG navigation, black electrode should be moved to position described in Section 4 Step 5.
In ECG navigation, blue R-wave remains inverted, does not return to normal	Cause:	Gross malposition (e.g. IJ malposition) as described in Section 1.3 under ECG Navigation.
	Solution:	Pull catheter back and readvance catheter.

In ECG navigation, blue R-wave doesn't invert or doesn't appear consistently	Cause:	R-wave is not present, not identifiable, or intermittent.
	Solution:	ECG navigation cannot be used if R-wave is not distinguishable. Use alternative navigation method.
	Cause:	ECG electrodes are in the incorrect positions.
	Solution:	Ensure ECG electrodes are in correct positions described in Section 4 Step 5.
Initial negative deflection of the P-wave occurs too soon	Cause:	Red electrode is placed too high on the patient.
	Solution:	Red electrode should be moved to position described in Section 4 Step 5.

7.3 Magnetic navigation troubleshooting

Magnetic navigation does not detect stylet (when enabled)  **Note:** Depth icons will not be present.	Cause:	Sensor incorrectly oriented.
	Solution:	Orient sensor correctly per procedure.
	Cause:	Stylet outside sensor depth range (1 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 [ ] or [ ]
	Cause:	Stylet at edge of sensor's depth range (1 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.
Magnetic navigation Stylet icon has erratic behavior	Cause:	Stylet at edge of sensor's depth range (1 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 (1 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.

8 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.

9 Sherlock 3CG™ TCS Printer Installation

Compatible printers connect by using USB. Connect the USB plug of the printer to an available USB port. For a list of compatible printers please see insert or contact your local sales representative.

10 Cleaning and Disinfection

10.1 Cleaning and Intermediate Disinfection Procedure using PDI® Super Sani-Cloths®

Step 1: Use one or more new towelettes to remove visible soil.

Step 2: Use two or more new towelettes to clean surfaces for at least two minutes.

Step 3: Repeat Step 2 using two new towelettes for an additional two minutes.

Note: The procedure achieves Intermediate Disinfection per FDA guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling", only when the sides and bottom of sensor are wet for a total of four minutes and when all other surfaces are wet for a total of two minutes.

Note: Please follow PDI® Super Sani-Cloths® instructions for use including wet time, dry time, and the use of personal protective equipment.

Note: If only cleaning is required, follow steps 1 and 2.

10.2 Disinfection Procedure

For a list of disinfectants approved for use on the sensor, display, power supply, remote control and optional accessories, contact an authorized Bard Access Systems, Inc. representative.

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.

11 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.

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. This does not apply to changing the battery in the display.
- 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.

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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.

12 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 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.

13 Technical Specifications

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

14 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.

BARD

ACCESS SYSTEMS

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: March 2020

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