Sapiens*
Tip Confirmation System
Sapiens® TCS for use with Sherlock® II TLS

- **Keep dry**
- **Fragile, handle with care**
- **Manufacturer**
- **CF Type Equipment**
- **Attention, see instructions for use**
- **Storage humidity limitation**
- **Storage temperature limitation**
- **Operating humidity limitation**
- **Operating temperature limitation**
- **Do not dispose with ordinary municipal waste**
- **Rx Only**
  - Federal (U.S.A.) law restricts this device to sale by or on the order of a physician
# Instructions For Use

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</tbody>
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In the context of providing instructions for use and troubleshooting, it is crucial to ensure that all components and instructions are followed accurately to maintain the integrity and efficacy of the Sapiens* TCS system. This guide offers detailed steps for assembly, software upgrades, and troubleshooting, complemented by sections on cleaning, disinfection, and warranty information, ensuring a comprehensive approach to operational and maintenance requirements.
1 Overview

1.1 Indications for Use

The Sapiens* Tip Confirmation System (TCS) is indicated for guidance and positioning of Peripherally Inserted Central Catheters (PICCs). The Sapiens* TCS provides real-time catheter tip location information by using the patient’s cardiac electrical activity. Sapiens* 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 catheter tip location.

1.2 Sapiens* TCS Description

The Sapiens* TCS is designed to aid in PICC tip positioning through ECG technology. It is designed to operate with Bard Access Systems’ catheter kits labeled and “Sherlock 3CG* TPS Stylet”. When used in conjunction with Sherlock* II Tip Location System (TLS) these kits provide both magnetic tracking and ECG positioning information.

Note: Sapiens* TCS will not work with catheter kits labeled . Refer to the Sherlock* II TLS Instructions for use.

ECG Positioning

The Sapiens* 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.

1.3 System Components

The Sapiens* TCS and authorized accessories:
- Sherlock* II TLS Sensor for use with Sapiens* TCS (The Sensor)
- Sapiens* TCS ECG Module
- Sapiens* TCS Display
- Sapiens* TCS Remote Control
- Sapiens* TCS Medical Grade Power Supply
- Sherlock 3CG* TPS 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* II TLS Sensor Holster
- Remote Control Holder
- Bard Access Systems’ approved printer

To order, contact Bard Access Systems’ Sales Representative or Customer Service at (800) 545-0890.
1.4 Warnings and Precautions

This section specifies warnings and precautions specific to the functionality of the Sapiens* TCS.
- See the Sherlock* II TLS Instructions for Use for magnetic navigation warnings, precautions and notes.
- See the Bard Access Systems’ catheter Instructions for Use for possible complications associated with central venous catheter placements and ECG positioning.

Warnings

Warning: This product should only be operated by qualified medical personnel.
Warning: Do not power the Sapiens* 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 Sapiens* TCS and may result in injury or equipment damage.
- Opening or servicing the Sapiens* 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 1.3.
Warning: If the Sapiens* 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: Sapiens* TCS is not intended to diagnose or treat disease.
Warning: Only Bard Access Systems’ authorized service personnel should attempt to service this equipment. The Sapiens* TCS contains static sensitive components and circuits. Failure to observe proper static control procedures may result in damage to the system.
Warning: If the Sapiens* TCS is visibly damaged, discontinue use immediately. Use of the damaged system may result in injury or equipment damage.
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 Sapiens* 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 Sapiens* TCS must only be operated by battery power when in contact with a patient.
Warning: The Sapiens* TCS must only be charged with the Sapiens* TCS Power Supply.
Warning: Do not remove Sapiens* 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.

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.
2 Assembling the Sapiens* TCS

2.1 Attaching the Sherlock* II TLS Sensor Holster to the roll stand
Refer to the Sherlock* II TLS Instructions for Use.

2.2 Connecting the Sensor to the Sapiens* TCS ECG Module
Connect the Sensor to the Sapiens* TCS ECG Module.

Connect the Sensor to the Site-Rite* Ultrasound System. Refer to the Sherlock* II TLS Instructions for Use.
3 Sapiens* TCS Information

3.1 Sapiens* TCS Graphical User Interface

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

- **EXTERNAL (or baseline) ECG**
  - Real-time external and intravascular ECG waveforms.

- **INTRAVASCULAR ECG**
  - Patient information will be shown on the procedural record.

- **MAIN SCREEN**
  - Channel Display
    - Changes the vertical position of the external (white) and intravascular (yellow) ECG waveforms on the Main Screen.
  - Scale Setting
    - Used to adjust the ECG signal amplitude.
  - Wave Selection
    - Select either the white or yellow ECG waves for manipulation.
  - Display Speed
    - Sets the speed of the ECG playback.

- **SAPIENS* TCS APPLICATION TOOLBAR**
  - Name
  - Patient ID
  - Date of Birth
  - Exit Site Marking
  - Scale: 1X
  - Display speed: 2

- **SOFTWARE VERSION**
  - Closes Sapiens software
3.2 Sapiens* TCS Controls

**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 reference screen.

**Clear.** Select to clear the patient information and Reference Screen.

**Pause/Play.** Select to pause or play the ECG waveform in acquisition and playback modes.

**Open.** Select to open procedural ECG waveform files or procedural printouts.

**Save.** Select to stop and save the ECG waveform recording.

**Save As.** Select to save a procedural record, which includes patient information and Reference Screen ECG waveforms.

**Print Preview.** Select to preview the procedural record.

**About.** Select to display information about the Sapiens* TCS software.

**Close.** Select to close the Sapiens* TCS Application.
3.3 Sapiens® TCS Application Toolbar

**Sapiens® TCS.** Opens the Sapiens® TCS Application.

**Sherlock® II TLS.** Opens the Sherlock® II TLS Application.

**Settings.** Opens the Sapiens® TCS Settings Menu.

**Battery Status.** Visual Battery Status Indicator: 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/blinkin at 20% of the remaining battery life.
3.4 Settings Button

Select to open the Sapiens* TCS System Settings window.

3.4.1 System Settings - General

<table>
<thead>
<tr>
<th>Button</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change Date/Time</td>
<td>Launches the operating system Date and Time properties window.</td>
</tr>
<tr>
<td>Update System Software</td>
<td>Provides system software updates when a USB flash drive is inserted containing a Sapiens* TCS-compatible installation software.</td>
</tr>
<tr>
<td>About</td>
<td>Indicates applications' version information.</td>
</tr>
<tr>
<td>Shutdown</td>
<td>Shuts down the Sapiens* TCS display.</td>
</tr>
<tr>
<td>Restart</td>
<td>Restarts the Sapiens* TCS display.</td>
</tr>
<tr>
<td>Close</td>
<td>Closes the System Settings window.</td>
</tr>
</tbody>
</table>
3.4.2 System Settings - Bluetooth*

| Add a Bluetooth* Remote Control | Adds the Sapiens* TCS Remote Control. |
| Show Bluetooth* Devices | Provides system software updates when a USB flash drive is inserted containing a Sapiens* TCS-compatible installation software. |
| Close | Closes the System Settings window. |

3.4.3 System Settings - Printers

| Set as Current Printer | Sets the default printer to the printer selected prior to clicking this button. **Note** – Sapiens* TCS application will print to the default printer. |
| Remove Printer From System | Deletes the selected printer. |
Enable Sherlock* II TLS Printing  When selected, clicking the Print to File button on the Sapiens* TCS application will print the Sherlock* II TLS screen view first, followed by the Sapiens* TCS Reference Screen.

Close  Closes the System Settings window.

3.4.4 System Settings - File Management

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Refresh</strong></td>
<td>Refreshes the files listed in the viewer.</td>
</tr>
<tr>
<td><strong>Hide EKG</strong></td>
<td>Hides all files with a .ekg extension from appearing in the viewer.</td>
</tr>
<tr>
<td><strong>Hide Images</strong></td>
<td>Hides all files with a .jpg extension from appearing in the viewer.</td>
</tr>
<tr>
<td><strong>New Folder</strong></td>
<td>Creates a new storage folder under the C:\Data archive.</td>
</tr>
<tr>
<td><strong>Delete</strong></td>
<td>Delete selected files or folders. <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><strong>Copy</strong></td>
<td>Copies selected files or folders.</td>
</tr>
<tr>
<td><strong>Select All</strong></td>
<td>Selects all files displayed in the viewer.</td>
</tr>
<tr>
<td><strong>Paste</strong></td>
<td>Pastes copied files or folders to a designated location.</td>
</tr>
<tr>
<td><strong>Close</strong></td>
<td>Closes the System Settings window.</td>
</tr>
</tbody>
</table>
3.4.5 System Settings - Log

The Log is intended as a reference for use in servicing by BAS Representatives.

3.5 Sapiens® TCS Remote Control

![Diagram of Sapiens TCS Remote Control]

- ACTIVITY LED
- PRINT TO FILE
- TOUCH PAD
- RIGHT MOUSE BUTTON
- LEFT MOUSE BUTTON
- BLUETOOTH LED
- FREEZE
- ACTIVITY LED
- PRINT TO FILE
- TOUCH PAD
- RIGHT MOUSE BUTTON
- LEFT MOUSE BUTTON
4 Sapiens* TCS Catheter Guidance

Step 1: Prepare Device
- Connect the Sensor to the Sapiens* TCS ECG Module and power on the Sapiens* TCS display.
- Verify the Status Bar indicator is green.
- Verify the battery charge is sufficient for the procedure.
- Enter Patient Information as needed.

Step 2: Position Patient and Perform Ultrasound Pre-scan
- Refer to the Bard Access Systems' Site~Rite* Ultrasound System Instructions for Use.

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

Step 4: Prepare Sensor
- Refer to Sherlock* II TLS Instructions for Use for magnet tracking information.
- Slide the Fin Assembly onto the sensor until fully seated.

Step 5: Position Sensor and ECG electrodes
- Refer to Sherlock* II TLS Instructions for Use for magnet tracking information.
- Place sensor in the sensor holder with the fin and ECG electrodes remaining outside the holder and tighten the cinch ring.

- Unplug the Sapiens* TCS Power Supply from the wall.

Warning: The Sapiens* TCS must only be operated by battery power when in contact with a patient.
- 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. Refer to Bard Access Systems’ catheter instructions for use.
Step 6: Evaluate External ECG waveform
- Refer to the Bard Access Systems’ catheter Instructions for Use.

Step 7: Perform Initial Magnet Tracking Calibration
- Select to switch to Sherlock* mode.
- Refer to the Sherlock* II TLS Instructions for Use.

Step 8: Prepare Catheter Sterile Field
- Refer to the Bard Access Systems’ catheter Instructions for Use.

Step 9: Access the Vein
- Refer to the Bard Access Systems’ Site~Rite* 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
- Refer to Sherlock* II TLS Instructions for Use for magnetic tracking information.

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.

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
- Attach a USB storage device or printer to an available USB port on the Sapiens* TCS Display.
- Select Print to File to save/print a procedural record.
5 Troubleshooting and Error Messages

5.1 System Errors

<table>
<thead>
<tr>
<th>Situation</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrodes not connected</td>
<td>If Sapiens® TCS does not detect any connection of electrodes to the patient, a message is displayed on the Status Bar. In such a case, verify that the skin electrodes are well attached to the patient’s skin, that the ECG cable clips are well attached to the snap nipple on the electrodes and that the Sapiens® TCS Adaptors are well connected to the red clip of the ECG cable. Verify that the ECG cable is well attached to the ECG module. If the error situation persists, you may replace the ECG skin electrodes with new ones. If the error continues, discontinue use and call the technical support hotline (800) 443-3385.</td>
</tr>
<tr>
<td>ECG module not connected</td>
<td>If Sapiens® TCS does not detect the presence of an ECG module, a message is displayed on the Status Bar. In such a case, verify that the USB cable between the ECG module and the display is well connected. Close and reopen the Sapiens® TCS software. If the error continues, discontinue use and call the technical support hotline (800) 443-3385.</td>
</tr>
<tr>
<td>ECG signal not displayed</td>
<td>The Sapiens® TCS uses a serial communication protocol and a USB-Serial converter between the display and the ECG module. If the USB connector is not connected when the Sapiens® TCS software application starts up or if the USB connector is disconnected before shutting down, the Sapiens® TCS software application must be restarted.</td>
</tr>
</tbody>
</table>

5.2 Procedural Troubleshooting

<table>
<thead>
<tr>
<th>Situation</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sapiens® TCS will not power on or power on but turns off immediately</td>
<td>Press and hold the power button for at least 3 seconds to power on. Connect system to an A/C outlet for battery recharge. If the power problems continue call the technical support hotline (800) 443-3385.</td>
</tr>
</tbody>
</table>
| 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. Refer to Section 4 step 5.  
Cause: Air bubble at the catheter tip.  
Solution: Flush the catheter lumen containing the stylet with saline.  
Cause: No stylet-to-fin connection.  
Solution: Fully seat the stylet connector on the fin. Refer to the Bard Access Systems’ catheter instructions for use. |
<table>
<thead>
<tr>
<th>Problem</th>
<th>Cause</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<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>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>ECG signal abnormal</td>
<td>Extraneous noise.</td>
<td>Avoid touching the stylet or electrodes.</td>
</tr>
<tr>
<td>Absent ECG signal</td>
<td>Damaged ECG electrodes.</td>
<td>Replace electrodes. Refer to Section 4 step 5.</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>Date and time incorrect</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></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>ECG module not connected</td>
<td>Body ECG leads swapped.</td>
<td>Place ECG leads correctly. See Section 4, Step 5.</td>
</tr>
<tr>
<td></td>
<td>No distinct P-wave.</td>
<td>Do not rely on ECG guidance for catheter tip confirmation. Refer to Warnings in Section 1.4.</td>
</tr>
<tr>
<td>Date and time incorrect</td>
<td>ECG module is not communicating with the Display.</td>
<td>Close the Sapiens* TCS application. Connect the ECG module to the Display with the provided USB cable. Restart the Sapiens* TCS application.</td>
</tr>
<tr>
<td></td>
<td>ECG module is not communicating with the Display.</td>
<td>Close the Sapiens* TCS application. Restart the Sapiens* TCS application.</td>
</tr>
<tr>
<td></td>
<td>Shutdown the Display.</td>
<td>Reboot the Display.</td>
</tr>
<tr>
<td>Date and time incorrect</td>
<td>Close the Sapiens* TCS application.</td>
<td>Connect the ECG module to the Display with the provided USB cable in a different USB port. Restart the Sapiens* TCS application.</td>
</tr>
<tr>
<td></td>
<td>Date and time need to be set or reset.</td>
<td>Close the Sapiens* TCS application. Select the “Change Date and Time” link from the pop-up menu and follow the prompts. Restart the Sapiens* TCS application.</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.</td>
<td>Pair the Remote Control following instructions in Section 7.</td>
</tr>
</tbody>
</table>

If problems continue, call the technical support hotline at (800) 443-3385.
6 Sapiens* TCS Remote Control Installation

1. Turn on the Sapiens* Tip Confirmation System (TCS) display and the Sapiens* TCS Remote Control.
2. Click the Settings icon in the application toolbar.
3. Click the Bluetooth tab in the system settings window.

4. Position the Sapiens* TCS Remote Control within two feet of the Sapiens* system. 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 Systems Setting window, click the Add a Bluetooth Remote Control button.

7 Sapiens* TCS Printer Installation

7.1 Brother* printer

1. Connect the USB cable to an available USB port on the Sapiens* TCS display.
2. Turn on the Sapiens* TCS display and the Brother* printer.
3. Ensure the slider switch on the printer is set to IrDA.
4. Select the System Settings icon from the Application Toolbar.
5. Select the Printer tab in the System Settings window.
6. Select the Brother* printer icon.

![Brother Printer Icon]

7. Select the “Set as Current Printer” button.

![Set as Current Printer Button]

7.2 Sony* Printer

1. Connect the printer USB cable to an available USB port on the Sapiens* 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 Sapiens* TCS display.
9. Select the System Settings icon from the Application Toolbar.
10. Select on the Printer tab in the System Settings window.

![Sony Printer Icon]

![Set as Current Printer Button]
11. Select the Sony* printer icon.

![](image)

12. Select the “Set as Current Printer” button.

8 Cleaning and Disinfection

8.1 Cleaning Procedure

To clean the Sapiens* TCS,

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

8.2 Disinfection Procedure

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

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

**Warning:** Do not attempt to sterilize the Sapiens* TCS sensor. Damage to the equipment may occur.
9 Warranty
The manufacturer, Bard Access Systems, Inc., warrants to the original purchaser that this product will be free from defects in material and workmanship for a period of one year from the date of purchase. If this product proves to be so defective, purchaser may return the same to Bard Access Systems, Inc. for repair, replacement or credit at Bard Access Systems Inc.'s option in accordance with Bard Access Systems Inc.'s Return Goods Policy found in the current price list. The warranty on the repaired or replaced unit continues from the purchase date of the original unit. This warranty does not cover damages resulting from misuse, abuse, modification, or alteration of this product or the repair of this product by anyone other than an authorized Bard Access Systems, Inc. representative.

Without limitation, the following actions void the warranty of the Sapiens® TCS:
- Opening or servicing the Sapiens® TCS sensor by anyone other than Bard Access Systems’ authorized service personnel.
- Removing system labels by anyone other than by Bard Access Systems’ authorized service personnel.
- Connecting the Sapiens® TCS sensor to any unauthorized system or accessory. Refer to Section 1.3.

TO THE EXTENT ALLOWABLE BY APPLICABLE LAW, THIS LIMITED PRODUCT WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. THE LIABILITY AND REMEDY STATED IN THIS LIMITED PRODUCT WARRANTY WILL BE THE SOLE LIABILITY OF BARD ACCESS SYSTEMS, INC. AND REMEDY AVAILABLE TO PURCHASER FOR THIS PRODUCT, WHETHER IN CONTRACT, TORT (INCLUDING NEGLIGENCE) OR OTHERWISE.

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

Some states/countries do not allow an exclusion of implied warranties, incidental or consequential damages. You may be entitled to additional remedies under the laws of your state/country.

10 Service and Repair
There is no periodic or preventative maintenance required for the Sapiens® TCS.

For servicing information or to return your Sapiens® 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 Sapiens® 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 Sapiens® TCS sensor by anyone other than Bard Access Systems' authorized service personnel will void the warranty and may result in injury or equipment damage.

11 Technical Specifications

11.1 Sapiens® TCS Sensor Operational and Storage Conditions
Operating Temperature: 15°C to 38°C (59°F to 100°F)
Storage Temperature: -18°C to 40°C (22°F to 104°F)
Operating Humidity: 5% to 85% non-condensing
Storage Humidity: 5% to 95% non-condensing

12 Disposal Information
To return the Sapiens® 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 users information. In the event two years have elapsed between this date and product use, the user should contact Bard Access Systems, Inc. to see if additional product information is available. Revision date: July, 2011

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