### LIST OF ALL APPLICABLE ICONS

<table>
<thead>
<tr>
<th>Icon</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="icon1.png" alt="Manufacturer" /></td>
<td>Manufacturer</td>
</tr>
<tr>
<td><img src="icon2.png" alt="Consult instructions for use" /></td>
<td>Consult instructions for use</td>
</tr>
<tr>
<td><img src="icon3.png" alt="Rx Only" /></td>
<td>Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician</td>
</tr>
<tr>
<td><img src="icon4.png" alt="SN" /></td>
<td>Serial Number</td>
</tr>
<tr>
<td><img src="icon5.png" alt="Date of Manufacture" /></td>
<td>Date of Manufacture</td>
</tr>
<tr>
<td><img src="icon6.png" alt="Direct Current" /></td>
<td>Direct Current</td>
</tr>
<tr>
<td><img src="icon7.png" alt="Do not dispose of battery with ordinary municipal waste" /></td>
<td>Do not dispose of battery with ordinary municipal waste</td>
</tr>
<tr>
<td><img src="icon8.png" alt="Type CF applied part" /></td>
<td>Type CF applied part</td>
</tr>
<tr>
<td><img src="icon9.png" alt="Do not dispose with ordinary municipal waste" /></td>
<td>Do not dispose with ordinary municipal waste</td>
</tr>
<tr>
<td><img src="icon10.png" alt="The Green Dot" /></td>
<td>The Green Dot</td>
</tr>
<tr>
<td><img src="icon11.png" alt="Catalog Number" /></td>
<td>Catalog Number</td>
</tr>
<tr>
<td><img src="icon12.png" alt="Caution" /></td>
<td>Caution</td>
</tr>
<tr>
<td><img src="icon13.png" alt="Class II Electrical Equipment" /></td>
<td>Class II Electrical Equipment</td>
</tr>
<tr>
<td><img src="icon14.png" alt="Operate Indoors Only" /></td>
<td>Operate Indoors Only</td>
</tr>
</tbody>
</table>
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1.0 **Nautilus Delta™ TCS Description**

The Nautilus Delta™ TCS is designed to aid in central venous access device (CVAD) tip positioning through Electrocardiogram (ECG) technology. It is designed to operate with Bard catheter kits labeled [\[\]].

**ECG Confirmation**

The Nautilus Delta™ 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.
ECG Navigation

The Nautilus Delta™ TCS system displays a blue ECG navigation signal (when enabled) 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.

Nautilus Delta™ Tip Confirmation System (TCS) Components and Accessories

The Nautilus Delta™ TCS ECG Cable (ECG Cable)

b) Nautilus Delta™ TCS Patient Module (Patient Module)

c) Nautilus Delta™ TCS Display (Display)

d) Nautilus Delta™ TCS Software running on the Display

The following are accessories, ancillary devices, or spare parts to the Nautilus Delta™ TCS:

- Nautilus Delta™ E Electrical Adaptor
- Sherlock 3CG™ TPS Stylet
- Remote
- Optional Printer
2.0 Indications for Use

The Nautilus Delta™ Tip Confirmation System (TCS) is indicated for navigation and positioning of central venous access devices (CVADs) of at least 3 Fr in size. The Nautilus Delta™ TCS provides real-time catheter tip location information by using 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.

In adult patients and in adolescents (greater than 12 through 21 years of age), the Nautilus Delta™ 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), the Nautilus Delta™ TCS can be used with PICCs and with centrally inserted central catheters (CICCs); in infants (greater than 1 month to 2 years of age) and in neonates (from birth to 1 month of age), the Nautilus Delta™ TCS can be used with 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 central venous catheter insertion, the use of an additional method is required to confirm catheter tip location.

3.0 Contraindications

There are no contraindications specific to the Nautilus Delta™ TCS.

4.0 Warnings

Warning Before using the Nautilus Delta™ 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 Nautilus Delta™ TCS.

Warning In patients where alterations of cardiac rhythm significantly change the presentation of the P wave (e.g., P-wave not present, P-wave not identifiable, P-wave intermittent) as in atrial fibrillation, atrial flutter, severe tachycardia, and pacemaker driven rhythm, the use of an additional method, according to your institutional guidelines, is required to confirm catheter tip location.

Warning 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, the use of an additional method, according to your institutional guidelines, is required to confirm catheter tip location.

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 The Nautilus Delta™ TCS can interfere with pacemaker devices. If you have a pacemaker or other electrical medical devices, you should consult your physician before using the product.

Warning Do not power the Nautilus Delta™ TCS in the presence of flammable anesthetics or gases. Explosion may result.

Warning If the Nautilus Delta™ TCS is visibly damaged or warmer than the ambient temperature, discontinue use immediately. Use of damaged device may result in injury or equipment damage.
4.0 Warnings (cont’d)

Warning Read and follow the instructions for use provided with the NAUTILUS DELTA™ E Electrical Adaptor when using it with the NAUTILUS DELTA™ TCS.

Warning The NAUTILUS DELTA™ TCS is not intended to diagnose or treat disease.

Warning The NAUTILUS DELTA™ TCS is not intended to be used as monitoring equipment.

Warning The NAUTILUS DELTA™ TCS is not intended to be used as life-supporting equipment.

Warning The NAUTILUS DELTA™ TCS only works for a sinus rhythm of the heart.

Warning If no ECG waveforms are detected, verify the connection between the patient’s skin and the electrodes, between the electrodes and the ECG cable, and between the NAUTILUS DELTA™ E Electrical Adaptor and the ECG cable, as it may be caused by an impedance mismatch between the patient and the ECG electrodes. 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 In certain patients, unstable ECG waveforms may be detected because of the manipulation of the NAUTILUS DELTA™ E Electrical Adaptor by the operator. Verify that the connection between the NAUTILUS DELTA™ E Electrical Adaptor and the central venous catheter and the connection between the NAUTILUS DELTA™ E Electrical Adaptor and the Patient Module are free from contact with any other material and do not touch the NAUTILUS DELTA™ E 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 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 Place skin electrodes carefully at locations indicated in these Instructions for Use and ensure good skin-electrode contact. Use commercially available skin electrodes/pads with snap buttons according to the manufacturer’s instructions for use. 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 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 Do not place and/or use the NAUTILUS DELTA™ 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 personal 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 NAUTILUS DELTA™ TCS must only be charged with the power supply provided with the NAUTILUS DELTA™ TCS.

Warning Do not charge the NAUTILUS DELTA™ TCS while using the device in a medical procedure.

Warning Do not remove the NAUTILUS DELTA™ TCS labels.

Warning Ensure all connecting cables and connections are electrically insulated and do not come into contact with other electrical cables or metal surfaces.

Warning Do not submerge or spray any of the NAUTILUS DELTA™ TCS components or accessories or allow fluid to enter any of the connector(s). Damage to the equipment may occur.
4.0 Warnings (cont’d)

Warning  Use of incorrect cleaners can result in optical impairment of the LCD and/or damage to the mobile platform. Always refer to the cleaner manufacturer’s guidelines and material safety data sheets for proper handling and use of the products.

Warning  Dispose of the product according to local standards and regulations for electronic devices.

Warning  The battery used in this product may present a risk of fire or chemical burn if damaged or not handled properly.

Warning  Do not attempt to sterilize the Patient Module, Display or Printer. Damage to the equipment may occur.

Warning  Equipment such as CT scanners, X-rays and fluoroscopy systems, cauteries and diathermy equipment, operating in close proximity may emit strong electromagnetic or radio frequency interference (RFI) which could interfere with the display of ECG waveforms by the Nautilus Delta™ TCS. Do not place and/or use the Nautilus Delta™ TCS in the presence of such equipment.

Warning  Active electric motor driven equipment, such as pumps, may interfere with the display of the ECG waveforms by the Nautilus Delta™ TCS. Do not place and/or use the Nautilus Delta™ TCS in the presence of such equipment.

Warning  Electric equipment which requires direct contact with the patient may interfere with the display of ECG waveforms by the Nautilus Delta™ TCS. Do not use electric cautery, electric scalpels, and ablation equipment while using the device.

Warning  The use of accessories and cables other than those listed in the instructions for use may result in increased electromagnetic emission and/or decreased immunity of the device.

Warning  It is possible that an electrostatic discharge could result in equipment ceasing to operate. If this occurs, please restart the Patient Module and continue the procedure. 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  Field repair of this device is not possible. Do not attempt to open the case, repair or replace components of the Nautilus Delta™ TCS. The following actions void the warranty of the Nautilus Delta™ TCS and may result in injury or equipment damage:

- Opening or servicing any component of the Nautilus Delta™ TCS by anyone other than Bard Access Systems’ authorized service personnel. This does not apply to changing the battery in the Printer or the Display.
- Removing system labels by anyone other than Bard Access Systems’ authorized service personnel.
- Connecting the Nautilus Delta™ TCS or applied patient components to any unauthorized system or accessory.
- Installation of unauthorized software.
- Modification of system software settings without authorization by Bard Access Systems.

Warning  Only qualified personnel should attempt to service this equipment. The Nautilus Delta™ TCS contains static sensitive components and circuits. Failure to observe proper static control procedures may result in damage to the system.
5.0 Precautions

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

Caution: The Nautilus Delta™ TCS complies with International 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 Nautilus Delta™ 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 Nautilus Delta™ TCS.

Caution: Use the Nautilus Delta™ TCS within its designated range of approximately 10 meters. Moving outside this range may cause missing or lost data.

Caution: The full performance of a new battery is achieved only after two or three complete charge and discharge cycles.

Caution: Do not leave a fully charged battery connected to a charger, since overcharging may shorten its lifetime.

Caution: If left unused, a fully charged battery will lose its charge over time.

Caution: In order to prevent the unauthorized access to patient information stored on the internal storage device of the Display running the Nautilus Delta™ TCS Mobile Medical Application, setting up password protection on the Display is recommended. Additional protection can be obtained by enabling the encryption protection provided with the Display. To set up a password and/or encryption protection on the Display, follow the instructions for use provided by the manufacturer of the Display.

Caution: For detailed central venous catheter preparation and insertion information, follow the instructions stated in the catheter’s instructions for use provided by the catheter manufacturer.

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

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

Caution: Placement of electrodes outside of their correct regions may result in reduced ECG performance. See section 7.

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 Nautilus Delta™ TCS Display.
6.0 Assembling the Nautilus Delta™ TCS

6.1 Attaching the Patient Module to the Roll Stand

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

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

6.2 Connecting the Patient Module to the Display

The Patient Module connects to the USB port on the Display.

6.3 Connecting the ECG Cable to the Patient Module

The ECG Cable connects to the Patient Module.
7.0 NAUTILUS DELTA™ TCS Information

7.1 NAUTILUS DELTA™ TCS Graphical Interface, Controls and Indicators

**INTRAVASCULAR ECG VIEW**

**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.

- External (baseline) ECG
- R-Peak Indicator Enabled
- Intravascular ECG

**FRONT PANEL CONTROLS/INDICATORS**

Press for Navigation ECG view
## 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 NAUTILUS DELTA™ TCS Display.                                  |
| ![Settings](image)
| **Settings**: Select to open the system settings menu.                         |
| ![Battery](image)
| **Battery Charging**: When the unit is charging the battery, the AC connected |
| indicator will overlay the battery status.                                    |
| ![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/ blinking at 20% of the remaining battery life.      |
**FRONT PANEL CONTROLS/INDICATORS**

- **Waveform Selection**: Select either the Intravascular (yellow) or Navigation (blue) ECG waves for manipulation.

- **Freeze**: Select to copy the current ECG waveforms from the Main Screen to the Reference Screen.

- **Print**: 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 menu.

---

**SOFTWARE VERSION**

- **ECG Tools Menu**
- **ECG Display Adjustment**
- **Patient Information**
  Patient Information will be shown on the procedural record.

The Menu Controls below are accessible when the Menu button is activated.
## MENU CONTROLS

<table>
<thead>
<tr>
<th>R-peak Enabled</th>
<th>R-peak Disabled</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>R-peak:</strong> Select to turn off and on R-peak Identifier.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Demo</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Demo:</strong> Select to initiate demonstration mode. For training, contact your Bard Access Systems’ Sales Representative.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Tools</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Tools:</strong> Open ECG Tools Menu.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Scale</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Scale:</strong> Select to adjust the ECG signal amplitude of the External (white), Intravascular (yellow), or Navigation (blue) ECG waveforms on the Main Screen.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Level</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Level:</strong> Select to adjust the vertical position of the External (white), Intravascular (yellow), or Navigation (blue) ECG waveforms on the Main Screen.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Speed</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Speed:</strong> Select to adjust the speed of the ECG playback.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Exit</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Exit:</strong> Select to close Menu.</td>
</tr>
</tbody>
</table>
The ECG Tools Menu Controls below are accessible when the ECG Tools Menu button is activated.

<table>
<thead>
<tr>
<th>ECG TOOLS MENU CONTROLS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Save</strong></td>
</tr>
<tr>
<td><strong>ivGain</strong></td>
</tr>
<tr>
<td><strong>ceGain</strong></td>
</tr>
<tr>
<td><strong>Reset</strong></td>
</tr>
<tr>
<td><strong>Exit</strong></td>
</tr>
</tbody>
</table>
7.2 Shutdown Menu
The Shutdown Menu Controls below are accessible when the Shutdown button [ ] is activated.

<table>
<thead>
<tr>
<th>SHUTDOWN MENU CONTROLS</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Nautilus Delta</td>
<td>Nautilus Delta: Restarts the NAUTILUS DELTA™ TCS Software Application.</td>
</tr>
<tr>
<td>Shutdown</td>
<td>Shutdown: Shuts down the Display.</td>
</tr>
<tr>
<td>Restart</td>
<td>Restart: Restarts the Display.</td>
</tr>
<tr>
<td>Lock</td>
<td>Lock: Locks the password enabled Display.</td>
</tr>
<tr>
<td>Cancel</td>
<td>Cancel: Closes the Shutdown Menu Controls.</td>
</tr>
</tbody>
</table>

7.3 Settings Icon
Select [ ] to open the NAUTILUS DELTA™ TCS Settings Window.

7.3.1 Settings – General

<table>
<thead>
<tr>
<th>Setting</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change Date and Time</td>
<td>Opens Date and Time properties window.</td>
</tr>
<tr>
<td>Change Language</td>
<td>Opens 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 Nautilus Delta™ TCS compatible installation is inserted.</td>
</tr>
<tr>
<td>--------------</td>
<td>-------------------------------------------------------------------------------------------------</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>Close</td>
<td>Closes the Settings Menu.</td>
</tr>
</tbody>
</table>

| Enable       | Enables the password protection, according to the value entered.                                  |
| Disable      | Disables the password protection.                                                                 |
| Close        | Closes the Password Window.                                                                        |

7.3.2 Settings – Printers

<table>
<thead>
<tr>
<th>Set Current Printer</th>
<th>Sets the selected printer as current.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Note</strong> – Nautilus Delta™ 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>
### 7.3.3 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 log files 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.</td>
</tr>
<tr>
<td></td>
<td><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>
8.0 NAUTILUS DELTA™ TCS Catheter Guidance

Step 1: Prepare Device
- Place the Display in a location visible to the operator performing the placement procedure.
- Connect the Patient Module to the Display via USB cord.
- Connect the ECG Cable to the Patient Module.
- 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 (if applicable)
- Refer to catheter instructions for use.

Step 4: Prepare Patient Module
- Place Patient Module in the holder with the USB and ECG electrodes remaining outside the holder and tighten holder around cords with rubber bands.

Step 5: Position Patient Module
- Place the Patient Module in a location that accommodates the ECG Cable connection and operation throughout the placement procedure.
- It is recommended that the Bard logo on the Patient Module be face up and USB cord routed toward the patient’s feet.

Step 6: Prepare and Attach External ECG Electrodes
- Prepare and attach external ECG electrodes per the following steps:
  1. 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).

  2. Attach electrodes to all lead wires.

  3. Remove backing and press electrodes firmly onto skin at the specified locations.
     a) Place red electrode on the patient’s lower left abdomen, inferior to the umbilicus and laterally along the mid-axillary line.
     b) Place green electrode on the patient’s lower right abdomen.
     c) Place blue electrode on the patient’s skin below the jugular notch over the manubrium of the sternum.
Caution: Placement of electrodes outside of their correct regions 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. Use commercially available skin electrodes/pads with snap buttons according to manufacturer’s instructions for use. 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 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.

Step 7: Evaluate External ECG waveform
- Refer to the catheter instructions for use.

Step 8: Prepare Catheter Sterile Field
- Refer to the catheter instructions for use.

Step 9: Access the Vein
- Refer to the catheter instructions for use and ultrasound system instructions for use.

Step 10: Attach Through-Drape Connector to Patient Module
- Attach Through–Drape Connector to Patient Module via the Patient Module Fin connection.
- Refer to catheter instructions for use.

Step 11: Insert Catheter
- Refer to catheter instructions for use for catheter insertion.

Step 12: Catheter Tip Navigation and Confirmation
- 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. As the catheter advances to the cavo-atrial junction, clinicians should refer to the ECG Confirmation instructions below.

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 Through–Drape Connector to Patient Module 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 catheter instructions for use.

Warning: 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, the use of an additional method, according to your institutional guidelines, is required to confirm catheter tip location.
Step 13: Complete Catheter Placement
- Complete catheter insertion, securement and remaining procedure according to the catheter instructions for use and facility protocol.

Step 14: 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.

9.0 Troubleshooting and Error Messages

9.1 Errors Screens

<table>
<thead>
<tr>
<th>Patient Module Disconnected</th>
<th>Cause: Patient Module not connected to the Display.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Solution: Ensure the Patient Module is properly connected. Disconnect and reconnect the Patient Module.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Patient Module Disconnected</th>
<th>Cause: Patient Module cannot be detected by the Display.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Solution: Call the technical support hotline (800) 443-3385.</td>
</tr>
</tbody>
</table>
### 9.2 ECG Trouble Shooting

| **Nautilus Delta™ TCS display will not power on.** | **Cause:** Battery not charged.  
**Solution:** Plug unit in and verify battery is properly connected. |
|--------------------------------------------------|------------------------------------------------------------------|
| **Nautilus Delta™ TCS display powers on to blank screen** | **Cause:** Software is corrupted or Display is damaged.  
**Solution:** Reboot Display. If behavior continues call the technical support hotline (800) 443-3385. |
| **Nautilus Delta™ TCS powers on to application toolbar only** | **Cause:** Software is corrupted or Display is damaged.  
**Solution:** Reboot Display. If behavior continues call the technical support hotline (800) 443-3385. |
| **Nautilus Delta™ TCS will not power on or powers on but turns off immediately.** | **Cause:** System battery is discharged or not powered on.  
**Solution:** Press and hold the power button for at least 3 seconds to power on.  
**Solution:** Connect system to an A/C outlet for battery recharge.  
**Solution:** If the power problems continue call the technical support hotline (800) 443-3385. |
| **Flat-line ECG signal** | **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 connections (e.g. T-lock) are fully seated.  
**Solution:** Replace electrodes.  
**Cause:** Air bubble at the catheter tip.  
**Solution:** Flush the catheter with saline.  
**Cause:** No catheter-to-Patient Module Fin connection.  
**Solution:** Fully seat the Through-Drape Connector on the Patient Module Fin. Refer to the catheter instructions for use. |


## 9.2 ECG Trouble Shooting (cont’d)

| Poor ECG Signal | Cause: Catheter connectors not fully seated on Patient Module 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/guidewire or electrodes.  
| Solution: Turn equipment in the vicinity off and on to isolate disruptive equipment.  
| Solution: Relocate or re-orient interfering equipment.  
| Solution: Increase distance between interfering equipment and Nautilus Delta™ TCS.  
| Solution: Remove devices that are highly susceptible to EMI.  
| Solution: Restrict use of personal communicators (cell phones, computers) in areas with devices susceptible to EMI. |
| Cause: Damaged ECG electrodes.  
| Solution: Replace electrodes. |
| Cause: Catheter not locked with saline.  
| Solution: Ensure catheter connections are fully seated. Flush the catheter with saline. |
| Cause: ECG electrodes are in incorrect positions.  
| Solution: Ensure ECG electrodes are in correct positions. |

| 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/guidewire or electrodes. |
| Cause: Catheter not locked with saline.  
| Solution: Ensure catheter connections (e.g. T-lock) are fully seated.  
| Solution: Flush the catheter lumen used for confirmation 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: Patient Module/ECG Cable damaged.  
Solution: Call technical hotline at 1-800-443-3385 to replace Patient Module and/or ECG Cable.  
| Cause: Patient Module disconnected.  
Solution: Ensure the Patient Module is properly connected.  
| Cause: Patient Module is not communicating with Display.  
Solution: Reboot the Display.  
| Cause: Incorrect skin electrode placement or connection.  
Solution: Check the connection of the skin electrodes.  
| Date and time incorrect | Cause: Date and time need to be set or reset.  
Solution: Select the and choose the General icon. Select the Change Date and Time icon and follow the prompts.  
| Remote control not working | Cause: Batteries are low.  
Solution: Replace batteries with standard AAA batteries.  
| Cause: Remote Control is not connected with the Display.  
Solution: Ensure USB receiver is connected.  
| ECG Screen (main/reference screen) is not visible | Cause: Incompatible Patient Module.  
Solution: Use Patient Module with product code number 9770320.  
| Disconnect from Power | The following message appears on the Display screen.  
Disconnect system from A/C outlet before use.  
|
10.0 Battery Installation and Removal

10.1 Installation

1. Align the battery pack and insert into the battery bay.

2. Slide the battery pack firmly until it locks into place.

3. Verify the battery switch is in the locked position.

10.2 Removal

1. Slide the battery switch to the unlocked position.

2. After the battery switch is in the unlocked position, the battery will lift up from the battery bay.
3. Lift the battery pack from the battery bay.

11.0 Remote Control Installation

The remote control uses a USB receiver, connect the USB receiver to an available USB port.

12.0 NAUTILUS DELTA™ TCS Printer Installation

1. Connect the USB cable to an available USB port on the NAUTILUS DELTA™ TCS Display.
2. Turn on the Display and the Printer.
3. Select the Settings icon from the Application Toolbar.
4. Select the Printers button in the menu that appears.
5. Select the printer icon.
6. Select the “Set a Current Printer” button.

13.0 Cleaning and Disinfection

13.1 Cleaning

To clean the NAUTILUS DELTA™ TCS:
1. Turn off the system.
2. Disconnect the power supply from the Patient Module, ECG Cable, Display, USB power cable and optional accessories. Also disconnect the power supply from the wall socket if connected.
3. Dampen a nonabrasive cloth with either warm water or isopropyl alcohol.
4. Gently wipe the dampened cloth over exterior surfaces.

### 13.2 Disinfection

For a list of disinfectants approved for use for the Patient Module, ECG Cable, Display, Power supply, USB power cable and optional accessories, contact an authorized Bard Access Systems Inc. representative.

**Warning:** Do not submerge or spray any of the Nautilus Delta™ TCS components or accessories or allow fluid to enter any of the connector(s). Damage to the equipment may occur.

**Warning:** Do not attempt to sterilize the Patient Module, Display, ECG Cable or Printer. Damage to the equipment may occur.

### 14.0 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 defective, purchaser may return the same 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, modifications, or alterations 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 any component of the Nautilus Delta™ TCS.

**Warning:** Field repair of this device is not possible. Do not attempt to open the case, repair or replace components of the Nautilus Delta™ TCS. The following actions void the warranty of the Nautilus Delta™ TCS and may result in injury or equipment damage:

- Opening or servicing any component of the Nautilus Delta™ TCS by anyone other than Bard Access Systems’ authorized service personnel. This does not apply to changing the battery in the Printer or the Display.
- Removing system labels by anyone other than Bard Access Systems’ authorized service personnel.
- Connecting the Nautilus Delta™ TCS or applied patient components to any unauthorized system or accessory.
- Installation of unauthorized software.
- Modification of system software settings without authorization by Bard Access Systems.

TO THE EXTENT ALLOWABLE BY APPLICABLE LAW, THIS LIMITED PRODUCT WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. THE LIABILITY AND REMEDY STATED IN THIS LIMITED PRODUCT WARRANTY WILL BE THE SOLE LIABILITY OF BARD ACCESS SYSTEMS, INC. AND REMEDY AVAILABLE TO PURCHASER FOR THIS PRODUCT, WHETHER IN CONTRACT, TORT (INCLUDING NEGLIGENCE) OR OTHERWISE. IN NO EVENT WILL BARD ACCESS SYSTEMS, INC. BE LIABLE TO YOU FOR ANY INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM YOUR HANDLING OR USE OF THIS PRODUCT EVEN IF BARD ACCESS SYSTEMS, INC. HAS BEEN ADVISED OF THE POSSIBILITY OR LIKELIHOOD OF SUCH DAMAGES. IN NO EVENT WILL BARD ACCESS SYSTEMS, INC.’S LIABILITY UNDER THIS WARRANTY WITH RESPECT TO THIS PRODUCT EXCEED THE PURCHASE PRICE PAID TO BARD ACCESS SYSTEMS, INC. FOR SUCH PRODUCT.

Some 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 country.
15.0 Service and Repair

There is no periodic or preventative maintenance required for the **Nautilus Delta™ TCS**. For servicing information or to return any component of your **Nautilus Delta™ TCS** for repair, please contact Bard Access Systems' technical support hotline at (800) 443-3385.

16.0 Technical Specifications

- Operating Temperature Limitation: 5°C to 40°C
- Storage Temperature Limitation: -18°C to 40°C
- Operating Humidity Limitation: 5% to 90% non-condensing
- Storage Humidity Limitation: 5% to 95% non-condensing
- Contains Lithium Ion Battery

17.0 Disposal Information

To return the **Nautilus Delta™ TCS** for end of life recycling, please contact your nearest Bard sales or Distributor office in the country of purchase.

18.0 Deleting Patient Information

**Note:** This procedure will permanently delete all patient information from your system.

1. Select the Settings button.
2. Select the File Management button.
3. Select the Select All button.
4. Select the Delete button.
## 19.0 Manufacturer's Declaration

**Nautilus Delta™ TCS Electromagnetic Compatibility (EMC) Tables**

### Emissions

<table>
<thead>
<tr>
<th>EMissions Test</th>
<th>Compliance</th>
<th>Electromagnetic Environment - Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF Emissions CISPR 11</td>
<td>N/A</td>
<td>The <strong>Nautilus Delta™ TCS</strong> uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td>
</tr>
<tr>
<td>RF Emissions CISPR 11</td>
<td>Class A</td>
<td>The <strong>Nautilus Delta™ TCS</strong> is suitable for use in all establishments, other than domestic, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td>
</tr>
<tr>
<td>Harmonics IEC 61000-3-2</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Flicker IEC 61000-3-3</td>
<td>N/A</td>
<td></td>
</tr>
</tbody>
</table>

### Immunity

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC 60601 Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment - Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>ESD EN/IEC 61000-4-2</td>
<td>±6kV contact</td>
<td>±6kV contact</td>
<td>Floors should be wood, concrete, or ceramic tile. If floors are synthetic, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td></td>
<td>±8kV air</td>
<td>±8kV air</td>
<td></td>
</tr>
<tr>
<td>EFT EN/IEC 61000-4-4</td>
<td>±2kV Mains</td>
<td>N/A</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td></td>
<td>±1kV Input/Output</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Lines</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surge EN/IEC 61000-4-5</td>
<td>±1kV Differential</td>
<td>N/A</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td></td>
<td>±2kV Common</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Voltage Dips/Dropout EN/IEC 61000-4-11</td>
<td>&gt;95% Dip for 0.5 Cycle</td>
<td>N/A</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td></td>
<td>60% Dip for 5 Cycles</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>30% Dip for 25 Cycles</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>&gt;95% Dip for 5 seconds</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Power Frequency 50/60 Hz Magnetic Field EN/IEC 61000-4-8</td>
<td>3 A/m</td>
<td>3 A/m</td>
<td>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td>
</tr>
</tbody>
</table>
The Nautilus Delta™ TCS is intended for use in the electromagnetic environment specified below. The customer or user of the Nautilus Delta™ TCS should ensure that it is used in such an environment.

<table>
<thead>
<tr>
<th>IMMUNITY TEST</th>
<th>IEC 60601 TEST LEVEL</th>
<th>COMPLIANCE LEVEL</th>
<th>ELECTROMAGNETIC ENVIRONMENT - GUIDANCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conducted RF</td>
<td>EN/IEC 61000-4-6</td>
<td>3 Vrms 150 kHz to 80 MHz</td>
<td>3 Vrms</td>
</tr>
<tr>
<td>Radiated RF</td>
<td>EN/IEC 61000-4-3</td>
<td>3 V/m 80 MHz to 2.5 GHz</td>
<td>3 V/m</td>
</tr>
</tbody>
</table>

Portable and mobile RF communications equipment should be separated from the Nautilus Delta™ TCS by no less than the distances calculated/listed below:

\[
D = 1.2 \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}
\]

\[
D = 2.3 \sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}
\]

Where \( P \) is the max power in watts and \( D \) is the recommended separation distance in meters.

Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels.

Interference may occur in the vicinity of equipment containing a transmitter.

An issue or revision date for these instructions is included for the user’s 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: May 2017