BD Prevue™ II Peripheral Vascular Access System (DMS-S47)

Instructions for Use and Technical Manual

SYMBOLS

bd.com/elit — Consult instructions for use

Humidity Limitation

Keep Dry

Do not dispose with ordinary municipal waste

Federal Communications Commission This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Date of Manufacture

Class II electrical equipment

Quantity

Atmospheric Pressure Limitation

Temperature Limitation

Manufacturer

Type BF Applied Part

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

IPX1 — Drip Proof Equipment

REF — Catalog Number

SN — Serial Number

15V 4A — Direct Current

Warning: Magnetic Field

Caution

FCC Statement :

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.
This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
-Reorient or relocate the receiving antenna.
-Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
-Consult the dealer or an experienced radio/TV technician for help.

You are cautioned that changes or modifications not expressly approved by the part responsible for compliance could void the user's authority to operate the equipment.

FCC frequency stability Statement: (for WIFI 5G)
Frequency Stability: The grantee ensured that the EUT meets Section 15.407(g) requirements.

Industry Canada Statement :

This device complies with Industry Canada's licence-exempt RSSs.
Operation is subject to the following two conditions:
(1) this device may not cause interference, and
(2) this device must accept any interference, including interference that may cause undesired operation of the device.

Avis d'industrie Canada
Le present appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence.
L'exploitation est autorisee aux deux conditions suivantes:
(1) l'appareil ne doit pas produire de brouillage, et, and
(2) l'utilisateur de l'appareil doit accepter tout brouillage radioelectrique subi, meme si le brouillage est susceptible d'en compromettre le fonctionnement.

Industry Canada Class B Emission Compliance Statement
This Class B digital apparatus complies with Canadian ICES-003.

Avis de conformite a la reglementation d'Industrie Canada
Cet appareil numerique de la classe B est conforme a la norme NMB-003 du Canada.

RF Exposure Information (SAR)
This device meets the government's requirements for exposure to radio waves. This device is designed and manufactured not to exceed the emission limits for exposure to radio frequency (RF) energy set by the Federal Communications Commission of the U.S. Government.
The exposure standard for wireless devices employing a unit of measurement is known as the Specific Absorption Rate, or SAR. The SAR limit set by the FCC is 1.6W/kg.
The FCC has granted an Equipment Authorization for this device with all reported SAR levels evaluated as in compliance with the FCC RF exposure guidelines. SAR information on this device is on file with the FCC and can be found under the Display Grant section of www.fcc.gov/oet/ea/fccid after searching on FCC ID: M82-DMSSA47

IC Radiation Exposure Statement:
The portable device is designed to meet the requirements for exposure to radio waves established by the ISED. These requirements set a SAR limit of 1.6 W/kg averaged over one gram of tissue. The highest SAR value reported under this standard during product certification for use when properly worn on the body.

L'appareil portable est concu pour repondre aux exigences d'exposition aux ondes radio etablies par l'ISED. Ces exigences fixent une limite DAS de 1,6 W/kg en moyenne sur un gramme de tissu. La valeur SAR la plus elevee signalee dans le cadre de cette norme lors de la certification du produit a utiliser lorsqu'il est correctement porte sur le corps.

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1. OVERVIEW

1.1. BD Prevue™ II Peripheral Vascular Access System Device Description

The BD Prevue™ II Peripheral Vascular Access System is a portable device that features real-time 2D ultrasound imaging, customized vascular access applications, procedure documentation, vessel measurement tools, and electronic connectivity (if enabled).

1.2. Cue™ Needle Tracking System Description

The BD Prevue™ II Peripheral Vascular Access System is equipped with Cue™ Needle Tracking System which is designed to track and display the location and trajectory of a needle under ultrasound guidance. The technology consists of software installed on an ultrasound system and sensors incorporated into the ultrasound probes. The sensors detect a passive magnetic field emitted from the needle. The software interprets the data from the sensors and creates a virtual image of the needle on the ultrasound display, providing clinicians with a visual representation of the needle during the insertion process.

The Cue™ Needle Tracking System requires the use of either the Cue™ Traditional Probe or Cue™ Vascular Access Probe, the Cue™ Magnetizer and a Cue™ enabled needle. The Cue™ Traditional Probe and Vascular Access Probe contain sensors for tracking Cue™ compatible needles (following magnetization by the Cue™ Magnetizer). The tracked needle's current position, trajectory, and intersection window are displayed over the ultrasound image.

1.3. BD Prevue™ II Peripheral Vascular Access System Indications for Use

The BD Prevue™ II Peripheral Vascular Access System is intended for diagnostic ultrasound imaging of the human body. Specific clinical applications include:

- Pediatric
- Peripheral Vessel
- Vascular Access.

Typical examinations performed using the BD Prevue™ II Peripheral Vascular Access System include:

Imaging Applications	Exam Type (Adult and Pediatric)
Vascular	Assessment of vessels in the extremities and neck (e.g., jugular, carotid) leading to or coming from the heart, superficial veins in the arms and legs (e.g., basilic, cephalic, brachial, femoral, radial, saphenous), and vessel mapping. Assessment of superficial thoracic vessels (e.g., axillary, innominate, subclavian).
Vascular Access	Guidance for PICC, CVC, dialysis catheter, port, PIV, midline, arterial line placement, access to fistula and grafts, and general vein and artery access.

Cue™ Needle Tracking System is intended to provide visual needle tracking to assist with ultrasound guided vascular access.

1.4. Clinical Applications for Cue™ Needle Tracking System

Clinical applications which are appropriate when using the Cue™ Needle Tracking System are:

- Pediatric
- Peripheral Vessel
- Vascular Access

1.5. BD Prevue™ II Peripheral Vascular Access System Components

- BD Prevue™ II Peripheral Vascular Access System Console
- BD Prevue™ II Peripheral Vascular Access System Traditional Probe
- BD Prevue™ II Peripheral Vascular Access System Vascular Access Probe
- BD Prevue™ II Peripheral Vascular Access System Cue™ Magnetizer

1.6. BD Prevue™ II Peripheral Vascular Access System Compatible Accessories

The BD Prevue™ II Peripheral Vascular Access System is compatible with the following accessories:

- Site~Rite® Probe Covers
- BD Prevue™ II Peripheral Vascular Access System Roll Stand
- Probe holder accessory
- Cable Wrap Accessory
- USB storage device (flash/pen drive) with no external power connection
- Prevue™ II Cue™ Magnetizer Cover

1.7. Needles for Use with Cue™ Needle Tracking System

Needles for use with Cue™ Needle Tracking System:

- Cue™ Needle Tracking System enabled needles, marked with Cue™ compatibility symbol

2. WARNINGS AND CAUTIONS

2.1. BD Prevue™ II Peripheral Vascular Access System Residual Risks

Potential complications related to the insertion and use of BD Prevue II Vascular Access System include but are not limited to delayed procedure; prolonged procedure; allergic reaction; anaphylaxis; infection; current leakage - electric shock; fire hazard; first degree burn; cavitation; misdiagnosis; blockage; multiple sticks; puncture of unintended structure; tissue/vessel injury; cardiac device failure; multiple sticks; impact- device falling-tipping; repeat motion injury; patient discomfort; minor scrape or cut; eye injury.

2.2. BD Prevue™ II Peripheral Vascular Access System Warnings

Warning: Do not operate the BD Prevue™ II Peripheral Vascular Access System or the AC adapter in the presence of flammable anesthetics or gases; explosion may result.

Warning: Use only the BD Prevue™ II Peripheral Vascular Access System AC adapter to charge the system. Using any other device to charge the system may damage the battery, cause intermittent or unpredictable operation, damage the system, result in injury, and will void the warranty.

Warning: The following actions will void the warranty of the BD Prevue™ II Peripheral Vascular Access System and may result in injury or equipment damage:

- Opening or servicing any component by anyone other than service personnel authorized by BD.
- Removing system labels by anyone other than service personnel authorized by BD.
- Connecting the BD Prevue™ II Peripheral Vascular Access System to any AC adapter other than the system adapter.
- Connecting the BD Prevue™ II Peripheral Vascular Access System to any unauthorized accessory. Refer to the list of authorized accessories in the “Overview” section.
- Installing unauthorized software.
- Modification of system software without authorization by BD.

Warning: Inspect the AC adapter and battery cord for damage. If any of the prongs are damaged, use battery power until a replacement cord is obtained.

Warning: Verify that all accessories attached to the system comply with applicable safety standards. Use of non-compliant accessories may increase the risk to the patient or user.

Warning: The use of accessories other than those specified in the “Overview” section may result in increased emissions or decreased immunity of the BD Prevue™ II Peripheral Vascular Access System.

Warning: Equipment that relies on basic insulation only should not be used with this system. Failure to comply could result in increased risk to the patient or user.

Warning: Do not pull on cables or overload the roll stand; doing so may cause the system to tip. Refer to the roll stand instructions for weight limits or additional warnings.

Warning: Prior to use each time, inspect the system for damage. If any problems are found, discontinue use immediately and contact service personnel authorized by BD. Using a damaged system could cause injury to a patient or user.

Warning: Unapproved power cords should not be used with this system; doing so may increase risk to the patient or user and/or damage the system.

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

Warning: Do not use the BD Prevue™ II Peripheral Vascular Access System for ophthalmic indications; ophthalmic use may cause patient injury.

Warning: Misuse of the BD Prevue™ II Peripheral Vascular Access System may result in damage to the equipment or increase risk to the patient or user.

Warning: Do not place and/or use the BD Prevue™ II Peripheral Vascular Access System and its components or accessories 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. If a needle tracking technology is enabled, the magnetic and the RF fields associated with the MRI environment may interfere with the display of needle location. Consult the MRI manufacturer for more information.

Warning: Failure to properly clean and disinfect the system can lead to cross contamination between patients.

2.3. Cue™ Needle Tracking System Warnings

Warning: Use only Cue™ Needle Tracking System enabled needles with the Cue™ Needle Tracking System. Use of unapproved needles may result in patient injury.

Warning: Misuse of the Cue™ Needle Tracking System may result in damage to the equipment or personal injury.

Warning: The Cue™ Magnetizer contains strong magnets which may affect devices sensitive to magnetic fields.

2.4. BD Prevue™ II Peripheral Vascular Access System Cautions

Caution: To avoid unnecessary strain on the user, use the medical device in a manner that is ergonomically correct.

Caution: During use, the AC connector needs to be easily accessible. In case of emergency, remove the power cord as soon as possible.

Caution: Do not force connections; improper installation may damage the connector or system.

Caution: Use only BD cleaning and disinfection procedures. Failure to do so may damage the device.

Caution: Use only approved or recommended cleaners or disinfectants to avoid damaging the device.

Caution: Do not attempt to sterilize the BD Prevue™ II Peripheral Vascular Access System or probe; damage to the equipment may occur as a result.

Caution: Ensure the unit is secure to the roll-stand mount. Failure to do so may cause the display to disconnect from the mount.

Caution: The BD Prevue™ II Peripheral Vascular Access System contains an internal battery. Dispose of dead battery packs in accordance with local regulations; improper disposal may present an environmental hazard.

Caution: Do not allow liquid to enter the system, AC adapter, connectors, or ports; damage to the equipment may occur.

Caution: Only qualified personnel should attempt to service this equipment. The BD Prevue™ II Peripheral Vascular Access System contains static sensitive components and circuits. Failure to observe proper static-control procedures may result in damage to the system.

Caution: To avoid damage to the device operating system, shut down the device through the power control window. (See Section 5.2)

Caution: The adverse biological effects of ultrasound on tissue appear to be threshold effects. When tissue is repeatedly exposed to ultrasound, with intervals in between, there will likely be no cumulative biological effect. If, however, a certain threshold has been passed, biological effects may occur. While the BD Prevue™ II Peripheral Vascular Access System acoustic-output parameters fall well below all US Food and Drug Administration (FDA) thresholds for adverse biological effects, any given ultrasound procedure should be performed using the principle of ALARA (As Low As Reasonably Achievable). The licensed medical practitioner should limit the time of patient exposure to ultrasonic radiation using the principles of ALARA.

Caution: Hot water (in excess of 113°F or 45°C) may damage the system or the probe.

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

Caution: Cardiac-rhythm disturbances during perfusion studies using gas ultrasound contrast agents have been observed in the diagnostic range of Mechanical Index (MI) values. See the specific package insert for the specific contrast agent being used for details.

Caution: Do not twist, bend, swing, or pull the probe cable in excess of that required during normal use of the probe. Excessive force on the cable may cause equipment failure, intermittent operation, or unpredictable operation.

Caution: When using the BD Prevue™ II Peripheral Vascular Access System probe in a sterile environment, the probe and part of the probe cable must be covered with a sterile, acoustically transparent plastic probe cover.

Caution: When disinfecting the probe with a liquid disinfectant, do not soak the probe cable, cable bend relief, or probe buttons; doing so may damage the probe.

Caution: Apply to the acoustic window (or face) of the probe only commercially available ultrasonic couplant that has been specifically formulated for use in medical applications.

Caution: Use water or rubbing alcohol and a soft cloth to remove ultrasonic couplant from the acoustic window (or face) of the probe; failure to do so may scratch the acoustic window.

Caution: Do not allow the ultrasonic couplant to dry on the acoustic window (or face) of the probe. If the couplant should dry, use water or rubbing alcohol and a soft cloth to remove it. Never use a tool of any kind to remove dry ultrasonic couplant from the acoustic window (or face) of the probe.

Caution: Some commercially available probe covers contain latex. Natural rubber latex may cause allergic reactions. Refer to the US FDA alert titled: “Medical Alert: Allergic Reactions to Latex –Containing Medical Devices,” issued March 29, 1991. BD distributes sterile probe covers and needle-guide kits that are not made with natural rubber latex.

Caution: Do not subject the probe to excessive vibration; doing so may dislodge sensitive components and cause intermittent or unpredictable operation.

Caution: If a probe is damaged in any way, discontinue using it immediately, as damage to the system may occur.

Caution: Avoid subjecting the system or probe to excessive mechanical shock (e.g. throw and/or drop); damage to the system may occur as a result.

Caution: Do not use the probe with high-frequency surgical equipment; doing so may damage the BD Prevue™ II Peripheral Vascular Access System.

Caution: Do not connect to an unsecured network; doing so may compromise data security.

Caution: This equipment is not designed to meet the standards for Home Healthcare Environments in accordance with IEC 60601-1-11:2010. This equipment should be operated in clinical environments only.

Caution: Do not submerge the probe in liquid or allow fluid to enter the connectors. Damage to the equipment may occur.

Caution: Prior to each use, inspect the integrity of all power cords and connectors as well as the integrity of the unit itself. If any problems are found, discontinue use immediately and contact an authorized service representative. Use of a damaged power cord could damage the machine.

Caution: Do not force the probe connector; damage to the connector and system could result.

Caution: Only use the provided screw when attaching the Cue™ Magnetizer to the system as others may impact the functionality of the Cue™ Magnetizer.

2.5. Cue™ Needle Tracking System Cautions

Caution: Keep the needle and any ferromagnetic objects, e.g., wired undergarments, metal instruments, watches, jewelry, Cue™ Magnetizer, electronics, metal bed rails, etc. at least 3 feet away from probe when calibrating. Failure to do so may impact the accuracy of needle tracking.

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 3 feet.

Caution: Excessive movement of the probe may result in a temporary loss of needle tracking.

Caution: The Cue™ Magnetizer produces a magnetic field. It should be kept away from any device that is sensitive to magnetic fields.

Caution: Follow all care, handling and/or installation instructions included in this guide and on the packaging provided with the Cue™ Magnetizer and needles.

Caution: Single-use items (e.g. needle trays, needles and sheaths/ covers) must not be reused under any circumstances.

Caution: Movement of the probe during calibration may result in calibration error.

Caution: If needle tracking is not functioning properly, discontinue use of Cue™ Needle Tracking System.

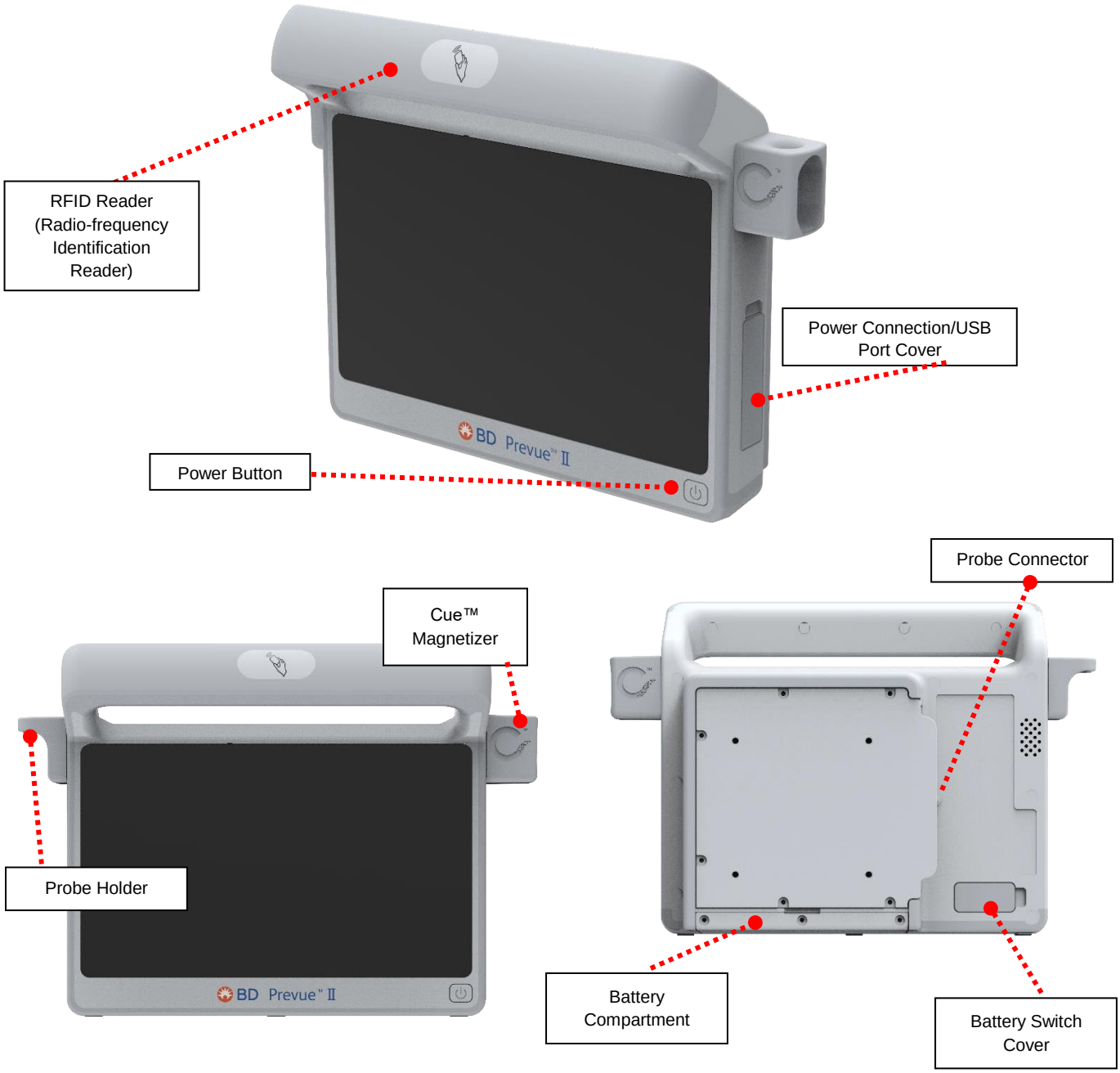
Caution: Improper technique and environmental conditions may introduce variation in accuracy

Caution: Magnetize the needle with its needle cover on. Failure to do so will cause the needle to be magnetized improperly

Caution: Prior to magnetization, keep the needle away from magnetic sources. Failure to do so may negatively impact needle tracking functionality

3. PHYSICAL FEATURES

3.1. Console Features



For installation of approved mounting accessories, see Section 19.1.

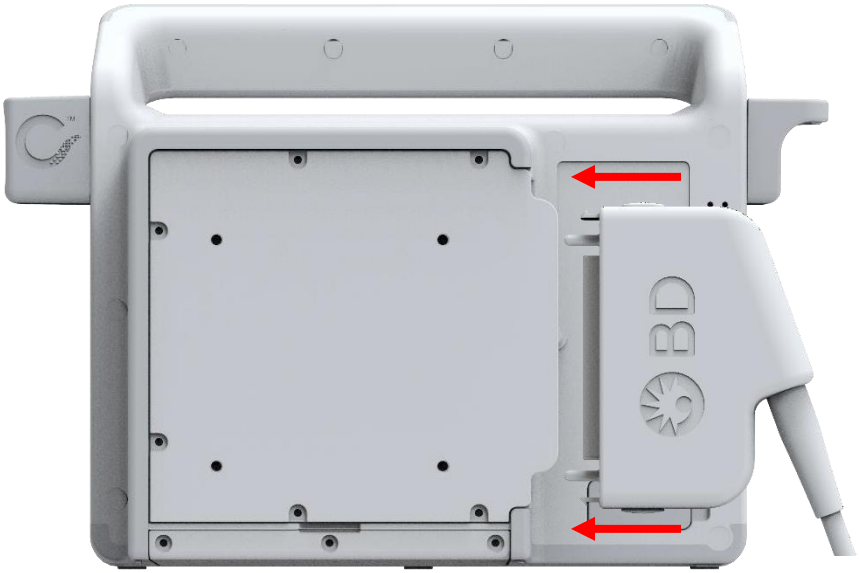
3.2. Compatible Probes

BD Prevue™ II Peripheral Vascular Access System Traditional Probe

BD Prevue™ II Peripheral Vascular Access System Probe

3.3. Connecting the Ultrasound Probe

To connect the probe, align the probe connector and gently insert the probe into the console.



Note: If the EC204 error appears, connect/reconnect the probe and restart the system.

Caution: Do not force the probe connector; damage to the connector and system could result.

<u>To remove the probe:</u>

1. Press the two latches on the probe connector.
2. Gently pull on the connector to disconnect the probe.

3.4. Power Button LED Status Indicator

The power button LED indicates the following:

- Static white: system is on
- Blinking white: The system is in sleep mode
- Blinking red: the battery power is low
- Blinking blue: the system is off and charging
- Static blue: The system is fully charged

3.5. Connecting the Cord Wrap

1) Identify the four screw holes on the back of the console.

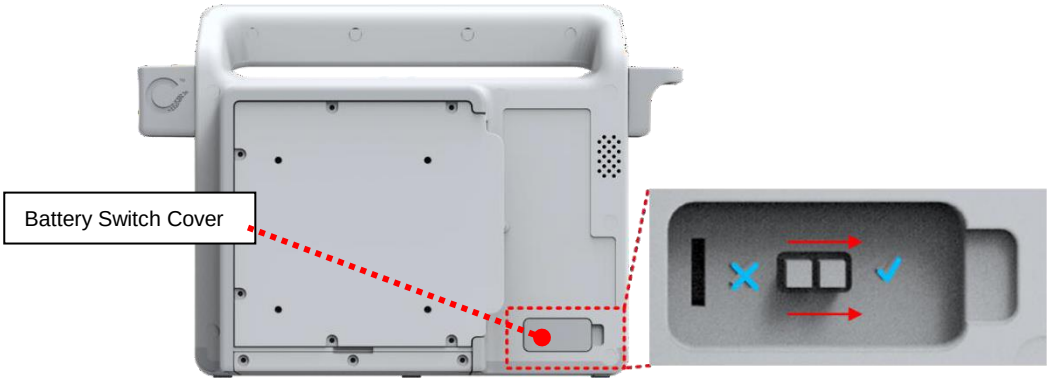
2) Screw in the Cord Wrap on the upper 2 screw holes.
Note: If a Roll Stand Mount is also being used. Attach the Roll Stand Mount with the lower 2 screws and attach the Cord Wrap to the top 2.

Caution: Ensure the unit is secure to the roll-stand mount. Failure to do so may cause the display to disconnect from the mount.

4. CONNECTING THE BATTERY

During shipping or storage, the battery may be disconnected from the system to allow extended storage life. To enable the system to be powered from the battery, the battery switch must be turned on prior to use.

To activate the battery, open the battery cover on the back of the system. Move the switch to the ✓ position.



To extend the storage life of the battery, return the switch to the X position prior to prolonged storage. Failure to do so will degrade battery life.

5. POWER OPTIONS

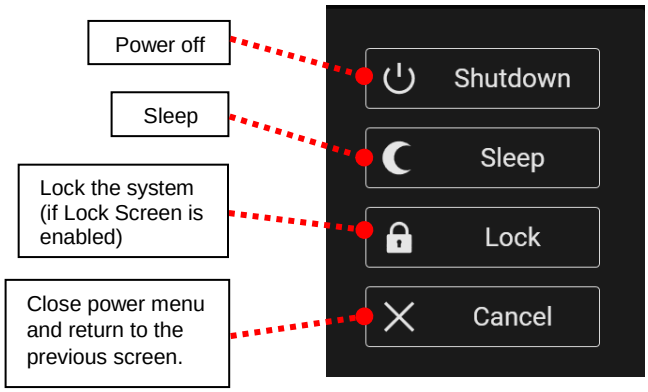
5.1. Power On

To turn on the system, press the power switch on the lower right side of the front of the unit.

5.2. Power Menu

The power menu can be accessed the following ways:

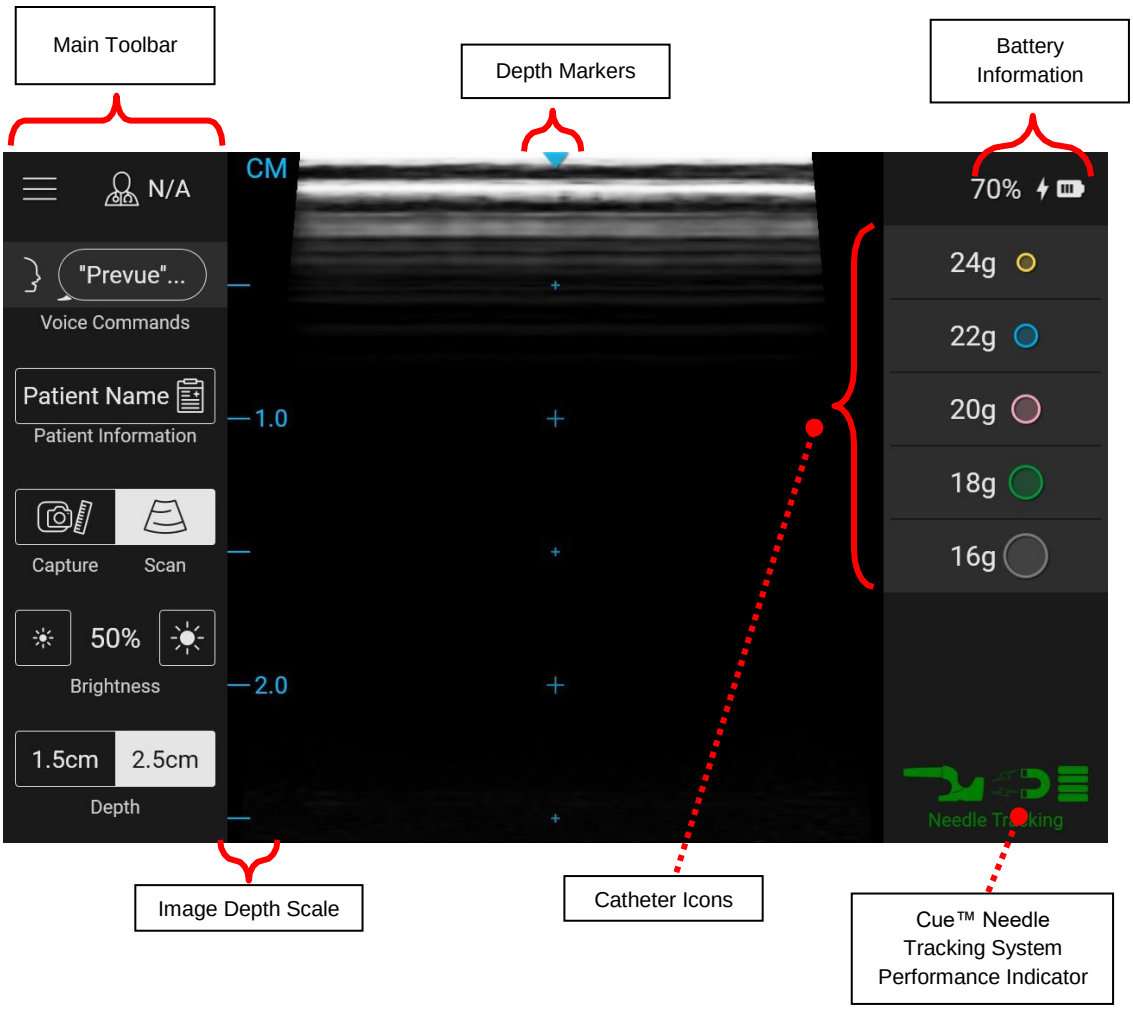
1. To access the power menu, press the power button on the front of the device.
2. To access the power menu using the touch screen, select the menu button on the main ultrasound screen. Select the power button towards the bottom of the menu (see Section 8).



6. NAVIGATING THE DISPLAY

Use the touchscreen to navigate through the different features shown on the screen. Any feature or control can be selected by touching the corresponding button on the screen.

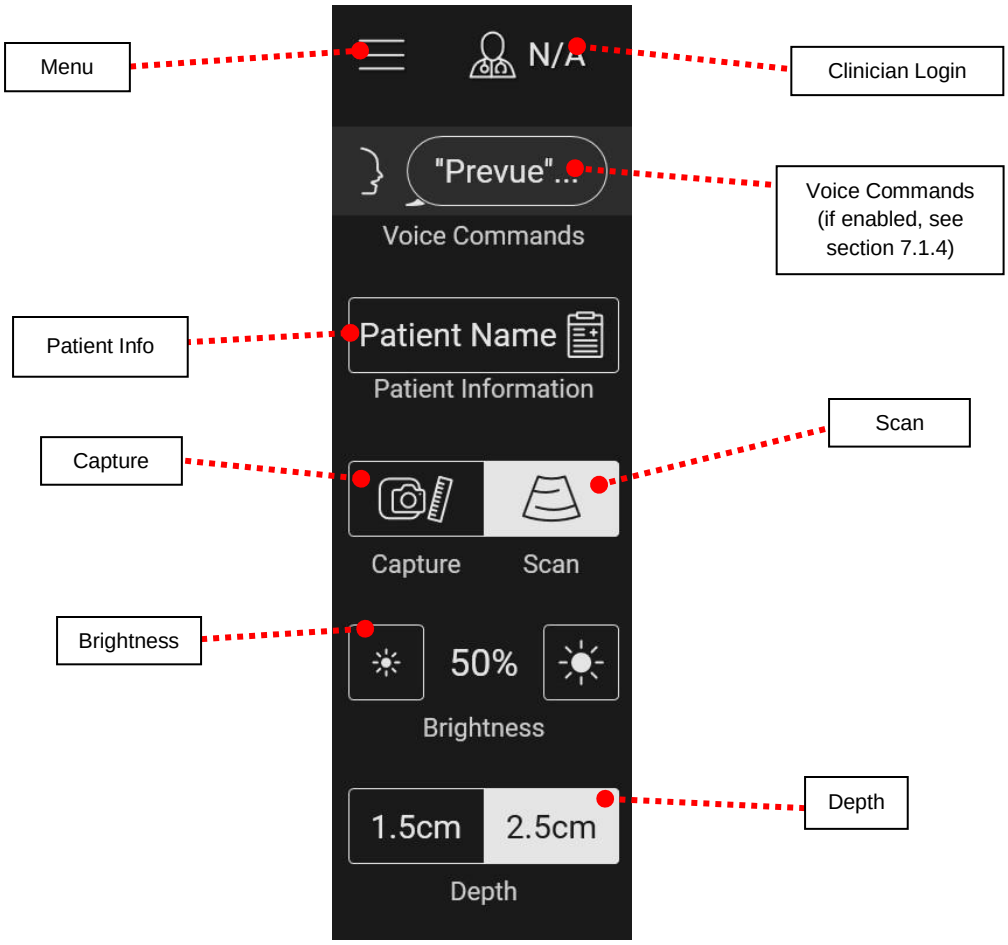
7. MAIN ULTRASOUND SCREEN



An explanation of the various parts of the main ultrasound screen is provided throughout the remainder of Section 7.

7.1. Main Toolbar

The main toolbar is located on the left side of the main ultrasound screen and contains the following buttons:



7.1.1. Menu

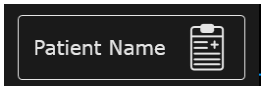
Selecting the menu button displays the System Menu. See section 8.

7.1.2. Clinician Login

To login or add a user, select the clinician login button. The clinician login screen will appear, allowing you to add a user or select an already entered user. For instructions on this process, refer to Section 13.

7.1.3. Patient Information

To enter patient information, select the button shown. The patient information screen will appear, allowing you to enter information. For instructions on this process, refer to Section 12.



7.1.4. Voice Commands (if enabled)

Selecting the Voice Commands button displays a list of available commands that can be used to vocally modify system settings.

The following voice commands are available:

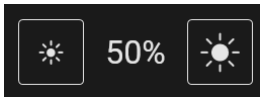
Prevue Capture Image	Pauses scanning, allowing for measurement or saving of images.
Prevue Scan Image	Resumes active scanning.
Prevue Save Image	Saves the captured image.
Prevue Change Depth	Sets the ultrasound depth.
Prevue Volume Up	Increases volume.
Prevue Volume Down	Decreases volume.
Prevue Brightness Up	Increases the brightness of the ultrasound image.
Prevue Brightness Down	Decreases the brightness of the ultrasound image.

7.1.5. Capture/Scan

Selecting the capture button when the system is actively scanning will show a static image of the last acquired ultrasound frame. If the scan button is selected when the system is showing a static image, the system will return to active scanning. Additional tools are available, as described in Section 9.

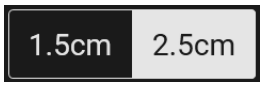
7.1.6. Brightness

Selecting the small brightness icon will reduce the brightness of the entire image. Selecting the large brightness icon will increase the brightness of the entire image. Select the brightness that provides the best ultrasound image for the targeted structure.



7.1.7. Depth

When the user selects the depth button, the image depth will toggle between a depth of 1.5 cm and 2.5 cm. The BD Prevue™ II Peripheral Vascular Access System image depth may be changed to image structures at different depths.



7.2. Battery Information

Four bars indicate 75%–100% of the battery's power remains.

Three bars indicate 50%–74% of the battery's power remains.

Two bars indicate 25%–49% of the battery's power remains.

One blinking bar indicates 0%–24% of the battery's power remains. In this case, connect the system to AC power to continue operation and/or recharge the battery. While the system charges, the icon of the battery will progressively be filled with bars until it reaches full battery charge.

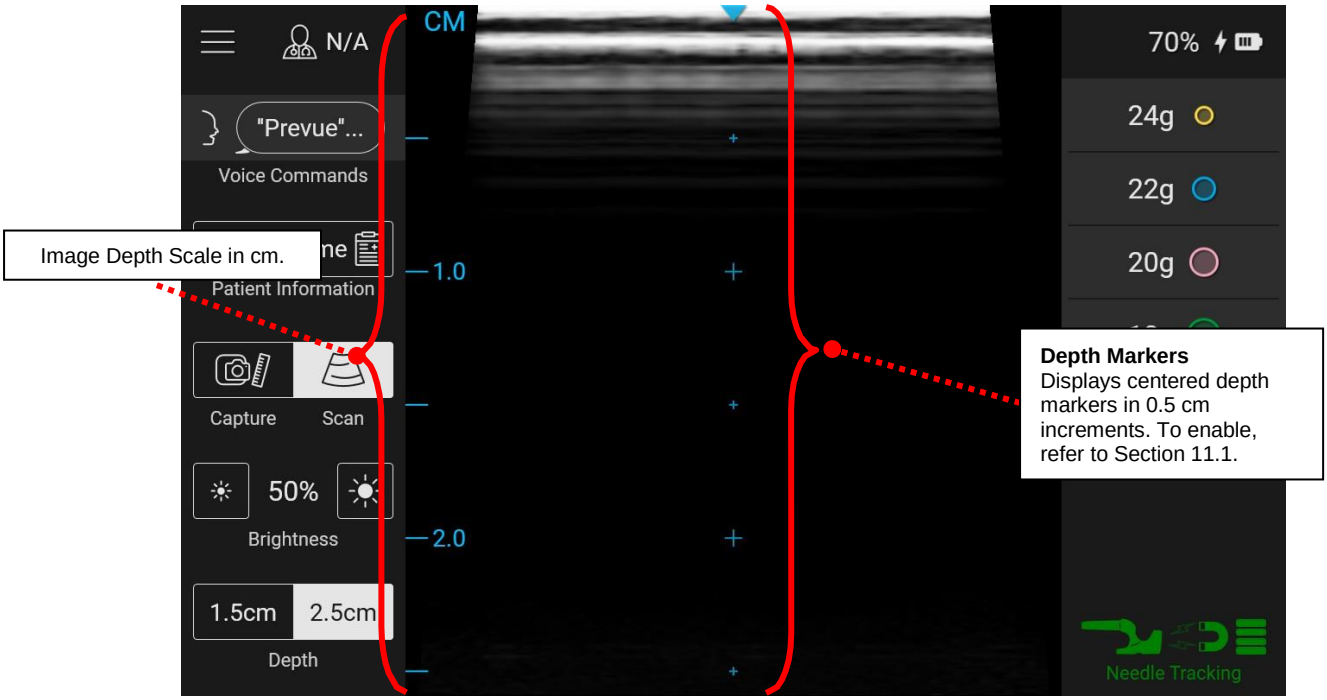
The charging icon indicates that the battery is connected to AC power and is charging.

A red exclamation point indicates a battery malfunction. See Section 16 for troubleshooting.

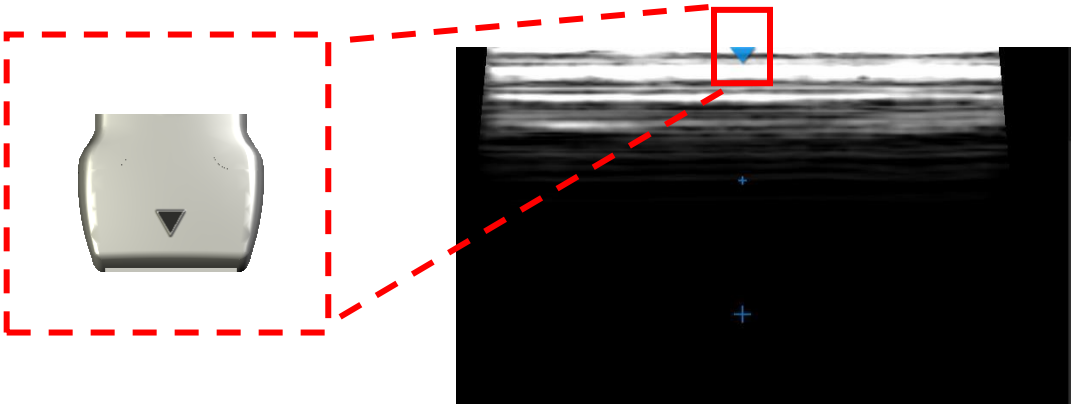
7.3. Catheter Icons

The catheter icons are displayed in proportion to the vessel image at a selected depth. Icons assist clinicians in determining the appropriate catheter size for the vessel being imaged.

7.4. Depth Markers and Image Depth Scale



7.5. Probe Orientation

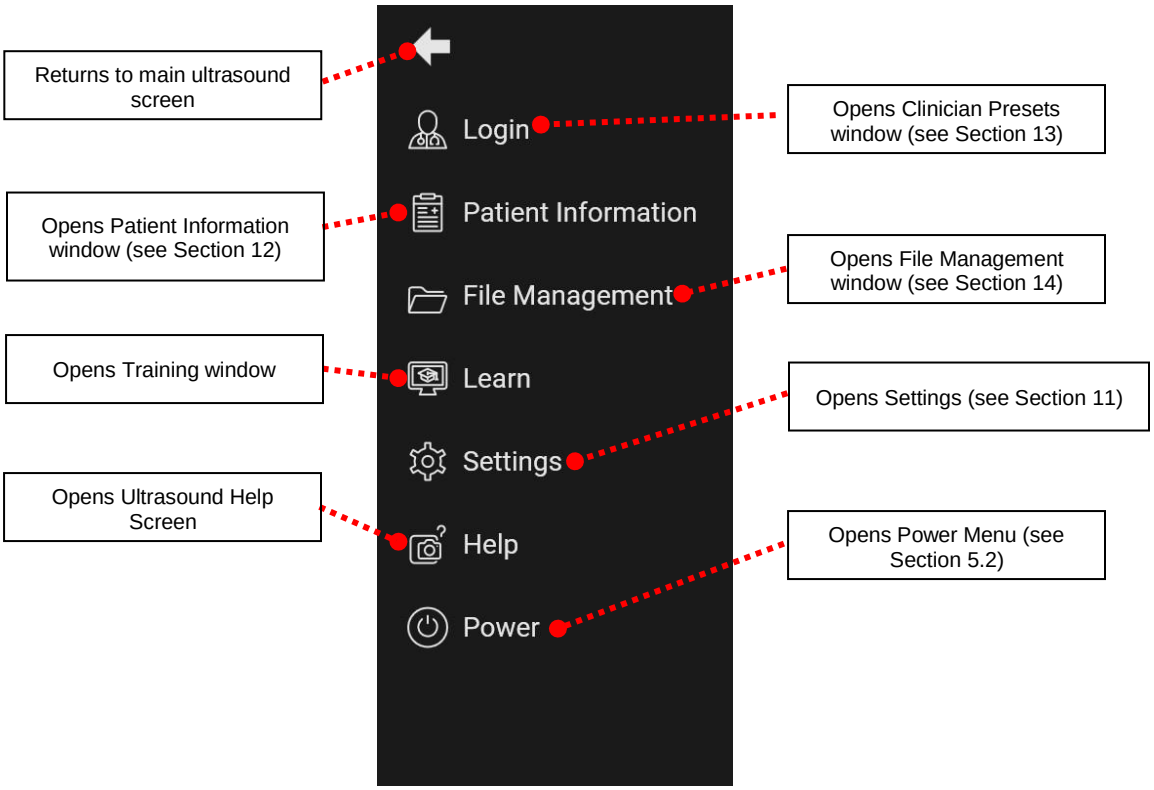


The probe orientation icon corresponds to the triangular center mark shown on the probe

When using the BD Prevue™ II Peripheral Vascular Access System probe for vascular access, hold it so that the triangular center mark points away from the patient's heart.

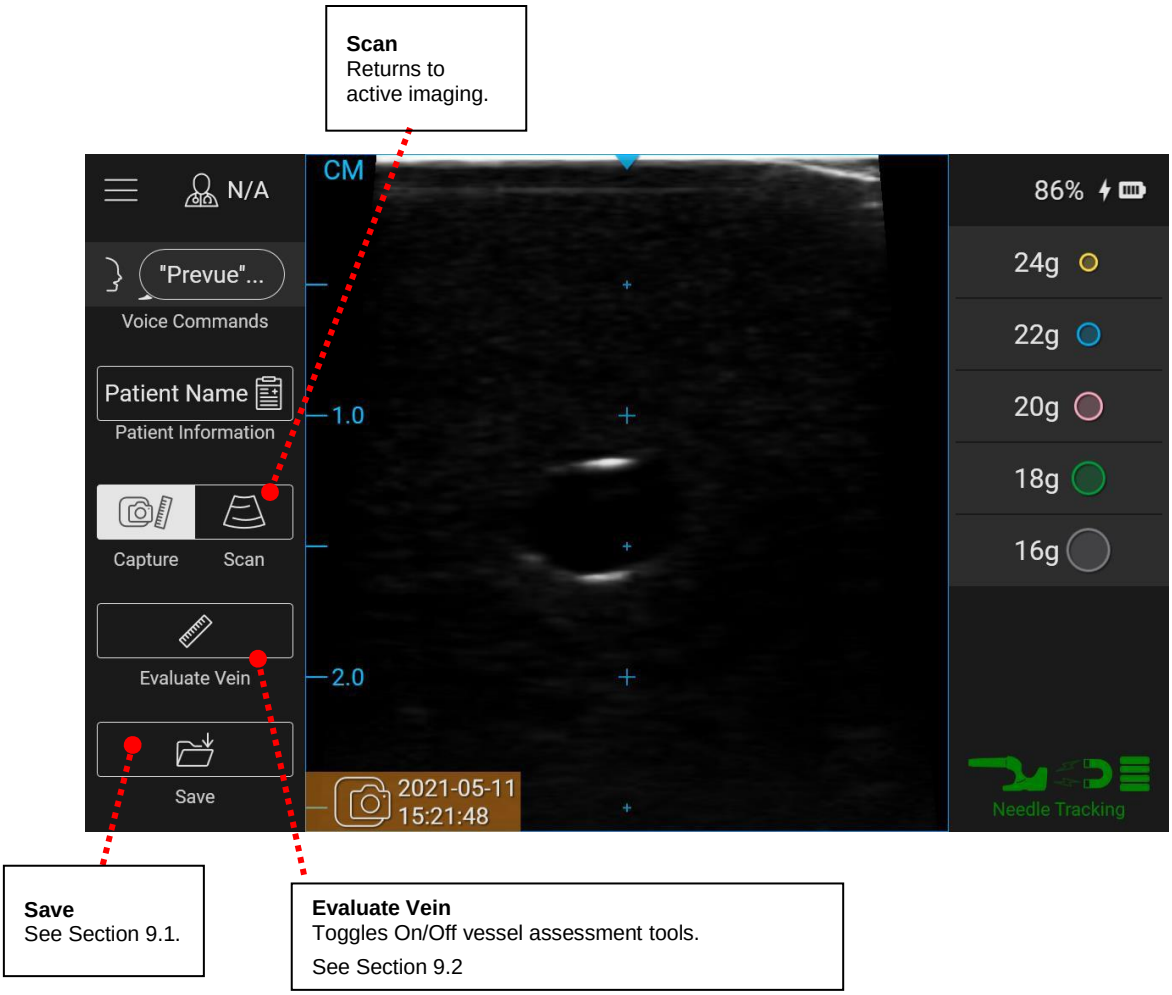
8. System Menu

The access the system menu select the System Menu button ( ) from the main ultrasound screen. The following menu will be shown on the left side of the screen:



9. CAPTURE MODE

Access capture mode by pressing the capture/scan button on the main ultrasound screen. The following screen will appear:



9.1. Save

When the Save button is selected, the current ultrasound image is saved to the system hard drive and any attached USB storage devices (if enabled – see section 11.4).

9.2. Evaluate Vein

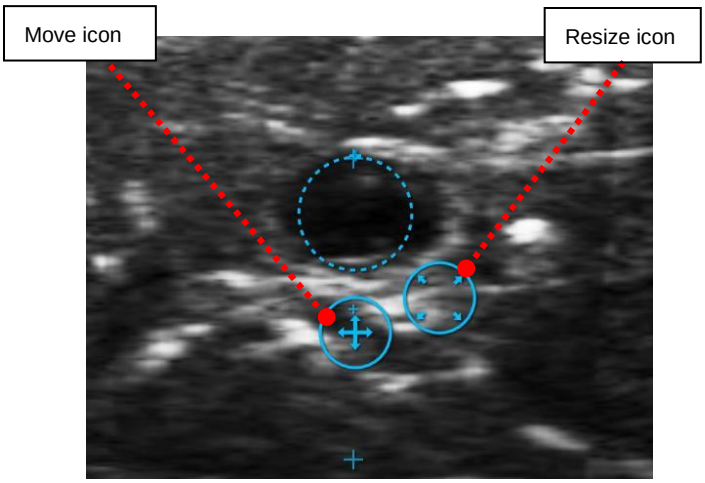
The BD Prevue™ II Peripheral Vascular Access System is equipped with vessel assessment tools to measure vessel diameter, determine maximum gauge size based on a given vein occupancy rule, and determine minimum IV catheter length based on a given remaining catheter length rule and assumed insertion angle.

The following steps describe how to take measurements with the BD Prevue™ II Peripheral Vascular Access System Measurement Tool.

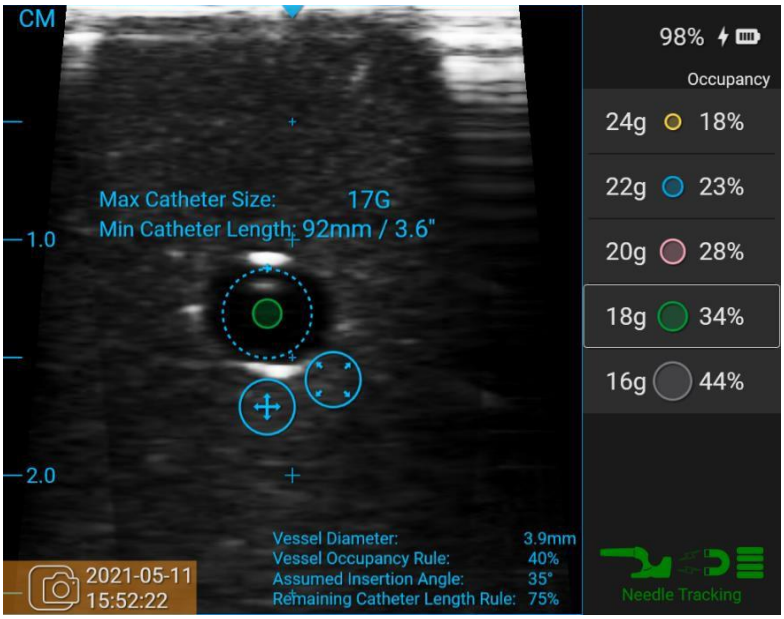
1) Ensure the rules are set in the ultrasound settings screen (see Section 11.2).

2) After capturing an ultrasound image, select the “Evaluate Vein” button.

3) Place the dotted circle in the middle of the vessel by pressing and holding the dotted circle or the move icon to the desired location. Resize the circle so that it matches the size of the vessel.



4) The screen will display the maximum gauge size and minimum catheter length that should be used to access the vessel in accordance with the rules that are set (see Section 11.2).

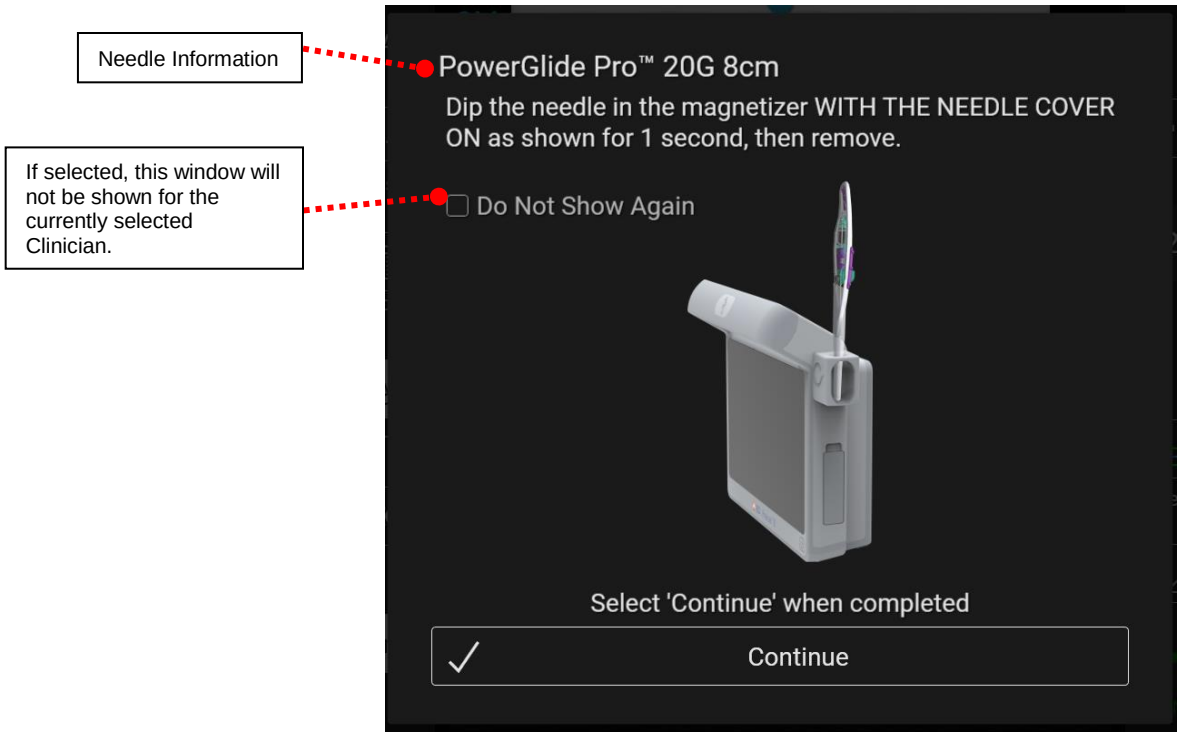


Note: See section 24 for system measurement error information.

10. CUE™ NEEDLE TRACKING SYSTEM MODE

10.1. Activating and Magnetizing the Cue™ Needle Tracking System Compatible Needle

Scan the RFID tag located on the Cue™ compatible vascular access device packaging. When the RFID tag is scanned, the following window will appear.



Dip a Cue™ Needle Tracking System enabled needle into the Cue™ Magnetizer for 1 second then remove. Select continue when complete.

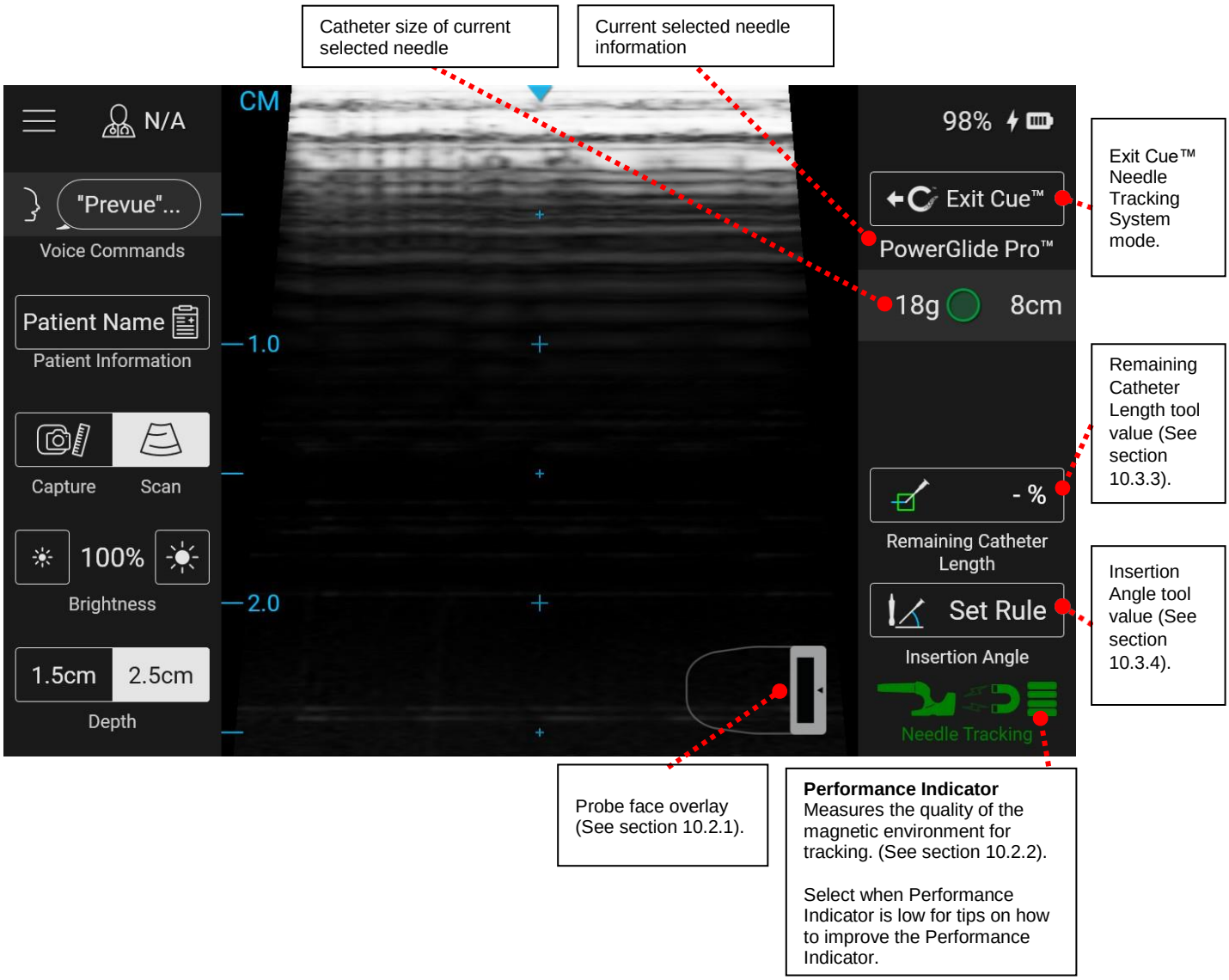
Optional: Place the Cue™ Magnetizer Cover into the Cue™ Magnetizer prior to dipping the needle.

The Cue™ Needle Tracking System enabled needle and software are now ready for needle tracking.

Caution: Magnetize the needle with its needle cover on. Failure to do so will cause the needle to be magnetized improperly

Caution: Prior to magnetization, keep the needle away from magnetic sources. Failure to do so may negatively impact needle tracking functionality.

10.2. Cue™ Needle Tracking System Home Screen



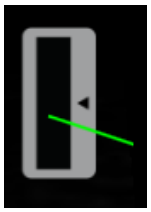
10.2.1. Probe Face Overlay

The probe face overlay shows the needle position with respect to the probe face.

Out-of-Plane Insertion

Probe View

Probe Face Overlay View



The probe face overlay for an out-of-plane insertion may be turned off in the Cue™ Needle Tracking System settings screen (see section 11.2)

In-Plane Insertion

When the needle is well aligned with the probe face, the needle graphic is green.

Note: In-plane needle tracking is not available with the BD Prevue™ II Vascular Access Probe.

Probe View

Probe Face Overlay View – Well Aligned

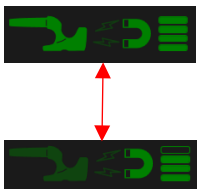
When the needle is not aligned with the probe face, the needle graphic is red.

Probe View

Probe Face Overlay View – Not Aligned

10.2.2. Performance Indicator

The Performance Indicator measures the quality of the magnetic environment around the probe. Stray magnetic fields can inhibit the probe's ability to detect an activated needle. More bars indicate a "cleaner" magnetic environment for detecting an activated needle.

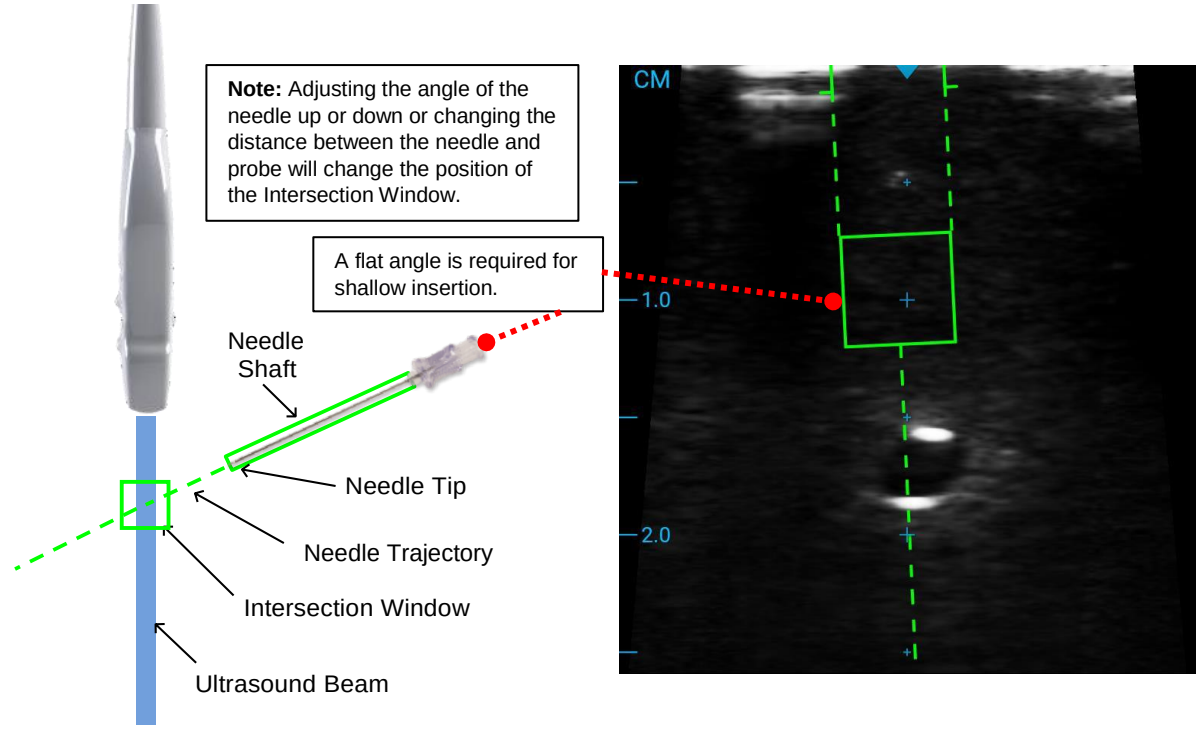
Performance Indicator	Indication:
 2-4 bars	Low magnetic fields are present. Conditions are optimal for the Cue™ Needle Tracking System.
 1 bar	Moderate magnetic fields are present. Conditions are moderate for the Cue™ Needle Tracking System.
 0 bars	Strong magnetic fields are present. Conditions are poor for the Cue™ Needle Tracking System, and needle tracking is disabled.
 Blinking Indicator	The system is detecting probe movement. Hold the probe still and wait for the Performance Indicator to stop blinking.
 Loading Cue™ Needle Tracking System	The system is restarting the Cue™ Needle Tracking System to load in a new needle or to recover from an error. Please wait until the loading is complete.
 Cue™ Needle Tracking System Error	The Cue™ Needle Tracking System has encountered an error. Refer to section 16.2.

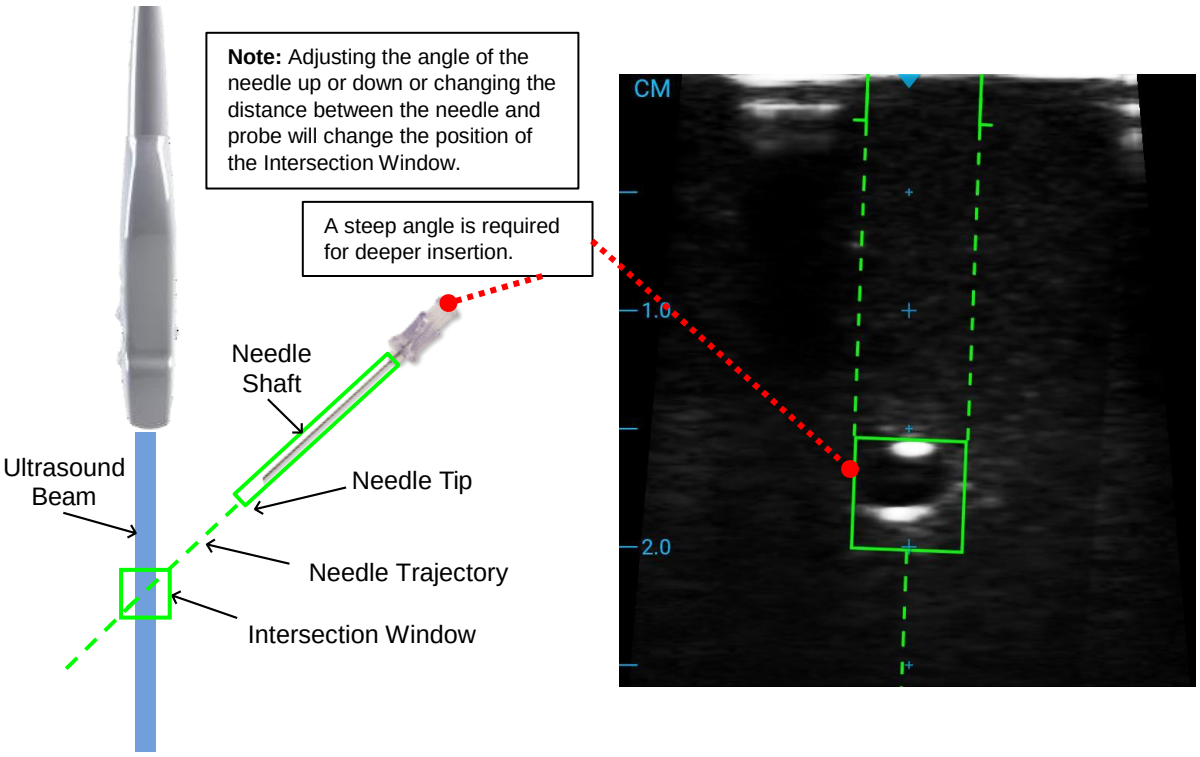
Perform the following steps to improve the Performance Indicator:

- Hold the probe still.
- If the Performance Indicator decreases during needle approach, withdraw the needle and slowly reapproach.
- Remove metal, magnetic, and electronic objects in close proximity (bed rails, jewelry, mobile phone, pumps, bed/table frames, Cue™ Magnetizer, etc.).
- If the problem persists, hold the probe stationary in the air away from all metal, magnetic, and electronic devices.
    - If the Performance Indicator improves, review previous troubleshooting tips.
    - If the Performance Indicators remains low, calibration may be required. This should be uncommon. See section 11.2.1.

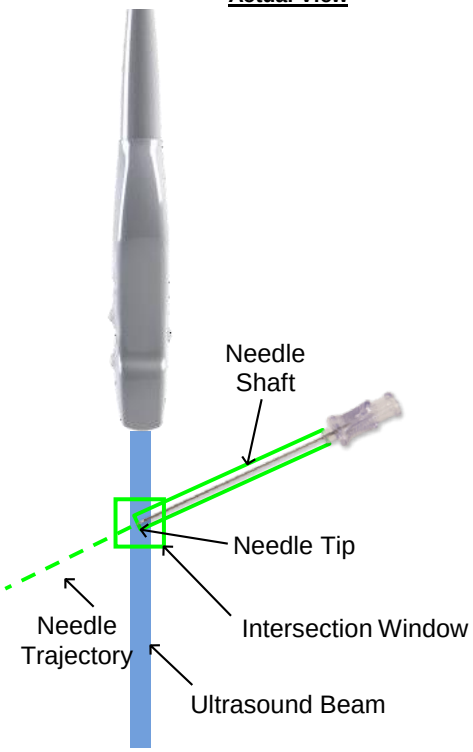
10.3. Cue™ Needle Tracking System Overlay

10.3.1. Out-of-Plane Insertion

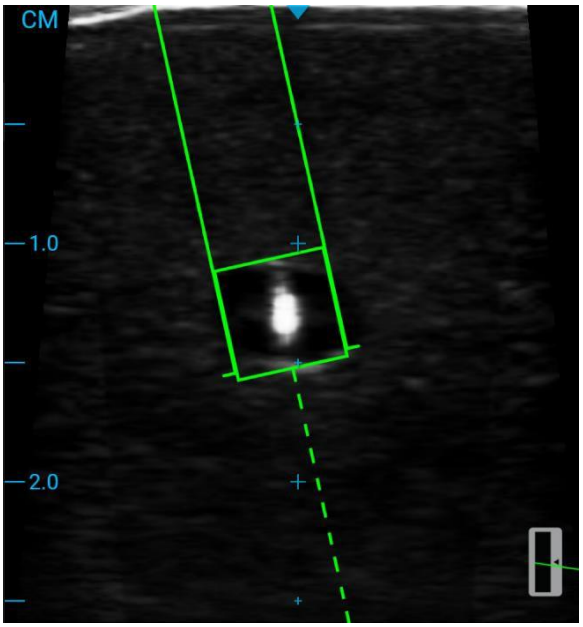




Actual View

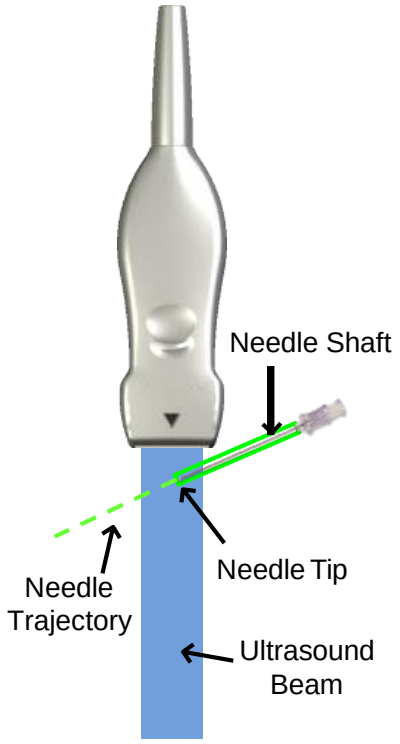


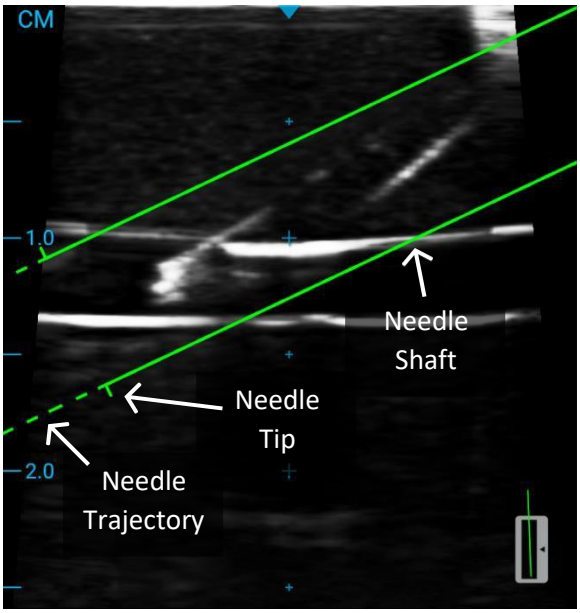
On-Screen View

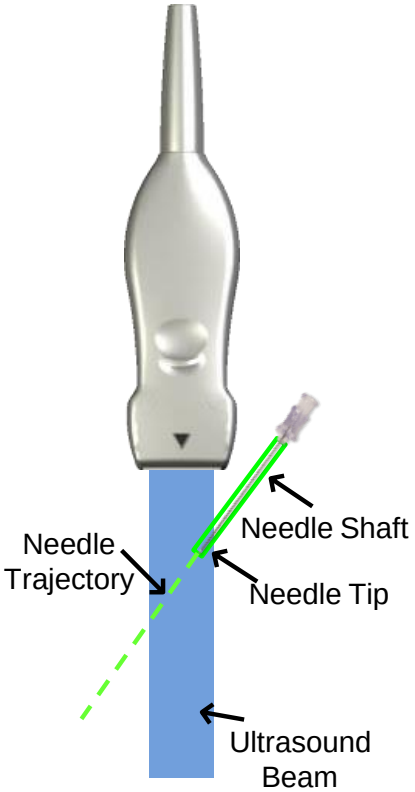


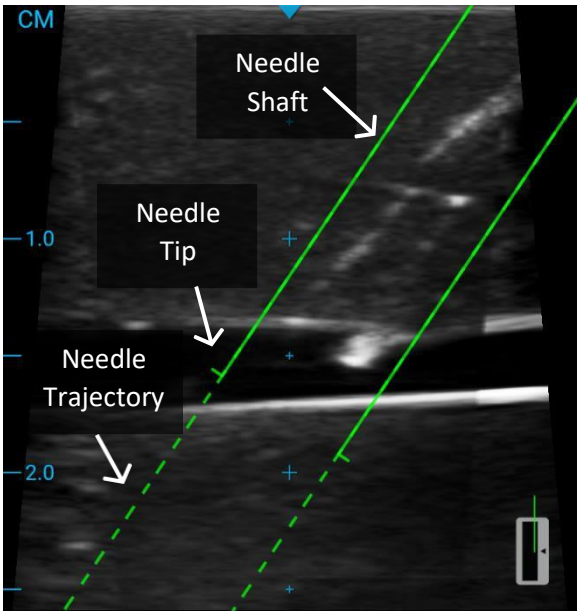
10.3.2. In-Plane Insertion

Note: In-plane needle tracking is not available with the BD Prevue™ II Vascular Access Probe.





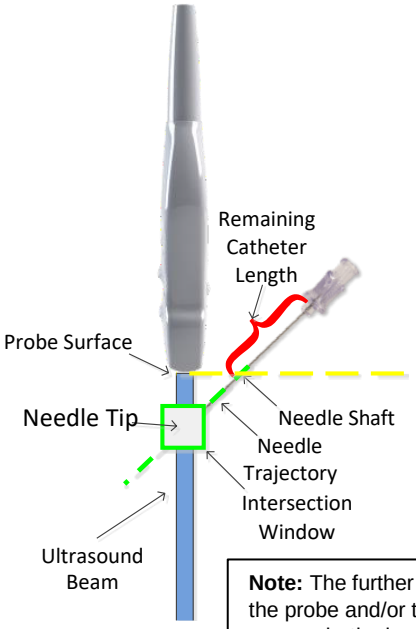


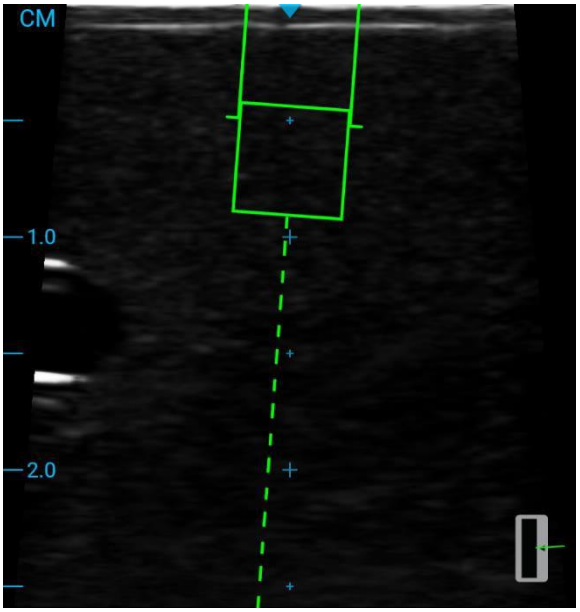


10.3.3. Remaining Catheter Length Tool

The Remaining Catheter Length tool displays the calculated remaining catheter length from the location of the calculated needle intersection point. Rules can be set (either by clicking on the button in scan mode or in the settings – see section 11.2) to dictate a minimum remaining catheter length threshold based upon a needle type and length. When the remaining catheter length value drops below the set threshold, the overlay, including the target box, and the remaining catheter length value text will change color to indicate the value is below the threshold.

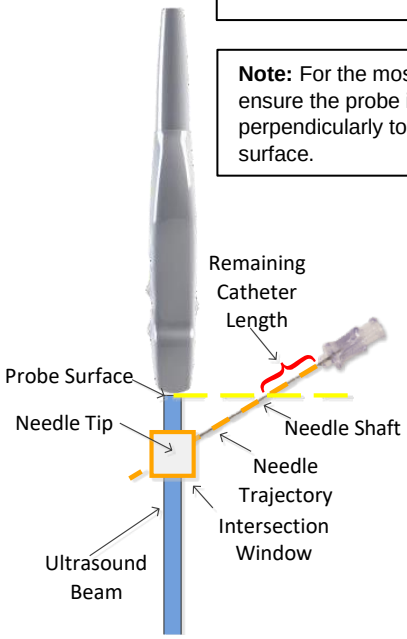
Actual View **On-Screen View**

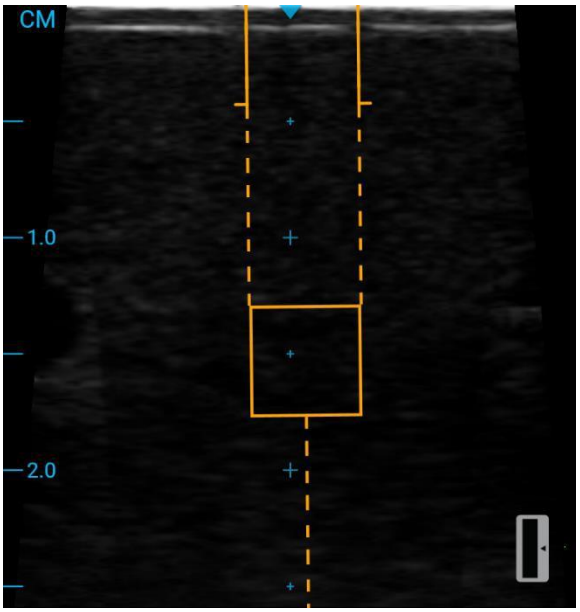




Note: The further the needle is from the probe and/or the shallower the approach, the lower the value of the Remaining Catheter Length with a lined-up vessel.

Note: For the most accurate result, ensure the probe is imaging perpendicularly to the imaged surface.





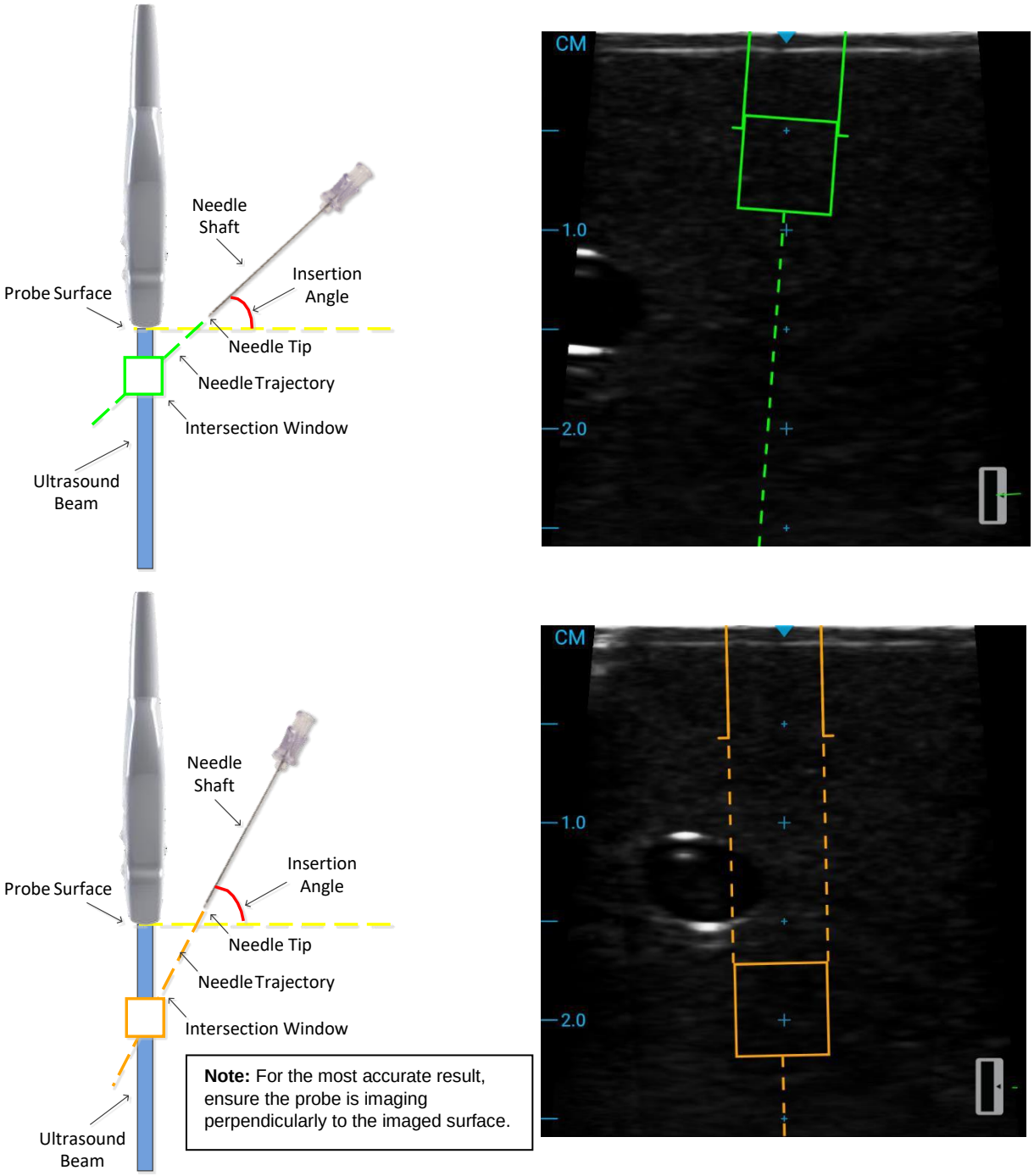
Caution: If needle tracking is not functioning properly, discontinue use of Cue™ Needle Tracking System.

Caution: Improper technique and environmental conditions may introduce variation in accuracy.

10.3.4. Insertion Angle Tool

The Insertion Angle tool displays the calculated angle measurement between the needle and the probe surface (refer to image below). Rules can be set (by clicking on the button in scan mode or in the settings – see section 11.2) to indicate a maximum insertion angle threshold. When the insertion angle value surpasses the set needle angle threshold, the overlay, including the target box, and the insertion angle value text will change color to indicate the value is above the threshold.

Actual View **On-Screen View**



Note: For the most accurate result, ensure the probe is imaging perpendicularly to the imaged surface.

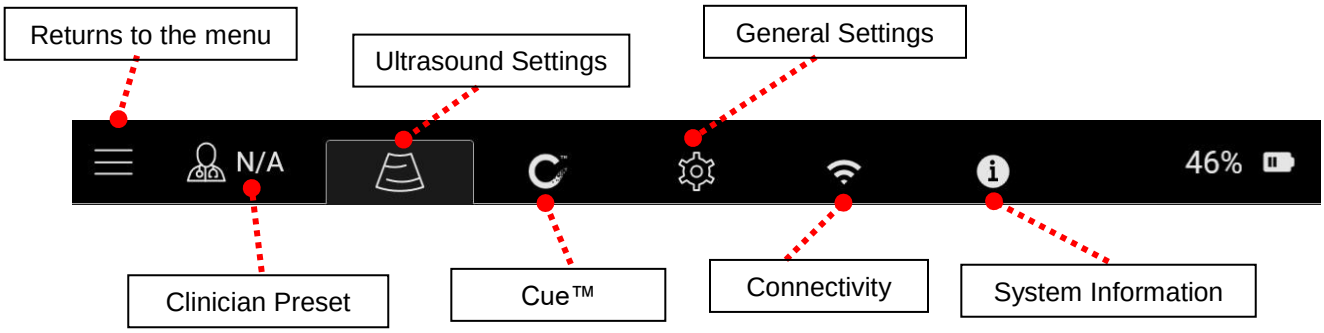
Caution: If needle tracking is not functioning properly, discontinue use of Cue™ Needle Tracking System.

Caution: Improper technique and environmental conditions may introduce variation in accuracy.

11. SYSTEM SETTINGS

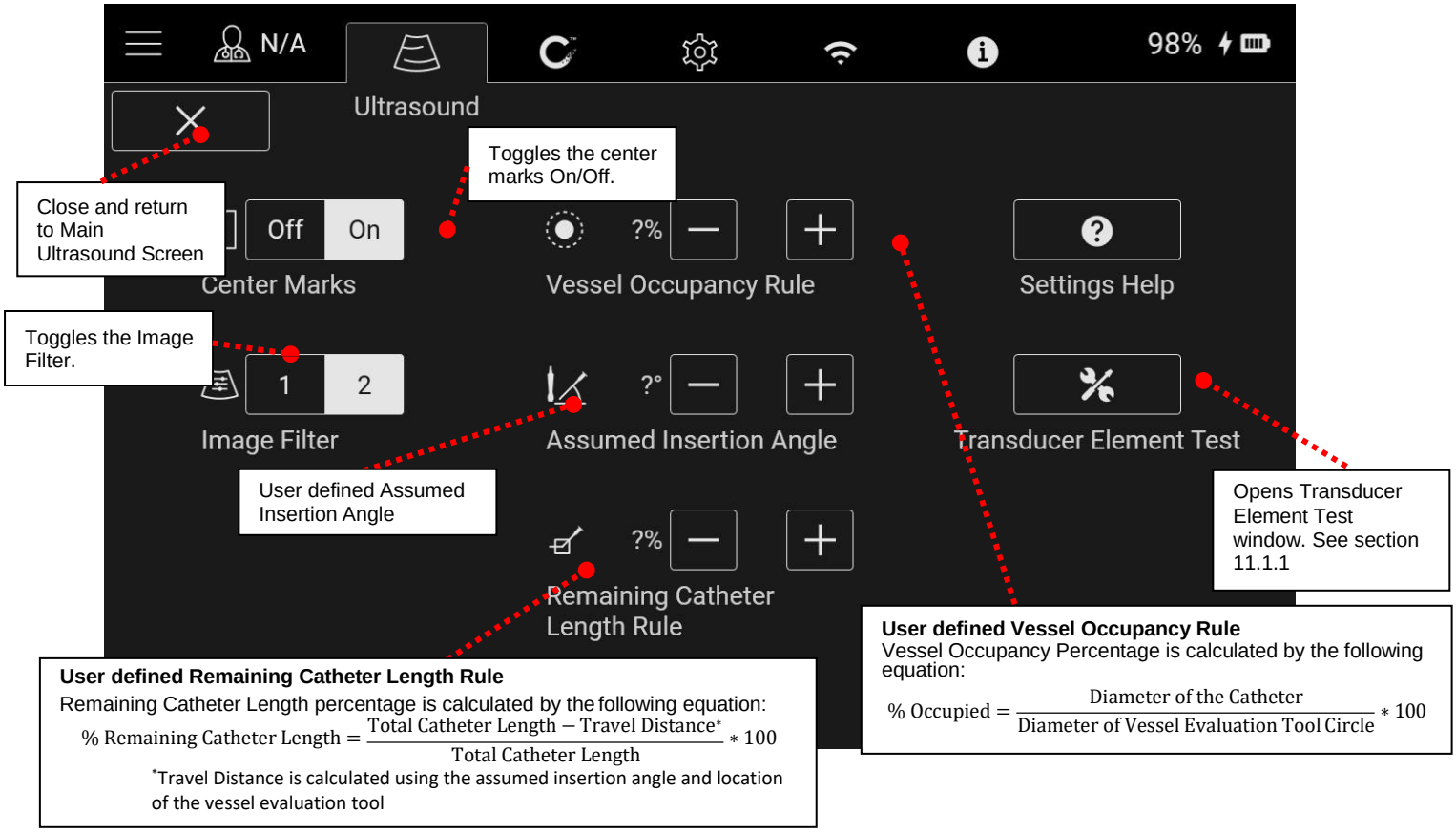
To access the system settings, press the menu button on the main ultrasound screen. In the menu, select the settings button.

The settings window consists of the following tabs:



11.1. Ultrasound Settings

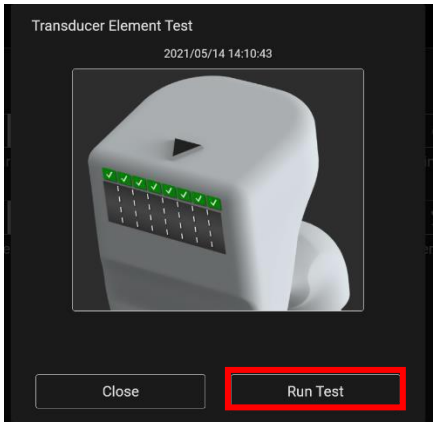
To access the ultrasound settings, click on the ultrasound settings tab on the settings screen. The following screen will appear:



11.1.1. Transducer Element Test

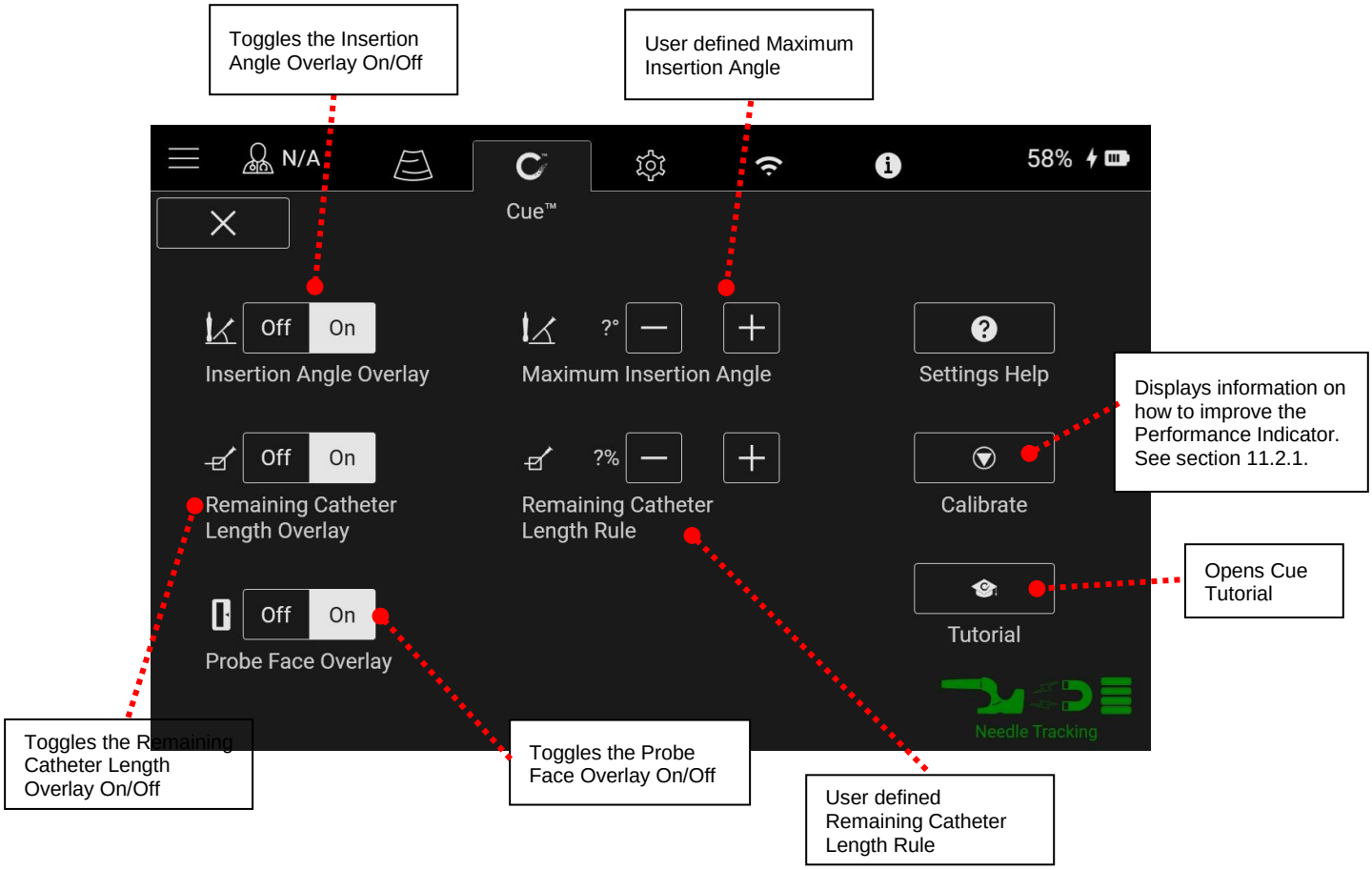
To carry out a transducer element test:

1. Open the Transducer Element Test window by selecting the Transducer Element Test button in the Ultrasound Settings screen.
2. Select “Run Test” (ensure that the probe surface is clean and dry prior to running).



11.2. Cue™ Needle Tracking System Settings

To access the Cue™ Needle Tracking System settings, click on the Cue™ Needle Tracking System settings tab on the settings screen. The following screen will appear:

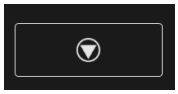


11.2.1. Calibration

Calibration may be required when the Performance Indicator (see section 10.2.2) measures a poor magnetic environment. To determine if calibration is necessary, hold the probe stationary in the air away from all metal, magnetic, and electronic devices. If the Performance Indicator improves, calibration is not required.

To calibrate the probe:

1. Select the calibrate button on the Cue™ Needle Tracking System settings screen.



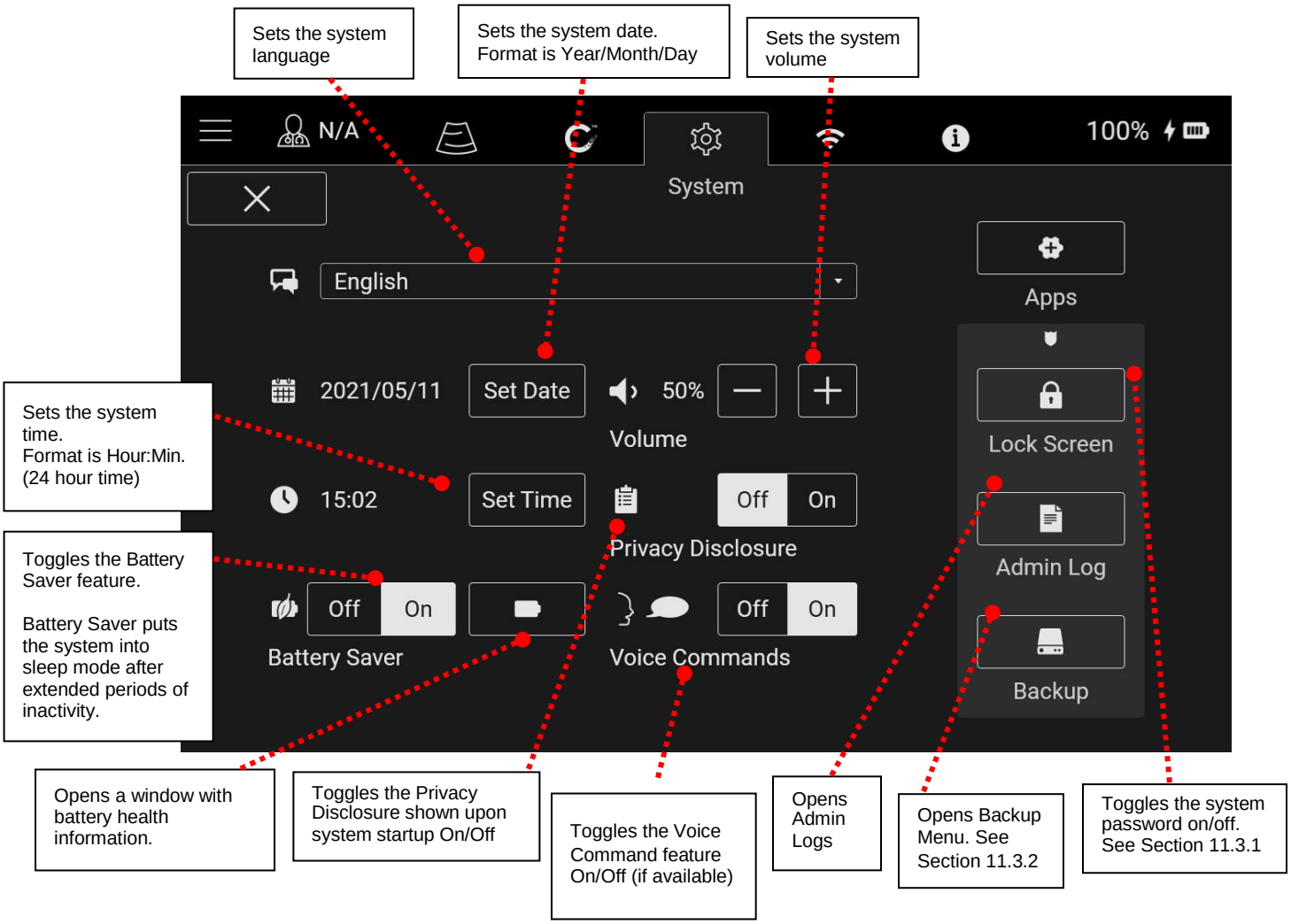
2. Follow the on-screen instructions to hold the probe in the air, at least 3 feet from any metal, magnetic, or electronic devices (including watches, cell phones, etc.).

3. While holding the probe still in the air, press the calibrate button. Maintain this position until the system indicates that calibration is complete.
4. Upon completion of calibration, the Performance Indicator should improve. A Performance Indicator of 3 bars or higher is recommended before beginning any procedure.

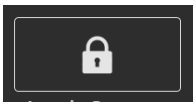
Note: Maintain a distance of 4 inches between the Cue™ probe and Cue™ Magnetizer to minimize the potential need for calibration.

11.3. General Settings

To access the general settings, click on the general settings tab on the settings screen. The following screen will appear.



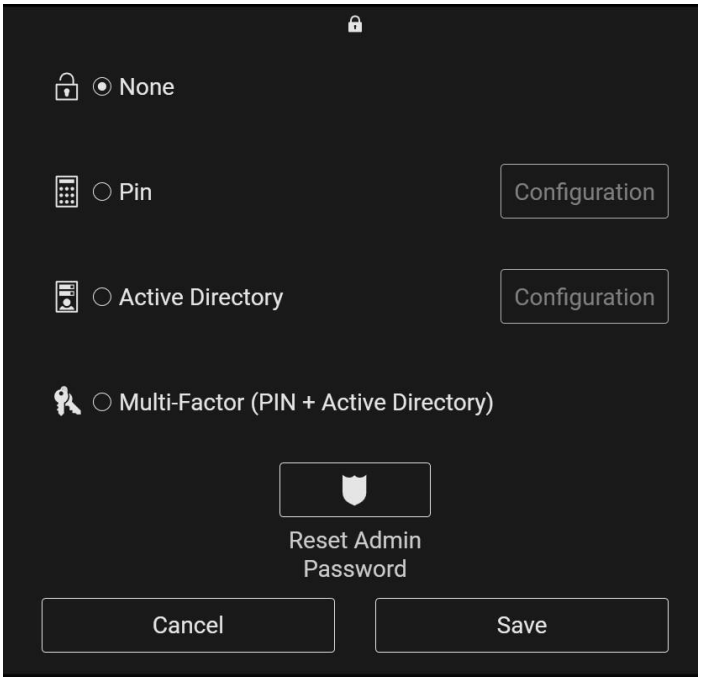
11.3.1. System Password

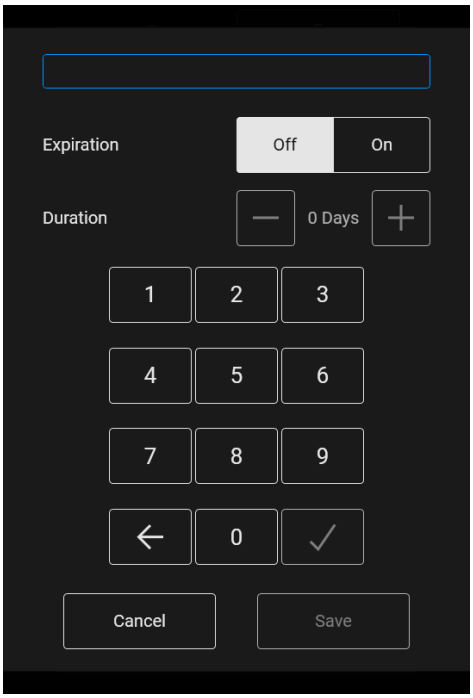


To configure password protection, enable the password option in the general settings tab.

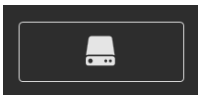
The first time password protection is enabled, the system will display a prompt to create an administrator password. The administrator password will be used to make any future configuration changes to the system password. If the administrator password is forgotten, contact customer service for a temporary password.

Upon creating or entering the administrator password, the following options will be displayed:

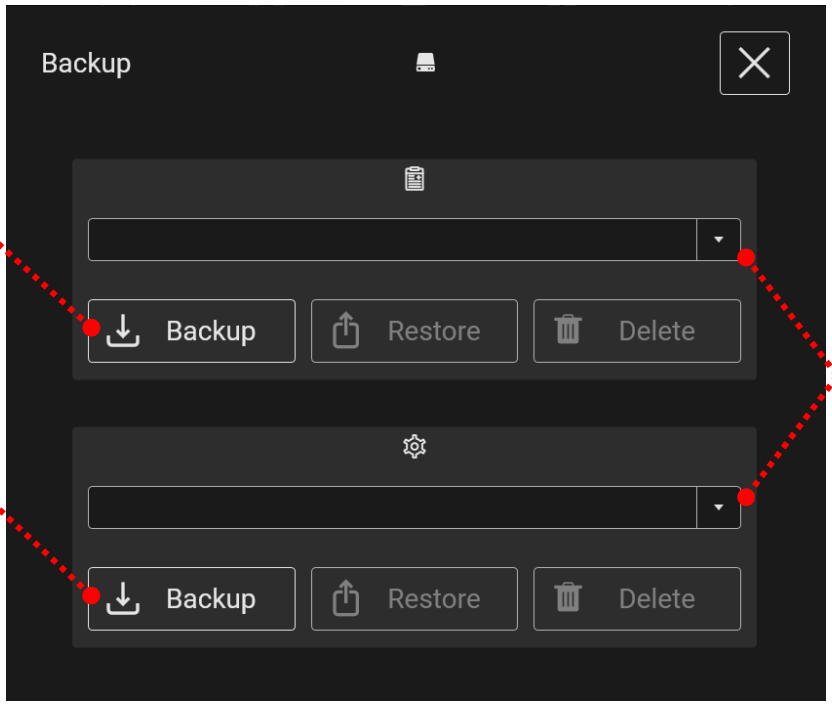




11.3.2. Backup Menu



To backup and restore patient and settings, select the ‘Backup’ button in the General Settings Tab (the admin password is required for access).



Backup patient data files.

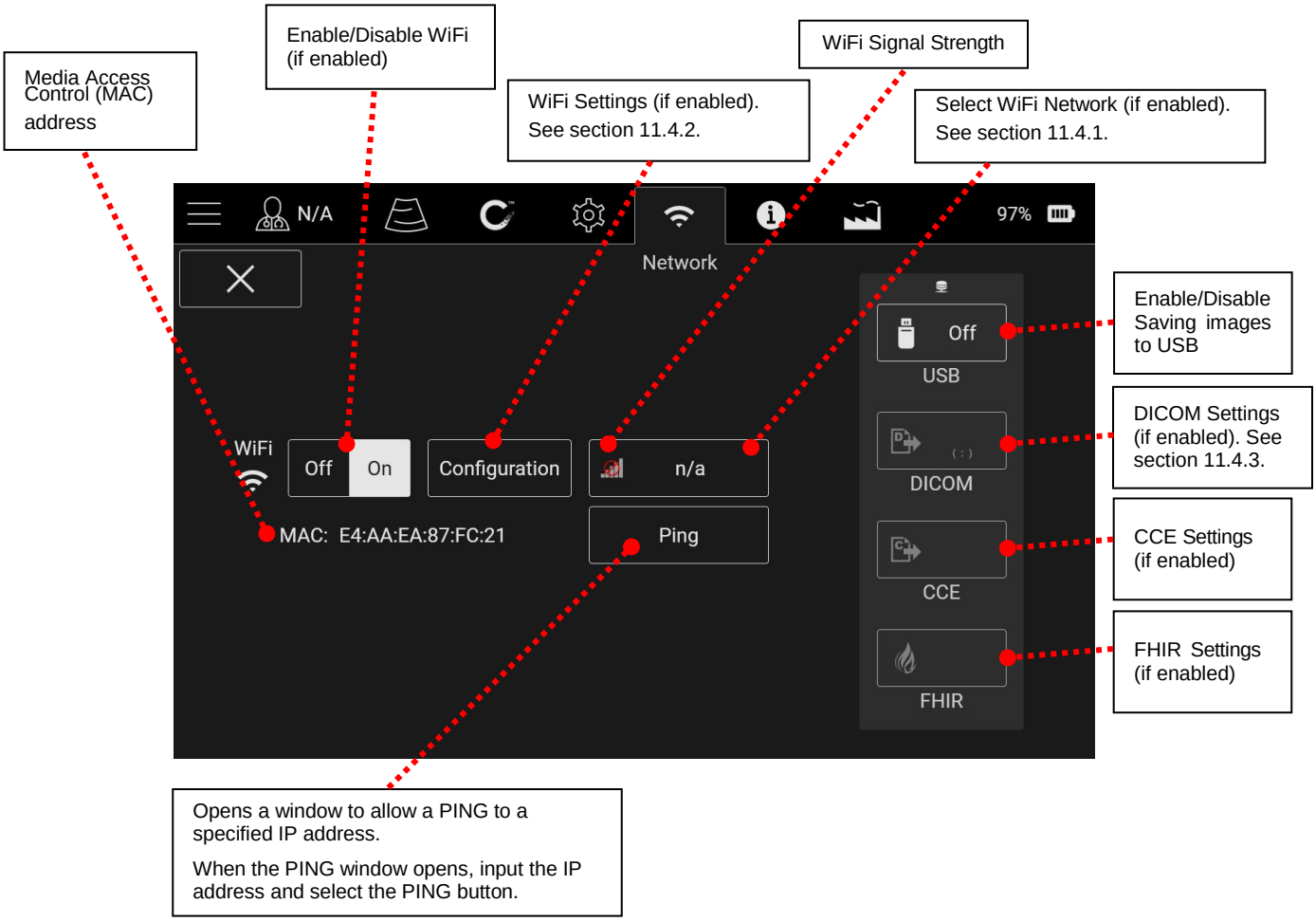
Backup settings.

Select drop-down to select and restore from a previous backup file.

11.4. Connectivity Settings

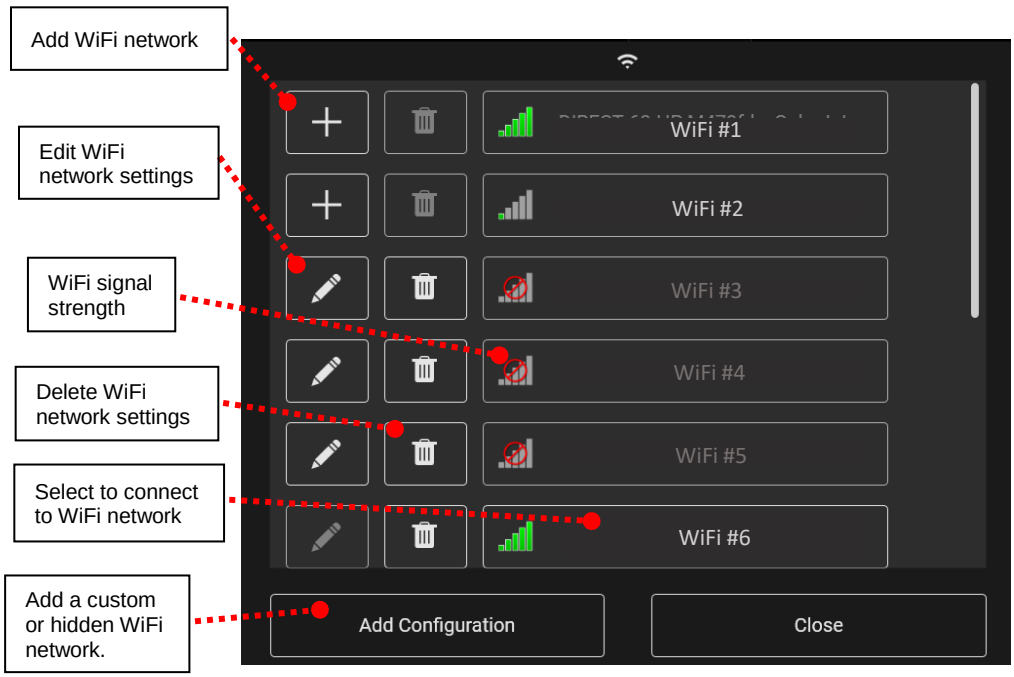
Note: The actions described in this section should only be taken by authorized personnel. To configure the BD Prevue™ II Peripheral Vascular Access System, contact your network administrator or a PACS administrator.

To access the connectivity settings, click on the connectivity settings tab on the settings screen. The following screen will appear:



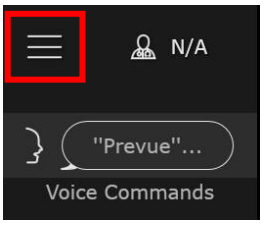
11.4.1. WiFi Networks

Select the WiFi network button to access and connect to WiFi networks. See sections 24 and 25 for technical specifications.

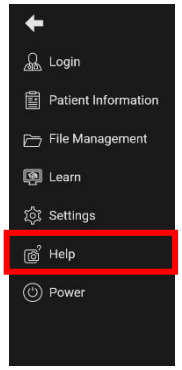


To connect the BD Prevue™ II Peripheral Vascular Access System to a WiFi network, perform the following steps:

1. Select the Menu button.

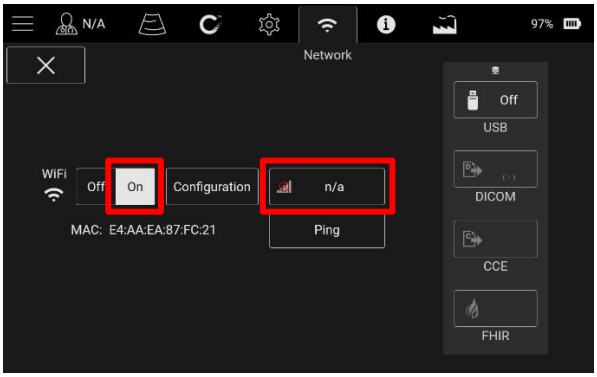


2. Select the Settings button.

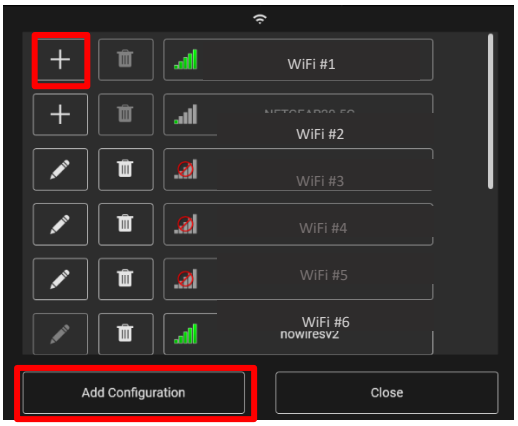


3. In the Settings window, select Connectivity Settings.

4. Enable Wifi (if not already enabled).
5. Select the WiFi network button.

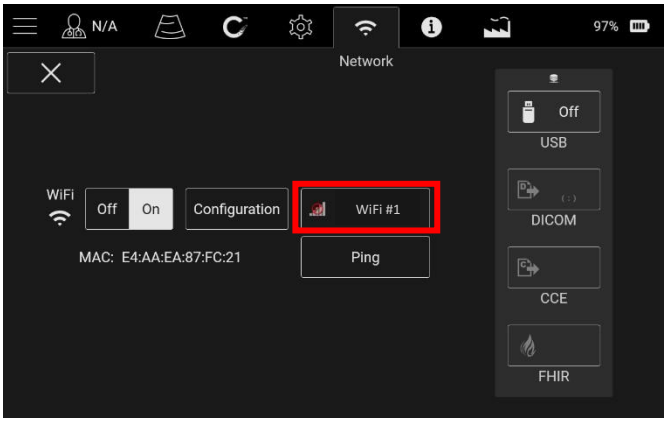


6. Add a visible WiFi network, or select the “Add Configuration” button to add a custom or hidden WiFi network.



7. Fill in the required information and select the “Save” button.

8. The system should now be connected to the WiFi network.



11.4.1.1. WPA2 Enterprise

To connect to a WPA2 Enterprise network, fill out the fields provided when Enterprise is selected on the Configuration Window when adding a WiFi Network.

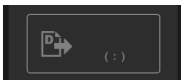
11.4.2. Configure Network Settings

Press the “Configuration” button to configure network settings for Wifi.

Select “Auto” to automatically configure the network settings.

Select “Static” to manually configure the network settings.

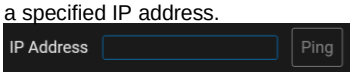
11.4.3. DICOM Settings (If enabled)



To configure DICOM settings, press the ‘DICOM Settings’ button.

Fill in the information to configure the PACS server.

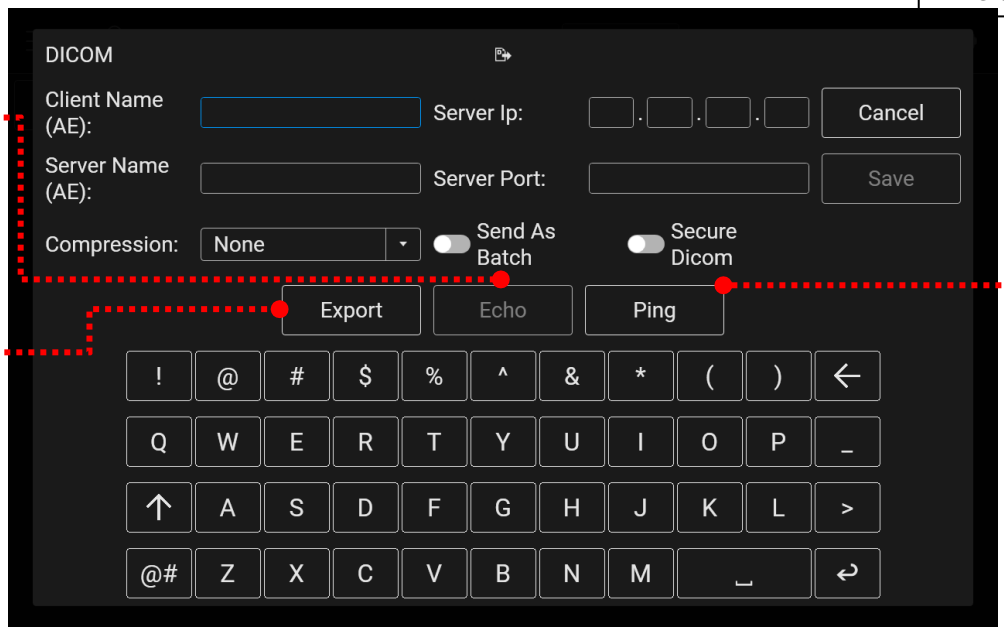
Opens a window to allow a PING to a specified IP address.



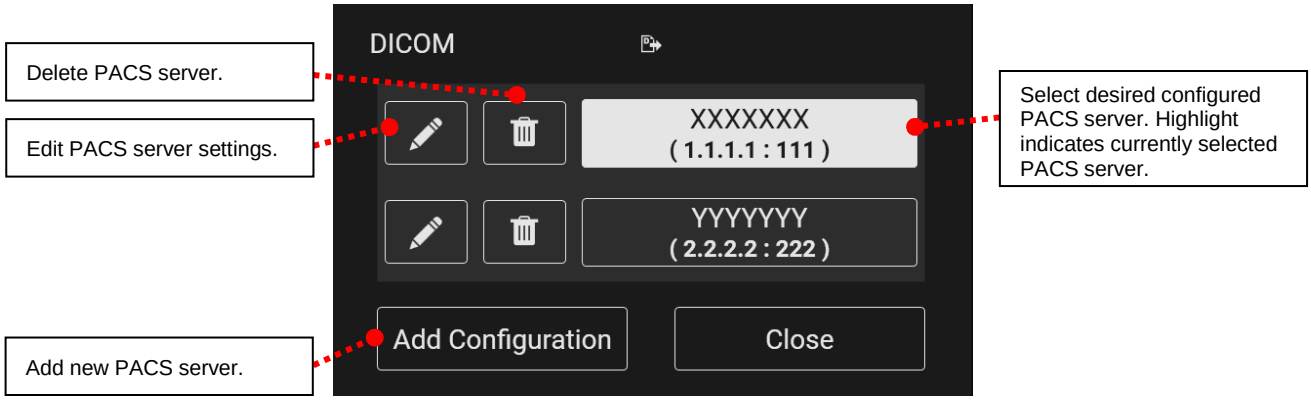
Input the IP address and select the PING button.

Sends a standardized DICOM ECHO request to the specified PACS system. A ✓ indicates success and a red ‘X’ indicates a failure.

Exports a client certificate to USB for Secure DICOM server-client authentication.



Multiple PACS servers may be configured. To select from configured PACS servers or to add/modify a PACS server, press the ‘DICOM Settings’ button.

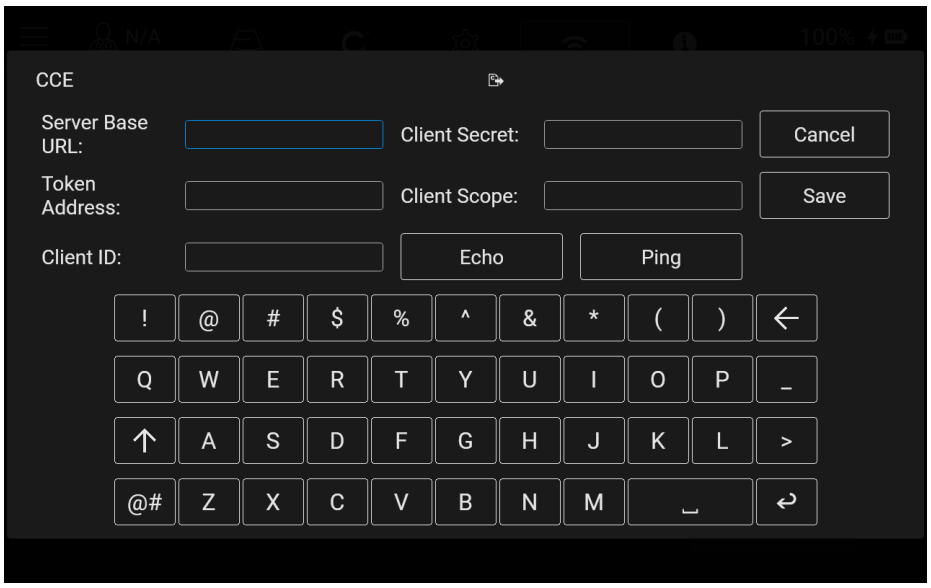


11.4.4. DICOM Conformance Statement

Files are formatted according to Digital Imaging and Communications in Medicine. The DICOM conformance statement is available upon request. Call Customer Service at 1-800-545-0890.

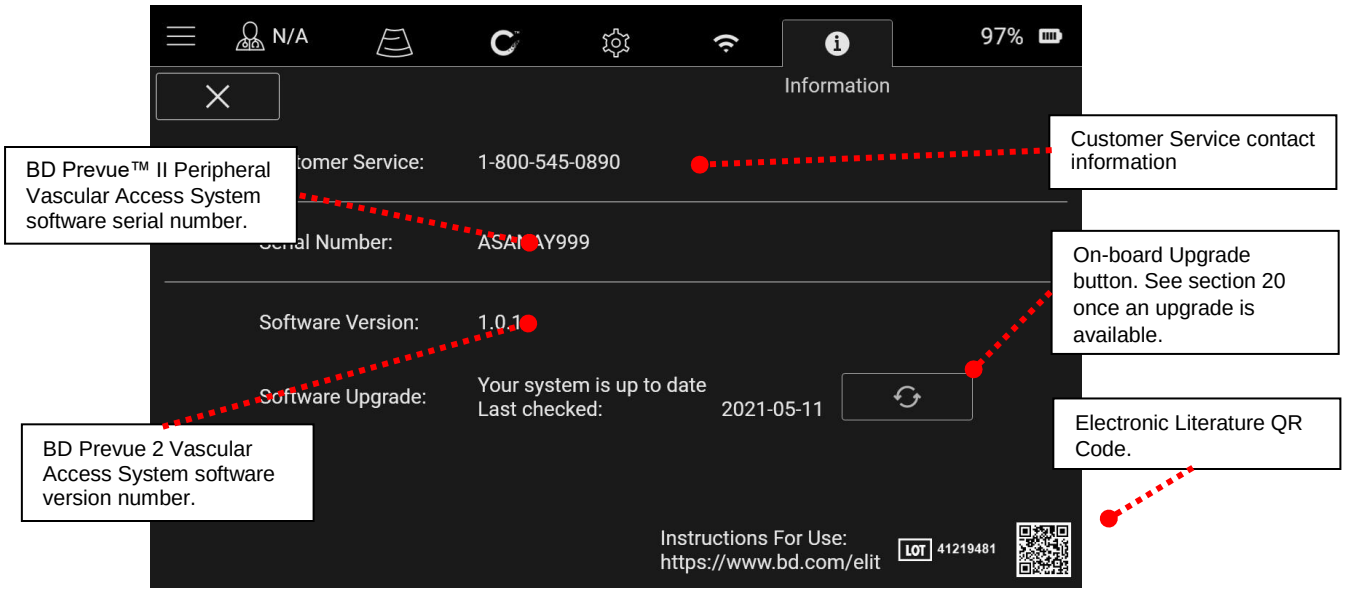
11.4.5. CCE (if enabled)

To connect to your hospital's CCE network, select CCE from the Connectivity Settings screen and fill in the fields provided on the resulting screen.



11.5. System Information

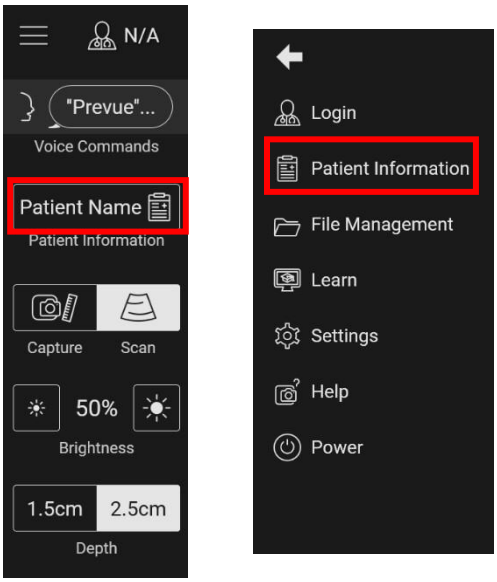
To access the system information, click on the system information tab at the top of the settings screen. The following screen will appear:



12. PATIENT INFORMATION

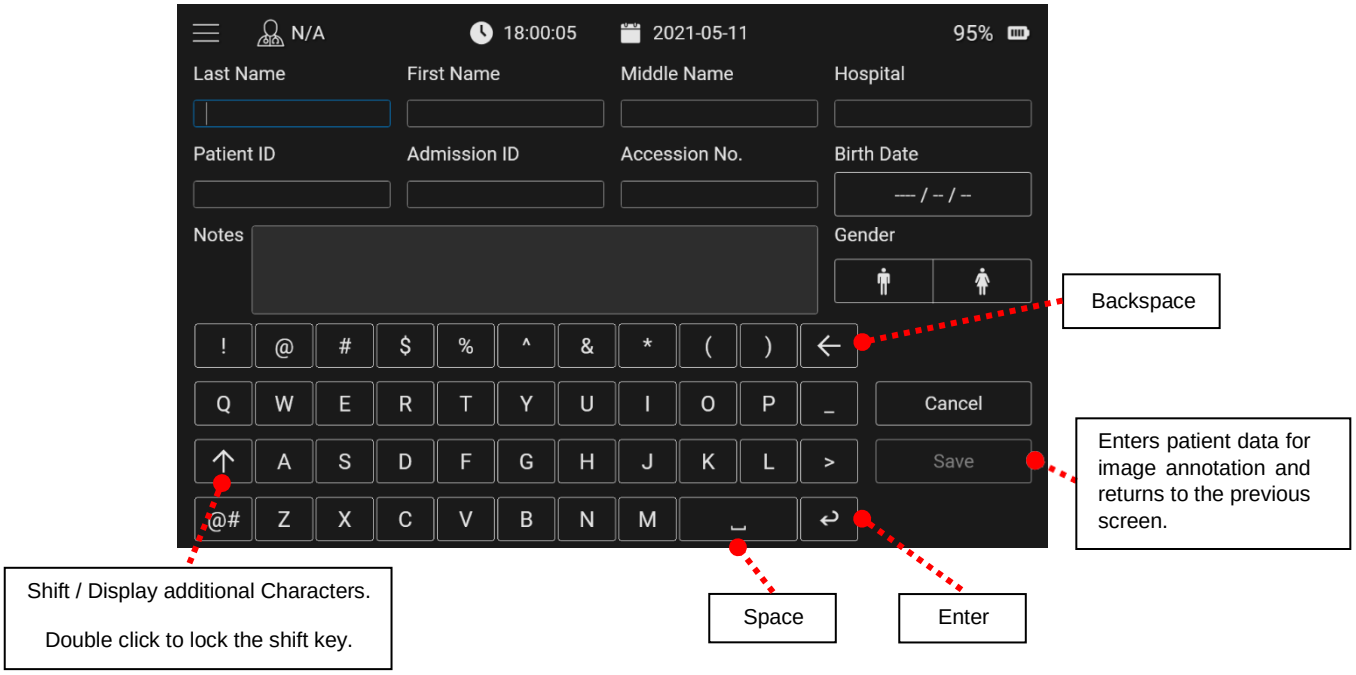
To enter patient information into the BD Prevue™ II Peripheral Vascular Access System:

1. Select the “Patient Name” patient information button from the main ultrasound screen or “Patient Information” from the menu.



2. The following options will appear:

3. Enter the desired patient information. All fields are optional. Entered data will be saved with images.



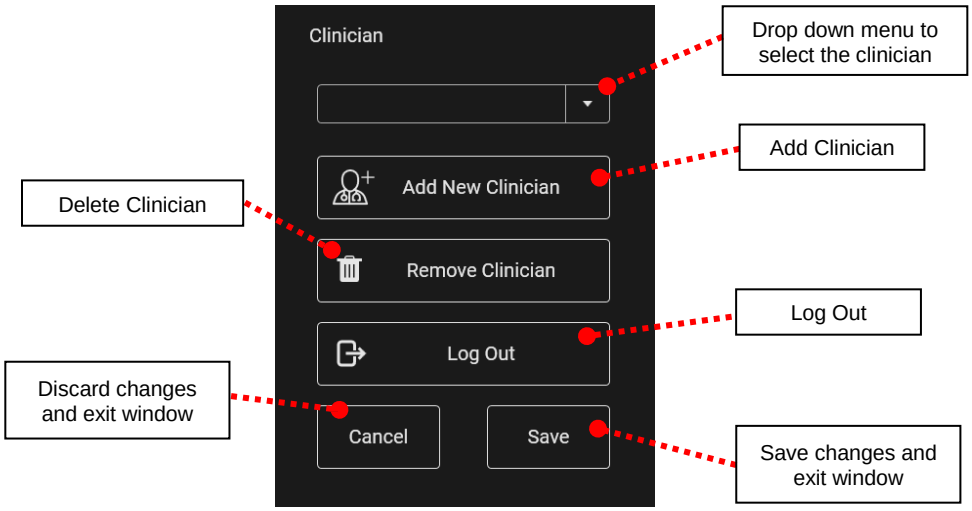
4. Select the “Save” button to retain the information and exit this screen.

13. CLINICIAN PRESETS

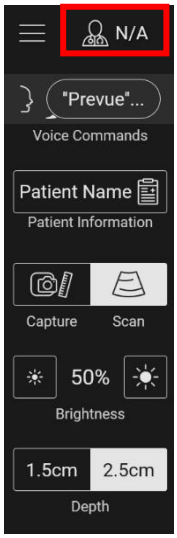
The BD Prevue™ II Peripheral Vascular Access System allows individual clinicians to retain their unique settings.

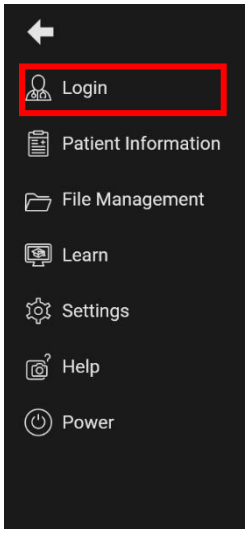
Clinician presets will automatically retain the following settings for each clinician name:

- Ultrasound image depth
- Ultrasound image brightness
- Center marks being on/off
- Probe Face Overlay being on/off



To access the clinician presets menu, select the clinician button on the main ultrasound screen or in the menu.





To access a preset, select the clinician name from the drop-down menu in the clinician presets menu. Any changes made to the settings will automatically be saved to the selected clinician name.

To create a preset:

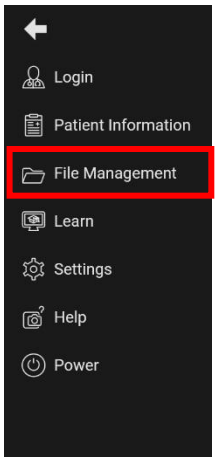
1. In the clinician preset menu select “Add New Clinician”.
2. In the window that appears, type the clinician name and select “Continue”.
3. In the clinician preset menu select “save”.
4. Adjust the system settings as desired.

To delete a clinician preset, select the clinician in the drop-down menu and press the “Remove Clinician” button.

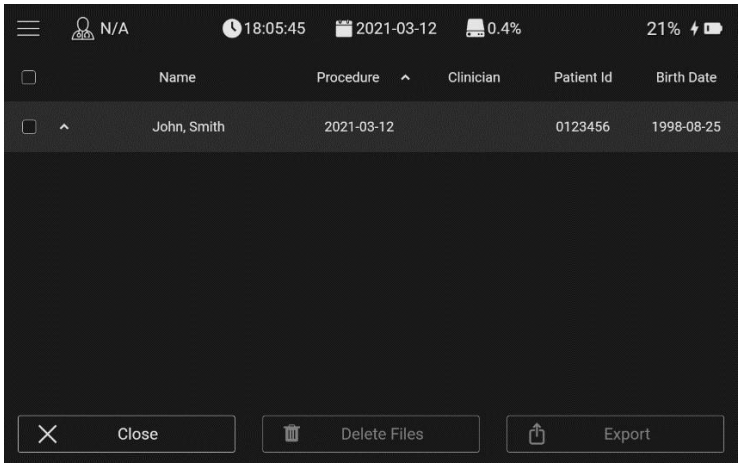
14. ACCESSING SAVED PATIENT IMAGES

The BD Prevue™ II Peripheral Vascular Access System allows you to view and manage saved images. To access saved images, do the following:

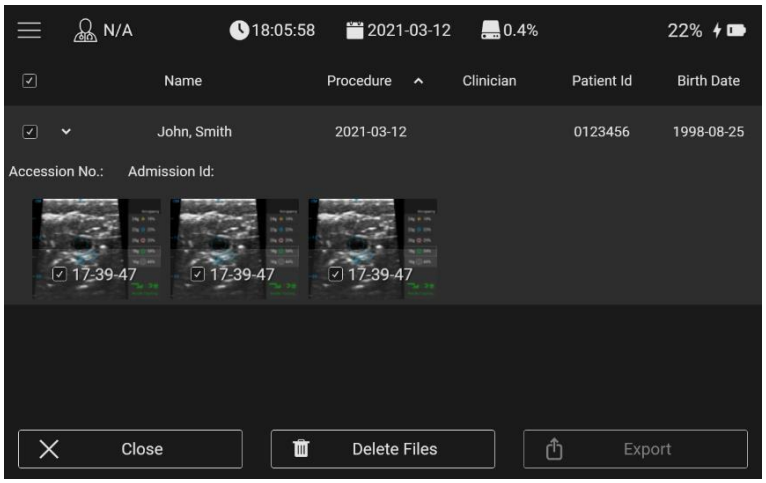
1. Open the menu and select “File Management” (see Section 8).



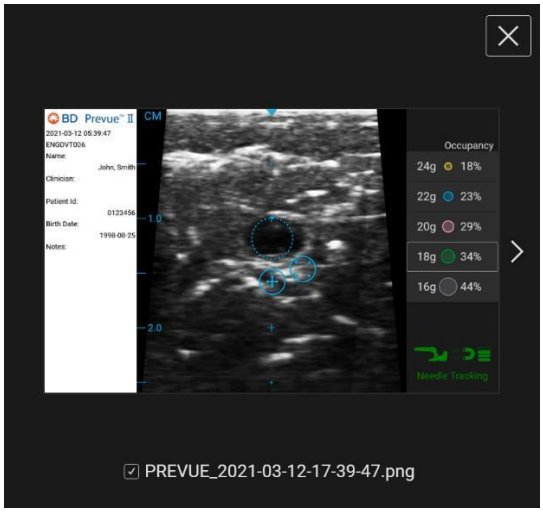
2. A list of all saved patients appears in the window. Select patients to view their respective images.



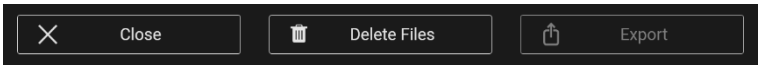
3. After selecting the patients, select the images to be managed.



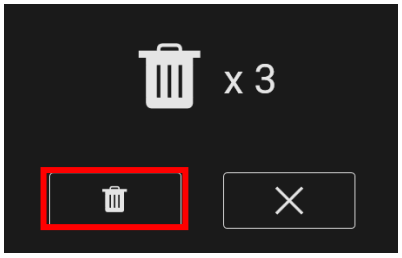
4. To preview an image, touch the center of the image in the image list. The following preview will appear:



5. Once the desired image(s) have been selected, choose an action to perform from the toolbar. If available, export will send the selected image(s) to any of the pre-configured methods (see section 11.4).



Note: To delete all patient data from the system, select all the patients in the patient list (see step 2) and press the delete button.



15. OPERATING THE BD PREVUE™ II PERIPHERAL VASCULAR ACCESS SYSTEM

The basic steps for operating the system in a procedure are listed below.

1) Turn on the system (by pressing the power switch on the bottom right side of the front of the system).
2) Verify the battery charge is sufficient for the procedure; otherwise connect the power adapter to the BD Prevue™ II Peripheral Vascular Access System.
3) Enter Patient Information as needed.
4) Position the patient and perform ultrasound assessment.
5) Apply conductive gel and probe covers per the Site~Rite® Probe Cover instructions for use. Refer to all notes, cautions, and warnings at the end of this section. To drape the probe for sterile use, do the following:
    a. Place the probe in the probe holder.
    b. Apply a layer of ultrasonic coupling gel on the acoustic window of the probe head.
    c. Make sure that the probe cover is fully rolled up.
    d. Place the probe cover over the probe head, being careful not to wipe off the coupling gel.
    e. Cover the probe and cable with the probe cover.
    f. Smooth the probe cover over the acoustic window of the probe head to remove any air bubbles or folds in the cover.
    g. Use the latex-free poly-bands to hold the probe cover in place.
    h. Apply a layer of sterile coupling gel to the covered acoustic window.
6) Adjust the image, as necessary.
7) Perform the procedure.
8) After use, the probe cover should be removed and disposed according to facility protocol. For cleaning the system, refer to “Cleaning and Disinfecting the Equipment,” Section 17.

Caution: When using the BD Prevue™ II Peripheral Vascular Access System probe in a sterile environment, the probe and part of the probe cable must be covered with a sterile, acoustically transparent plastic probe cover.

Caution: Some commercially available probe covers contain latex. Natural rubber latex may cause allergic reactions. Refer to the US FDA alert titled: “Medical Alert: Allergic Reactions to Latex –Containing Medical Devices,” issued March 29, 1991. BD distributes sterile probe covers and needle-guide kits that are not made with natural rubber latex.

Note: To purchase Site~Rite® Probe Covers, contact Bard Access Systems customer service at 1-800-545-0890 or visit our website at www.bardaccess.com.

15.1. Access Using the Cue™ Needle Tracking System

1. Prepare the BD Prevue™ II Peripheral Vascular Access System.
   a. Verify the battery charge is sufficient for the procedure; otherwise connect the power adapter to the BD Prevue™ II Peripheral Vascular Access System.
   b. Enter Patient Information as needed.
2. Position the patient and perform ultrasound assessment.
3. Prepare the sterile field.
   a. Ensure all metallic objects are removed from the surrounding location (at least 4 inches away). If an object, such as a bed rail, cannot be moved, take precautions to make the object stationary during the procedure.
   b. Ensure all magnetic objects (e.g. magnets, mobile phones, electric motors, etc.) are removed from the surrounding location (at least 3 feet away).
   c. Retrieve the Cue™ Needle Tracking System compatible device, open the device packaging and scan the RFID tag on the device onto the scan icon on the system handle.

   d. Drape the ultrasound probe for sterile use (Refer to Probe Cover Instructions for Use.)
   e. If applicable, anesthetize the insertion site (per institution protocol).
4. Prepare for insertion
   a. Re-scan the anatomy of interest using the BD Prevue™ II Peripheral Vascular Access System.
   b. Ensure the Performance Indicator indicates an adequate environment for needle tracking, see section 10.2.2.
   c. Remove the needle from the packaging, and dip the needle with the needle cover still on into the Cue™ Magnetizer (**Optional**: place the Cue™ Magnetizer Cover into the Cue™ Magnetizer prior to dipping the needle). Remove the needle from the Cue™ Magnetizer.

Caution: Keep the needle and any ferromagnetic objects, e.g., wired undergarments, metal instruments, watches, jewelry, Cue™ Magnetizer, electronics metal bed rails, etc. at least 3 feet away from probe when calibrating. Failure to do so may impact the accuracy of needle tracking.

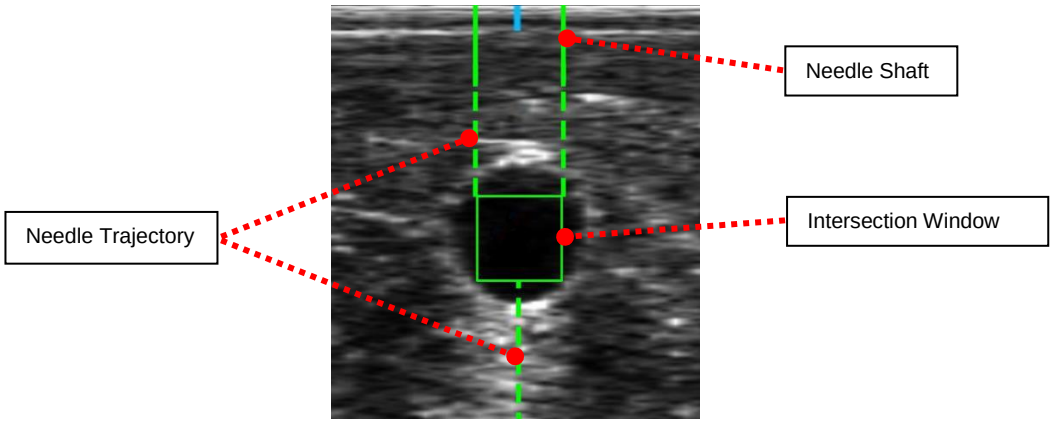
Caution: Equipment operating in close proximity may emit strong electromagnetic or radio frequency interference which could affect the performance of this device. Avoid operating the device near pumps, cauterizers, diathermy equipment, cellular phones, or other portable and mobile radio frequency communications equipment. Maintain equipment separation of at least 3 feet.

Caution: Excessive movement of the probe may result in a temporary loss of needle tracking.

5. ***Out-of-Plane*** Ultrasound Guided Insertion Using the Cue™ Needle Tracking System
   a. Retrieve the activated needle and move it towards the probe center mark at a 45 degree angle until it is within 0.5 cm from the probe. Ensure the Cue™ Needle Tracking System virtual needle overlay appears on the display and follows needle movement.

Caution: If needle tracking is not functioning properly, discontinue use of Cue™ Needle Tracking System.

   b. Position the needle by adjusting the insertion angle and distance from the probe to align the Intersection Window with the intended target structure. A steeper insertion angle may be necessary for deep structures while a shallow angle may be appropriate for superficial anatomy.

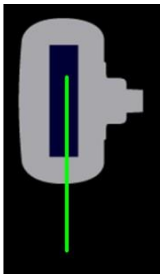


   c. While maintaining the needle angle, insert the Cue™ Needle Tracking System compatible needle into the skin. Refer to the specific device's Instructions for Use for more information.
   d. Proceed with insertion – watch needle advancement onscreen. The solid green lines represent the needle shaft and tip. The green square represents the area where the needle will intersect the ultrasound plane (color of line may vary, see sections 10.3.3 and 10.3.4).
   e. During advancement, maintain the Intersection Window centered with the intended target structure.
   f. When the solid green lines reach the Intersection Window, it means the needle has intersected the plane of the ultrasound beam within the Intersection Window. It does not mean insertion has been successful or the structure of interest has been reached.
   g. When attempting vessel access, watch for:
      - Anterior vessel wall indenting (once the puncture occurs the vessel will return to normal shape)
      - Blood return in the device
      - Needle reflection (flash of the needle tip) on the ultrasound image
   h. Complete procedure per suggested institutional guidelines.

6. ***In-Plane*** Ultrasound Guided Insertion Using the Cue™ Needle Tracking System
   Note: In-plane needle tracking is not available with the BD Prevue™ II Vascular Access Probe.
   a. Retrieve the activated needle and move it towards the side of the probe at a 45° angle until it is within 0.5 cm from the probe. Ensure the Cue™ Needle Tracking System virtual needle overlay appears on the display and follows needle movement.

Caution: If needle tracking is not functioning properly, discontinue use of Cue™ Needle Tracking System.

   b. Position the needle by adjusting the insertion angle and distance from the probe to align the Cue™ Needle Tracking System Overlay with intended target structure.



Note: In-Plane Mode does not have an Intersection Window.

   c. While maintaining the desired needle angle, insert the needle into the skin. Refer to the specific device's Instructions for Use for more information.
   d. Proceed with insertion – watch needle advancement onscreen. The solid green lines represent the needle shaft and tip.
   e. During advancement, maintain the needle trajectory in the center of the intended target structure. Maintain the needle so that the virtual needle is centered in the Probe Face Overlay and the virtual needle is green.
   f. When attempting vessel access, watch for:
      - Anterior vessel wall indenting (once the puncture occurs the vessel will return to normal shape)
      - Blood return in the needle hub
      - Needle reflection (flash of the needle) on the ultrasound image
   g. Complete procedure per suggested institutional guidelines

16. TROUBLESHOOTING

16.1. BD Prevue™ II Peripheral Vascular Access System Troubleshooting

Troubleshooting - BD Prevue™ II Peripheral Vascular Access System		
SYMPTOM	**DESCRIPTION**	**SOLUTIONS**
Error Code EC: 201-203 EC: 205 EC: 211	Ultrasound Hardware Failure	Reboot the System. **Note:** If error persists, call Customer Service at 1-800-545-0890. An alternate number may be available in the System Information Tab (see Section 11.5).
Error Code EC: 204	Probe Disconnect Error	If applicable, ensure the probe is securely connected to the system. See Section 3.3. **Note:** If error persists, call Customer Service at 1-800-545-0890. An alternate number may be available in the System Information Tab (see Section 11.5).
System plays a sound every minute	Low Battery	Connect system to power for continued operation and to recharge battery.
Error Code EC: 110	Battery Error	Connect AC adapter for operation. Ensure the battery switch is in the "✓" position. (See Section 4.) **Note:** If error persists, call Customer Service at 1-800-545-0890. An alternate number may be available in the System Information Tab (see Section 11.5).
Power Problem	System will not turn on or turns on but immediately turns off	1. Press and hold the power switch for at least 2 seconds to turn the system on. 2. Connect system to AC power for operation and to recharge the battery. **Note:** If error persists, call Customer Service at 1-800-545-0890. An alternate number may be available in the System Information Tab (see Section 11.5).
A/C adapter indicator does not change states when A/C power is connected	Connection error	1. Unplug the AC adapter and plug it back in to the system. 2. Restart the system if necessary. **Note:** If error persists, call Customer Service at 1-800-545-0890. An alternate number may be available in the System Information Tab (see Section 11.5).
Error Code EC:102	USB storage device error	The USB storage device may be full or may not be a compatible USB storage device. Replace the USB storage device. **Note:** If error persists, call Customer Service at 1-800-545-0890. An alternate number may be available in the System Information Tab (see Section 11.5).
Error Code EC:103	Hard Drive error	Restart the system. **Note:** If error persists, call Customer Service at 1-800-545-0890. An alternate number may be available in the System Information Tab (see Section 11.5).

Troubleshooting - BD Prevue™ II Peripheral Vascular Access System		
SYMPTOM	**DESCRIPTION**	**SOLUTIONS**
Poor Image		1. Adjust the image settings - Depth (see Section 7.1.7) - Brightness (see Section 7.1.6) 2. Lack of couplant. Apply ultrasound gel. **Note:** If error persists, call Customer Service at 1-800-545-0890. An alternate number may be available in the System Information Tab (see Section 11.5).
System becomes unresponsive		Press and hold the power switch on the front of the device until the system shuts down. (Note: This will take approximately 10 seconds.) Turn on the system. **Note:** If error persists, call Customer Service at 1-800-545-0890. An alternate number may be available in the System Information Tab (see Section 11.5).
Cannot connect to desired network		1. Confirm that the DICOM features are activated on the system (see Section 11.4.3). 2. Confirm that WiFi is enabled and the device is connected to your network (see Section 11.4.1). 3. Check the WiFi signal strength. 4. Contact your network administrator. Refer to section 11.4. **Note:** If error persists, call Customer Service at 1-800-545-0890. An alternate number may be available in the System Information Tab (see Section 11.5).
System password is lost		1. Contact customer service and provide the system date and serial number for a temporary password. Call Customer Service at 1-800-545-0890. An alternate number may be available in the System Information Tab (see Section 11.5).
Error Code EC:105	Deleting Error	1. Restart the system. Attempt to delete the file(s). **Note:** If error persists, call Customer Service at 1-800-545-0890. An alternate number may be available in the System Information Tab (see Section 11.5).
Error Code EC:106	Network Error	1. Ensure the device is connected to the desired network. 2. If using a static IP address, verify the static network settings. 3. Contact your network administrator. **Note:** If error persists, call Customer Service at 1-800-545-0890. An alternate number may be available in the System Information Tab (see Section 11.5).
Error Code EC:107	PACS Error	1. Ensure you are connected to the desired network. 2. Ensure that the system DICOM settings are compatible with the destination PACS system settings. 3. Contact your network administrator. **Note:** If error persists, call Customer Service at 1-800-545-0890. An alternate number may be available in the System Information Tab (see Section 11.5).
Error Code EC:108	PACS ECHO Error	1. Ensure you are connected to the desired network. 2. Ensure that the system DICOM settings are compatible with the destination PACS system settings. 3. Contact your network administrator. **Note:** If error persists, call Customer Service at 1-800-545-0890. An alternate number may be available in the System Information Tab (see Section 11.5).
Error Code EC:111	General System Error	1. Restart the system. **Note:** If error persists, call Customer Service at 1-800-545-0890. An alternate number may be available in the System Information Tab (see Section 11.5).

Troubleshooting - BD Prevue™ II Peripheral Vascular Access System		
SYMPTOM	**DESCRIPTION**	**SOLUTIONS**
Error Code EC:112	File Reading Error	1. Failed to read configuration file. Some user settings may be lost. **Note:** If error persists, call Customer Service at 1-800-545-0890. An alternate number may be available in the System Information Tab (see Section 11.5).
 Error in WiFi Networks list	WiFi Connection Error	1. Ensure the security key is correct. 2. Ensure the WiFi configuration is correct. 3. Contact your network administrator **Note:** If error persists, call Customer Service at 1-800-545-0890. An alternate number may be available in the System Information Tab (see Section 11.5).
Note: This device is equipped with a lithium ion battery. Lithium ion battery performance is known to degrade over time based on environmental and use conditions. These messages are intended to help manage the life of the battery.		
	Pre-Critical Warning	This window appears when the battery is approaching the end of its useful life. It is recommended that the battery be replaced.
	Critical Warning	This window appears when the battery's integrity has reached a critical stage, indicating the system detected the battery has reached the end of its useful life and that without AC power, the system is likely to shut down. The message will only disappear at startup when the system is connected to AC power.

16.2. Cue™ Needle Tracking System Troubleshooting

Troubleshooting - Cue™ Needle Tracking System		
SYMPTOM	**DESCRIPTION**	**SOLUTIONS**
Error Code EC: 501 	Cue™ Needle Tacking System Sensor Disconnect Error	1. Ensure the Cue™ Needle Tacking System Probe is securely connected to the system. 2. Restart the system. **Note:** If error persists, call Customer Service at 1-800-545-0890. An alternate number may be available in the System Information Tab (see Section 11.5).
Error Code EC: 502 	Calibration Error	1. Restart the system. 2. Ensure the probe is held in the air during calibration, see section 11.2.1. **Note:** If error persists, call Customer Service at 1-800-545-0890. An alternate number may be available in the System Information Tab (see Section 11.5).
Error Code EC: 503-509 	Cue™ Needle Tacking System Error	Restart the system. **Note:** If error persists, call Customer Service at 1-800-545-0890. An alternate number may be available in the System Information Tab (see Section 11.5).
Cue™ Needle Tracking System is not activated when the RFID is scanned.	**Likely cause:** The system is in capture mode.	Select the scan button to exit capture mode.
Cue™ Needle Tracking System Probe does not detect Cue™ Needle Tracking System Enabled Needle	**Likely cause:** The needle was introduced or re-introduced too quickly.	If tracking signal drops during needle approach, remove the needle at least two feet (61cm) away from the probe for at least three seconds, allow the Performance Indicator to stabilize, and slowly re-approach the probe.
	Likely cause: Magnetic field interference.	If the Performance Indicator is low, perform the following steps: • Hold the probe still • If the Performance Indicator decreases during needle approach, withdraw the needle and slowly re-approach. • Remove metal, magnetic, and electronic objects in close proximity to the probe (bed rails, jewelry, mobile phone, pumps, bed/table frames, Cue™ Magnetizer, etc.). • If problem persists, hold the probe stationary in the air away from all metal, magnetic, and electronic devices. • If the Performance Indicator improves, review previous troubleshooting tips **If the Performance Indicator remains low, calibration may be required. <u>This should be uncommon.</u> See section 11.2.1.**
	Likely cause: Probe is in need of calibration.	If problem persists, hold the probe stationary in the air away from all metal, magnetic, and electronic devices. • If the Performance Indicator improves, review previous troubleshooting tips • If the Performance Indicator remains low, calibration may be required. <u>This should be uncommon.</u> See section 11.2.1. • Note: **If error persists after calibration, call Customer Service at 1-800-545-0890. An alternate number may be available in the System Information Tab (see Section 11.5).**

Troubleshooting - Cue™ Needle Tracking System		
SYMPTOM	**DESCRIPTION**	**SOLUTIONS**

	Likely cause: Magnetic field interference	If the Performance Indicator is low, perform the following steps:
		• Hold the probe still
		• If the Performance Indicator decreases during needle approach, withdraw the needle and slowly re-approach.
		• Remove metal, magnetic, and electronic objects in close proximity to the probe (bed rails, jewelry, mobile phone, pumps, bed/table frames, Cue™ Magnetizer, etc.).
		• If problem persists, hold the probe stationary in the air away from all metal, magnetic, and electronic devices.
		  • If the Performance Indicator improves, review previous troubleshooting tips
		  • If the Performance Indicator remains low, calibration may be required. This should be uncommon. See Section 11.2.1.
		Note: If error persists after calibration, call Customer Service at 1-800-545-0890. An alternate number may be available in the System Information Tab (Section 11.5).

Needle tracking virtual needle image has erratic behavior	**Likely cause:** Excessive movement of probe and/or needle.	1. Anchor the probe in a stationary and upright position. 2. Stabilize the hand holding the needle. 3. Only modify the position of the needle to change the location of the Intersection Window.
Difficulty aligning and maintaining the Intersection Window on the target structure	**Likely cause:** Needle detection reset is required.	1. If prior to insertion, withdraw the needle and slowly re-approach. 2. If after needle insertion, withdraw the probe away from the needle and slowly re-approach. 3. If problem persists, activate a new needle.

	Likely cause: Performance Indicator too low.	If the Performance Indicator is low, perform the following steps:
		• Hold the probe still
		• If the Performance Indicator decreases during needle approach, withdraw the needle and slowly re-approach.
		• Remove metal, magnetic, and electronic objects in close proximity to the probe (bed rails, jewelry, mobile phone, pumps, bed/table frames, Cue™ Magnetizer, etc.).
		• If problem persists, hold the probe stationary in the air away from all metal, magnetic, and electronic devices.
		  • If the Performance Indicator improves, review previous troubleshooting tips
		  • If the Performance Indicator remains low, calibration may be required. This should be uncommon. See Section 11.2.1.
		• If the needle overlay disappears during insertion, withdraw the probe away from the needle and slowly re-approach to restart tracking.
		Note: If error persists after calibration, call Customer Service at 1-800-545-0890. An alternate number may be available in the System Information Tab (Section 11.5).

Troubleshooting - Cue™ Needle Tracking System		
SYMPTOM	**DESCRIPTION**	**SOLUTIONS**
Drop out – the needle overlay disappears during insertion	**Likely cause:** Needle detection reset is required.	1. If prior to insertion, withdraw the needle and slowly re-approach. 2. If after needle insertion, withdraw the probe away from the needle and slowly re-approach. 3. If problem persists, activate a new needle.

16.2.1. Cue™ Needle Tracking System Troubleshooting

To test the functionality of the Cue™ Needle Tracking System, perform the following steps:

1) Move all metal objects (including the needle) at least 4 inches away from the Cue™ Needle Tracking System Probe.
2) Move all active electronic devices and magnetic articles at least 3 feet away.
3) Obtain a small container of water.
4) Immerse the end of the probe into the container of water.
5) Check the Performance Indicator bars. Verify there are three or more bars. If there are less than three bars, perform calibration.
6) Introduce the needle to the probe slowly to observe the overlay. Place the Intersection Window at 1 cm depth below the ultrasound beam.
7) Advance the needle to the Intersection Window until there is a strong needle flash in the Intersection Window.
   Observe the location of the needle flash and the needle advancement lines, making sure they contact the Intersection Window and the needle flash appears in the Intersection Window.

17. CLEANING AND DISINFECTING THE EQUIPMENT

Thorough cleaning of all the contaminated surfaces is the first crucial step in providing adequate removal of contaminants and debris prior to the disinfection step. The reduction of patient-to-patient cross-contamination and the reduction of the risk of patient infection significantly depends on the thoroughness of the initial cleaning.

The following cleaning and disinfections steps should be performed as soon as possible at the point-of-use of the equipment. Prompt cleaning after use is the most effective measure to prevent the drying of soil on the device surface and to facilitate the subsequent disinfection steps. Any delay between the Cleaning step (Section 17.1) and the Disinfection step (Section 17.2) should be minimized as much as possible, as delays may create conditions favorable to microbial growth, possibly reducing the effectiveness of a proper disinfection.

17.1. Cleaning of the Equipment (Point-of-Use Processing)

1) Turn off the system.
2) Dampen a nonabrasive cloth with either warm water or isopropyl alcohol.
3) Thoroughly wipe the dampened cloth over exterior surfaces that require cleaning (e.g., probes, console, etc.), making sure to completely remove all soil, debris and other visible contaminants, including the removal of all particles or other matter from all surfaces and crevices.
4) Visually inspect the surfaces of the equipment to verify the adequacy of the cleaning. If the equipment is determined not to be visually clean, repeat the cleaning steps #2 and #3 above. If it is not possible to remove all soil and contaminants, properly dispose of the contaminated components and contact Customer Service at 1-800-545-0890 for replacements. Do not use visibly soiled equipment.
5) Allow the equipment to dry completely before proceeding to the Disinfection step below.

17.2. Disinfection of the Equipment

1) Use only medical grade disinfectants approved for use in a hospital setting. The disinfectants listed in Section 17.3 below are compatible with this equipment.
2) Use two or more towelettes to thoroughly disinfect all probe and other soiled surfaces for at least two minutes. Follow any specific directions for use specified by the manufacturer of the cleaning product used.
3) Repeat Step 2 using two new towelettes.
4) Allow the equipment to dry completely (if applicable, follow the drying instructions recommended by the disinfectant manufacturer) before using the equipment with the next patient.
5) Visually inspect the equipment for any damage or deterioration. Should the equipment show signs of unacceptable deterioration, properly dispose of the damaged components and contact Customer Service at 1-800-545-0890 for replacements. Do not use damaged equipment.

17.3. Compatible Cleaners

The following cleaning agents are compatible with the BD Prevue™ II Peripheral Vascular Access System and probes:

- PDI® Super Sani-Cloth® Germicidal Disposable Wipes
- PDI® Sani-Cloth® AF3
- PDI® Prime
- Clorox Healthcare™ Hydrogen Peroxide Cleaner Disinfectant Wipes
- Clorox Healthcare® Bleach Germicidal Cleaner
- Metrex™ Research CaviWipes® Disinfecting Towelettes
- Metrex™ Research CaviWipes1™

An updated list may be available by contacting Bard Access Systems for the "BD Prevue™ II Peripheral Vascular Access System Compatible Disinfectants" document. (800) 545-0890.

Warning: Failure to properly clean and disinfect the system can lead to cross contamination between patients.

Caution: Do not allow liquid to enter the system, AC adapter, connectors, or ports; damage to the equipment may occur.

Caution: Do not attempt to sterilize the BD Prevue™ II Peripheral Vascular Access System or probe; damage to the equipment may occur as a result.

Caution: Use only BD cleaning and disinfection procedures. Failure to do so may damage the device.

Caution: Use only approved or recommended cleaners or disinfectants to avoid damaging the equipment.

Note: When cleaning the system and components, it is important to remove all particles or other matter from all surfaces and crevices.

Note: Do not spray cleaners directly onto the BD Prevue™ II Peripheral Vascular Access System display.

Note: If disinfecting the probe with a liquid disinfectant, do not soak the probe cable or cable bend relief.

Note: Disinfection can take place under normal hospital environmental conditions.

18. WARRANTY

BD warrants to the original purchaser that this product will be free from defects in material and workmanship for a period of one (1) year from the date of purchase. If this product proves to be so defective, purchaser may return same to BD for repair, replacement, refund, or credit at BD's option. All returns must be authorized in advance in accordance with BD's Returned Goods Policy found in its then current Price List. The warranty on the repaired or replaced unit continues from the purchase date of the original unit. The liability of BD under this limited warranty does not extend to any abuse, misuse, modification, improper storage, alteration, further manufacture, packaging or processing of this product or repair by anyone other than a BD representative.

The following will also void this limited warranty:

- Opening or servicing any component of the BD Prevue™ II Peripheral Vascular Access System by anyone other than BD authorized service personnel.
- Removing system labels by anyone other than service personnel authorized by BD.
- Connecting the BD Prevue™ II Peripheral Vascular Access System display to any AC adapter other than the system adapter.
- Connecting the BD Prevue™ II Peripheral Vascular Access System to any unauthorized accessory. Refer to the list of authorized accessories in the "Overview" section.
- Installing unauthorized software.
- Modification of system software without authorization by BD.

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, AND BARD ACCESS SYSTEMS INC. WILL NOT BE LIABLE TO PURCHASERS FOR ANY INDIRECT, SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES ARISING OUT OF ITS HANDLING OR USE.

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.

19. SERVICE AND REPAIR

The BD Prevue™ II Peripheral Vascular Access System does not require any scheduled maintenance, system checks, or calibration. For servicing information or to return your BD Prevue™ II Peripheral Vascular Access System for repair, please contact BD technical/clinical support at 1-800-443-3385.

19.1. Accessory Replacement

19.1.1. Cue™ Magnetizer Replacement

If a Cue™ Magnetizer is needed, contact BD technical/clinical support at 1-800-443-3385. Once the new Cue™ Magnetizer is received, do the following (if a Cue™ Magnetizer is not already attached, skip to step 3):

1) Remove the Cue™ Magnetizer by pulling up and removing the Cue™ Magnetizer from the mount.

2) Remove the screw to remove the Cue™ Magnetizer Mount.

3) Identify the screw slot for the mount on the right side of the console.

4) Screw in the Cue™ Magnetizer Mount with the screw provided

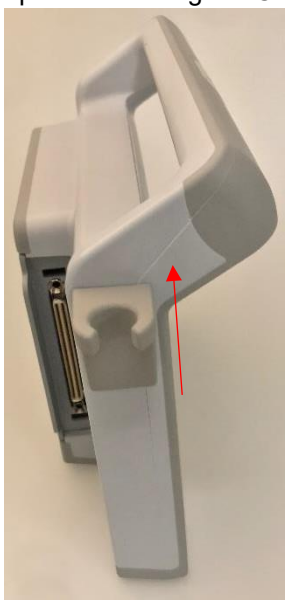
Caution: Only use the provided screw when attaching the Cue™ Magnetizer to the system as others may impact the functionality of the Cue™ Magnetizer.

5) Slide the Cue™ Magnetizer onto the Cue™ Magnetizer Mount.

19.1.2. Probe Holder Replacement

If a Probe Holder is needed, contact BD technical/clinical support at 1-800-443-3385. Once the new Probe Holder is received, do the following (if a Probe Holder is not already attached, skip to step 3):

1) Remove the Probe Holder by pulling up and removing the Cue™ Magnetizer from the mount.

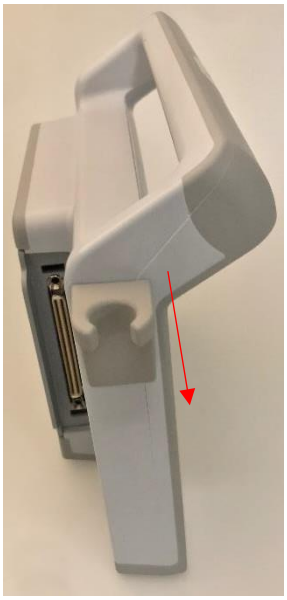


2) Remove the screw to remove the Probe Holder Mount.

3) Identify the screw slot for the mount on the left side of the console.

4) Screw in the Probe Holder Mount.

5) Slide the Probe Holder onto the Probe Holder Mount.



19.1.3. Cord Wrap Replacement

If a Cord Wrap is needed, contact BD technical/clinical support at 1-800-443-3385. Once the new Cord Wrap is received, do the following:

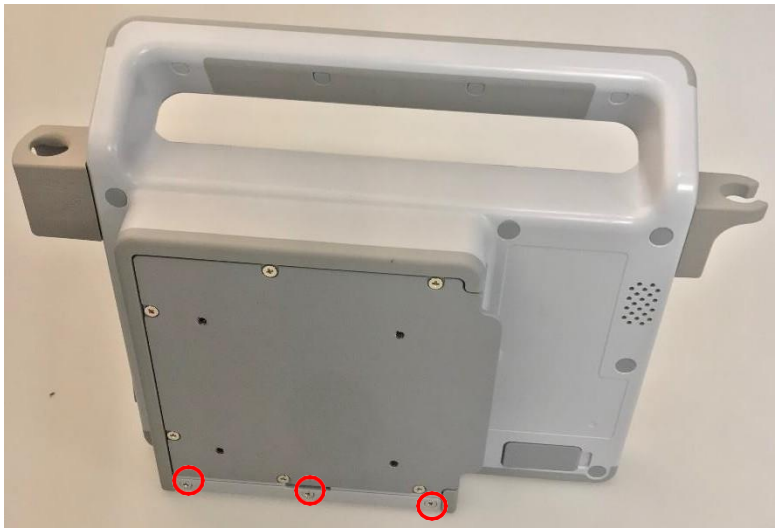
1) Identify the four screw holes on the back of the console.

2) Screw in the Cord Wrap on the upper 2 screw holes.
   Note: If a Roll Stand Mount is also being used. Attach the Roll Stand Mount with the lower 2 screws and attach the Cord Wrap to the top 2.

19.2. Battery Replacement

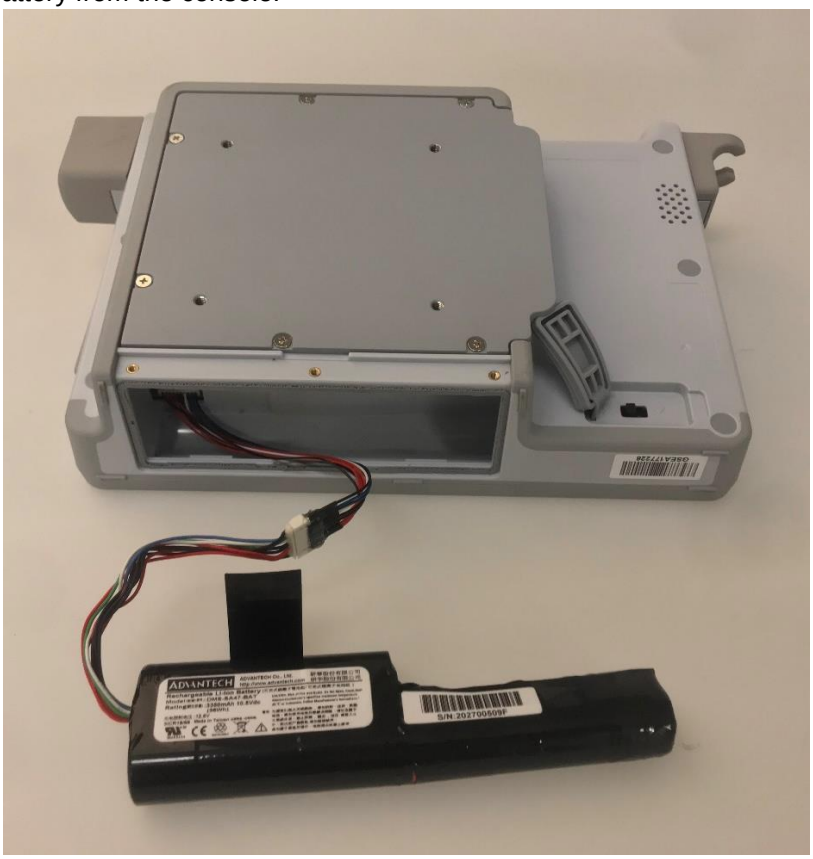
If a new battery is needed, contact BD technical/clinical support at 1-800-443-3385. Once the new battery is received, do the following:

1) Power off the system.
2) Remove the screws on the plate that covers the BD Prevue™ II battery.



3) Remove the plate covering the battery.

4) Remove the battery from the console.



5) Disconnect the battery from the internal battery cable, replace with the new battery, and reassemble the device.

20. UPGRADING

The BD Prevue™ II Peripheral Vascular Access System is equipped with On-board Upgrade functionality. For upgrading via On-bard Upgrade, do the following:

1) Ensure the device is connected to the internet. The On-board Upgrade process will download the upgrade automatically once connected.
2) Once the upgrade has been fully downloaded, navigate to the system information settings tab, which will provide information on the upgrade including the software version and the estimated upgrade time.
3) Select the upgrade button next to the upgrade information and select confirm to begin the upgrade process.
4) **Do not attempt to cancel the upgrade procedure as this may cause applications to malfunction.** If an error occurs during the upgrade procedure, reboot the system and repeat the upgrade procedure again. If the error persists, contact the BD technical/clinical support at 1-800-443-3385.
5) Restart the system.
6) Confirm desired software version is displayed in the system information (section 11.5). Additionally, the software upgrade information will indicate that the system is up to date and the upgrade button will no longer be selectable.

If you are unable to connect to the internet, contact your local BD representative for a USB drive with the latest version of BD applications. For U.S. customers only, available upgrades may also be obtained by visiting www.bardaccess.com/products/ultrasound. Once received, do the following:

1) Insert USB drive into one of the USB ports on the BD Prevue™ II Peripheral Vascular Access System.
2) Answer yes when prompted to proceed with the upgrade.
3) **Do not attempt to cancel the upgrade procedure or remove the USB drive, as this may cause applications to malfunction**. Follow the onscreen prompts to complete the software upgrade. If an error occurs during upgrading procedure, reboot the system and repeat the upgrade procedure again. If the error persists, contact the BD technical/clinical support at 1-800-443-3385.
4) Restart the system.
5) Confirm desired software version is displayed in the system information (section 11.5). Now it is safe to remove the USB drive.

21. DISPOSAL INFORMATION

To return the BD Prevue™ II Peripheral Vascular Access System for end-of-life recycling, please contact your nearest Bard sales or distribution office in the country of purchase.

Caution: The BD Prevue™ II Peripheral Vascular Access System contains an internal battery. Dispose of dead battery packs in accordance with local regulations; improper disposal may present an environmental hazard.

22. ACOUSTIC INFORMATION

The following acoustic information pertains to both the Traditional probe and the Vascular Access Probe, which are acoustically identical.

22.1. Acoustic Output Summary Table

Description	Operating Mode	$I_{spta.X}$ (X denotes statistically determined maximum)	FDA $I_{spta.3}$ Published Values	*MI* X (X denotes statistically determined maximum)	FDA *MI* Published Values
BD Prevue™ II Probes (Traditional probe and Vascular Access Probe)	B	12.69 mW/cm^2	Peripheral Vessel < 720 mW/cm^2 Cardiac < 430 mW/cm^2 Fetal Imaging & Other** < 94 mW/cm^2	0.91	Peripheral Vessel < 1.9 Cardiac < 1.9 Fetal Imaging & Other** < 1.9

** Abdominal, Intraoperative, Pediatric, Small Organ (breast, thyroid, testes, etc), Neonate Cephalic, Adult Cephalic.

22.2. Acoustic Output Reporting Table

Operating Mode: B-Mode (Traditional Probe and Vascular Access Probe)

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.65	0.0542		0.0542		0.22
Index Component Value				0.0542	0.0542	0.0542	0.0542	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	1.75					
	P	(mW)		3.05		3.05		
	P_{1X1}	(mW)		1.58		1.58		
	z_s	(cm)			1.13			
	z_b	(cm)					0.97	
	z_{MI}	(cm)	1.13					
	$Z_{pii,\alpha}$	(cm)	1.13					
	f_{awf}	(MHz)	7.18	7.18		7.18		7.18
Other Information	Prr	(Hz)	7424.0					
	Srr	(Hz)	116.0					
	n_{pps}		1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm2)	136.56					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm2)	7.48					
	I_{spta} at z_{pii} or z_{sii}	(mW/cm2)	13.17					
	P_r at z_{pii}	(MPa)	2.10					
Operating Control Conditions	10 MHz							
	9mm or 14mm focus (Max Value Reported)							

Note 1 Only one operating condition per index.
Note 2 Data should be entered for "at surface" and "below surface" both in the columns related to TIS or TIB.
Note 3 Information need not be provided regarding TIC for a TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.
Note 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.
Note 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.
Note 6 Unshaded cells should have a numerical value. The equipment setting related to the index has to be entered in the operating control section.
Note 7 The depths z_{pii} and $z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths z_{sii} and $z_{sii,\alpha}$ apply to SCANNING MODES.

23. EMC TABLES

Warning: The use of accessories other than those specified in the "Overview" section may result in increased emissions or decreased immunity of the BD Prevue™ II Peripheral Vascular Access System.

BD Prevue™ II Peripheral Vascular Access System EMC Tables

Guidance and Manufacturer's Declaration - Emissions		
The BD Prevue™ II Peripheral Vascular Access System is intended for use in the electromagnetic environment specified below. The customer or user of the BD Prevue™ II Peripheral Vascular Access System should ensure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment – Guidance**
RF Emissions CISPR 11 / EN55011	Group 1	The BD Prevue™ II Peripheral Vascular Access System 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.
RF Emissions CISPR 11 / EN55011	Class A	The BD Prevue™ II Peripheral Vascular Access System 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.
Harmonics IEC 61000-3-2	Class A	
Flicker IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration – Immunity			
The BD Prevue™ II Peripheral Vascular Access System is intended for use in the electromagnetic environment specified below. The customer or user of the BD Prevue™ II Peripheral Vascular Access System should ensure that it is used in such an environment.			
Immunity Test	**EN/IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
ESD EN/IEC 61000-4-2	±6kV Contact ±8kV Air	±6kV Contact ±8kV Air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the relative humidity should be at least 30%.
EFT EN/IEC 61000-4-4	±2kV Mains ±1kV Input/Output Lines	±2kV Mains ±1kV Input/Output Lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN/IEC 61000-4-5	±1kV Differential ±2kV Common	±1kV Differential ±2kV Common	Mains power quality should be that of a typical commercial or hospital environment.

Guidance and Manufacturer's Declaration – Immunity			
The BD Prevue™ II Peripheral Vascular Access System is intended for use in the electromagnetic environment specified below. The customer or user of the BD Prevue™ II Peripheral Vascular Access System should ensure that it is used in such an environment.			
Immunity Test	**EN/IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Voltage Dips/Dropout EN/IEC 61000-4-11	>95% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25 Cycles >95% Dip for 5 Seconds	>95% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25 Cycles >95% Dip for 5 Seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the BD Prevue™ II Peripheral Vascular Access System requires continued operation during power mains interruptions, it is recommended that the BD Prevue™ II Peripheral Vascular Access System be powered from an uninterruptible power supply or battery.
Power Frequency 50/60 Hz Magnetic Field EN/IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

Guidance and Manufacturer's Declaration – Emissions			
The BD Prevue™ II Peripheral Vascular Access System is intended for use in the electromagnetic environment specified below. The customer or user of the BD Prevue™ II Peripheral Vascular Access System should ensure that it is used in such an environment.			
Immunity Test	**EN/IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Conducted RF EN/IEC 61000-4-6 Radiated RF EN/IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile communications equipment should be separated from the BD Prevue™ II Peripheral Vascular Access System by no less than the distances calculated/listed below: D = 1.2 (√ P) D = 1.2 (√ P) 80 to 800 MHz D = 2.3 (√ P) 800 MHz to 2.5 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.

Recommended Separation Distances between portable and mobile RF Communications equipment and the BD Prevue™ II Peripheral Vascular Access System			
The BD Prevue™ II Peripheral Vascular Access System is intended for use in the electromagnetic environment in which radiated disturbances are controlled. The customer or user of the BD Prevue™ II Peripheral Vascular Access System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment and the BD Prevue™ II Peripheral Vascular Access System as recommended below, according to the maximum output power of the communications equipment.			
Max Output Power (Watts)	**Separation (m) 150 kHz to 80 MHz D = 1.2 (√ P)**	**Separation (m) 80 to 800 MHz D = 1.2 (√ P)**	**Separation (m) 800 MHz to 2.5 GHz D =2.3 (√ P)**
0.01	.1166	.1166	.2333
0.1	.3689	.3689	.7378
1	1.1666	1.1666	2.3333
10	3.6893	3.6893	7.3786
100	11.6666	11.6666	23.3333

Essential Performance
The BD Prevue™ II Peripheral Vascular Access System complies with Essential Performance Requirements specified in IEC 60601-1-2 and IEC 60601-2-37. The BD Prevue™ II Peripheral Vascular Access System is free from the following:
- Noise on a waveform or artifacts or distortion in an image or error of a displayed numerical value which cannot be attributed to a physiological effect and which may alter the diagnosis.
- The display of incorrect safety-related indications.
- The production of unintended or excessive ultrasound output.
- The production of unintended or excessive Transducer Assembly surface temperature.
- Deviations from reported system accuracy.
- Display from inaccurate Cue™ Needle Tracking System information that could negatively affect the procedure.

24. TECHNICAL SPECIFICATIONS

Operating and Storage Conditions	
Operating Temperature	41° F to 95° F (5°C to 35°C)
Storage Temperature	0° F to 104° F (-18°C to 40°C)
Operating Humidity	≤ 90% Relative Humidity (non-condensing)
Storage Humidity	≤ 90% Relative Humidity (non-condensing)

System Specifications	
Dimensions	226 x 197.5 x 95 mm
Weight	4.0 lb (1.8 kg)
Power Sources	A/C adapter, Internal Battery Pack
Power Consumption	65 Watts
IEC 60601-1	Class II, Type BF Applied Part, Continuous Operation, Internally Powered Equipment, Not Category AP or APG Equipment, IPX1.

System Battery Specifications	
Battery Chemistry	Lithium Ion
Battery Capacity (Full Charge):	3250mAh
Nominal Battery Output Voltage:	10.8VDC
Battery Output Current (Max):	3.0A
System Run Time on Full Charge	Up to 2 Hours
Charge Time (Full)	3 Hours

System AC Adapter Specifications	
Input voltage	100-240 VAC, 50/60 Hz
Input Current (Max)	1.8A
Output Voltage	19V
Output Current (Max)	3.43A

Probe Specifications	
Frequency	7.5–13 MHz
Elevation Focus	20mm
Maximum Scan Depth	2.5cm
Scan Width	20mm

Vessel Evaluation Error		
Measurement	**Error**	**Range**
Diameter	< 10%	0–20mm
Vessel Occupancy	< 10%	0–100%
Remaining Catheter Length	< 10%	0–100%

Cue™ Needle Tracking System Accuracy	
Needle tracking accuracy is within the Intersection Window* *Results have 95% confidence with 99.4% reliability from bench top testing in a controlled environment. Remaining Catheter Length and Insertion Angle error is <10%.	
Caution:	Improper technique and environmental conditions may introduce variation in accuracy.

25. BD Prevue™ II Peripheral Vascular Access System WIRELESS TECHNOLOGIES (if enabled)

The BD Prevue™ II Peripheral Vascular Access System incorporates a standard IEEE 802.11 b/g/n transceiver to provide a wireless Ethernet connection to DICOM servers and network PC's. This connection can be used for archiving data. Bluetooth™ capabilities are also included for wireless pairing to approved accessories. The Cue™ Activator contains an RFID reader.

RF and Wireless Technology Summary			
Function	Wireless Ethernet	Bluetooth™	RFID
Technology	802.11 ac/a/b/g/n	Bluetooth™ V5.0, V4.2, V4.1, V4.0 LE, V3.0+HS, V2.1+EDR, compatible with versions 1.1, 1.2 and 2.0.	ISO 14443
Transmit/Receive	Transmit/Receive	Transmit/Receive	Transmit/Receive
Frequency	ISM frequency Band (2.4/5 GHz) 802.11 a/ac 5.15-5.85 GHz 802.11 b/g 2.412-2.4835 GHz	2.402 - 2.480 GHz	13.56 MHz ± 7kHz
Modulation	802.11ac: 256QAM, 64QAM, 16QAM, QPSK, BPSK 802.11a: 64QAM, 16QAM, QPSK, BPSK 802.11b: CCK, DQPSK, DBPSK 802.11g: 64QAM, 16QAM, QPSK, BPSK 802.11n: BPSK, QPSK, 16QAM, 64QAM	GFSK, π/4-DQPSK and 8-DPSK	ASK modulation with a modified Miller encoding
Operating Range (meters)	<38	<10	4.5cm
Bandwidth	802.11 a/ac 5 GHz ISM Band 5.15-5.85 GHz 802.11 b/g	2.402 - 2.480 GHz	13.56 MHz ± 7kHz
Operating Range (meters)	<38	<10	4.5cm

Transmit Output Power

BT	Bluetooth: 4 dBm	
	BLE: -3 dBm	
WIFI 2.4GHz	802.11b/g:	Chain 1(Main): 18 dBm Chain 0(Aux): 18 dBm
	802.11n20/ac20/n40/ac40:	MIMO: 13 dBm
WIFI 5.2GHz	802.11a:	Chain 1(Main): 15.5 dBm Chain 0(Aux): 15 dBm
	802.11n20/ac20:	MIMO: 13 dBm
	802.11n40/ac40:	MIMO: 15.5 dBm
	802.11ac80:	MIMO: 16 dBm
WIFI 5.3GHz	802.11a:	Chain 1(Main): 17 dBm Chain 0(Aux): 16 dBm
	802.11n20/ac20:	MIMO: 13 dBm
	802.11n40/ac40:	MIMO: 13.3 dBm
	802.11ac80:	MIMO: 16 dBm
WIFI 5.5GHz	802.11a:	Chain 1(Main): 17 dBm Chain 0(Aux): 17 dBm
	802.11n20/ac20:	MIMO: 13 dBm
	802.11n40/ac40:	MIMO: 13.3 dBm
	802.11ac80:	MIMO: 16.5 dBm
WIFI 5.8GHz	802.11a:	Chain 1(Main): 17 dBm Chain 0(Aux): 17 dBm
	802.11n20/ac20:	MIMO: 13.5 dBm
	802.11n40/ac40:	13.3 dBm
	802.11ac80:	MIMO: 16 dBm

Quality of Service (QoS)

Since the BD Prevue™ II Peripheral Vascular Access System uses WLAN to transmit patient data to a DICOM system and does not relate to real-time scanning operations, these communications are on a best-efforts basis, where other data on the network may be given higher priority if there is a bandwidth conflict.

Quality of Service (QoS) – Wireless Ethernet

The wireless Ethernet on the BD Prevue™ II Peripheral Vascular Access System operates as a best-efforts device, as it does not directly involve or interfere with active scanning. As such, it does not require a formal QoS WLAN. If used on a QoS network, its transmitted data may receive a lower priority than video or voice that is also transmitted on the same network. The following table provides recommended metrics to achieve a high level of performance from the BD Prevue™ II Peripheral Vascular Access System wireless configuration.

Parameter	Specification	Comment
IEEE 802.11 Level	IEEE 802.11 ac/a/b/g/n	
Wireless Signal Rate	54 Mbps (IEEE 802.11a) 11 Mbps (IEEE 802.11b) 54 Mbps (IEEE 802.11g) MCS 15 (IEEE 802.11n) MCS 9 (IEEE 802.11ac)	Stated maximum for each standard. Data transfer will be lower and is directly affected by separation distance between the console and the wireless access point, network conditions, building layout, etc.
Distance to Access Point	< 38 meters	Though the stated maximum may be 38 meters, it is not usually achievable in hospital settings.
Security type*	WPA2 WEP/WPA-PSK/WPA2-PSK	WPA2 provides better security than former methods.
Encryption Types	AES DHCP DHCP basic DHCP renewal FreeRadius Ping Test PSK PSK-AES PSK-TKIP TKIP TLS TLS WPA2 TTLS WPA2 WPA WPA2 WPA2-PEAP WPA2-PEAP (Certificate) WPA2-PEAP-EAPMSCHAPV2 WPA2-PEAP-EAPMSCHAPV2 (Certificate) WPA2-PEAP-EAPTLS WPA2-PEAPv0 (EAPTLS) (Certificate) WPA2-PEAPv0 (MS-CHAPv2) (Certificate) WPA2-PSK ASCII WPA2-PSK hex key WPA2-TTLS WPA2-TTLS-CHAP WPA2-TTLS-CMSCHAP	-

Parameter	Specification	Comment
Encryption Types (Cont.)	WPA2-TTLS-EAPMSCHAPV2 WPA2-TTLS-EAPTLS WPA2-TTLS-MSCHAP WPA2-TTLS-MSCHAPV2 WPA2-TTLS-PAP WPA-MSCHAPV2 WPA-PEAP WPA-PEAP (Certificate) WPA-PEAP-EAPMSCHAPV2 WPA-PEAP-EAPMSCHAPV2 (Certificate) WPA-PEAP-EAPTLS WPA-PEAP-EAPTLS (Certificate) WPA-PEAPv0 (EAPTLS) WPA-PEAPv0 (EAPTLS) (Certificate) WPA-PEAPv0 (MS-CHAPv2) WPA-PEAPv0 (MS-CHAPv2) (Certificate) WPA-PSK ASCII WPA-PSK hex key WPA-TTLS WPA-TTLS-CHAP WPA-TTLS-CMSCHAP WPA-TTLS-EAPMSCHAPV2 WPA-TTLS-EAPTLS WPA-TTLS-MSCHAP WPA-TTLS-MSCHAPV2 WPA-TTLS-PAP	

Quality of Service (QoS) – Bluetooth

The Bluetooth™ functionality for the BD Prevue™ II Peripheral Vascular Access System operates on a best efforts basis, since latency in data transmission will not affect critical ultrasound imaging. As these connections are point to point, they do not require or rely on a formal QoS WLAN. The link capacity between devices is designed to provide the necessary bandwidth for proper data transmission, without competition for resources between devices.

To ensure a proper connection, keep the separation distance between Bluetooth™ devices and the BD Prevue™ II Peripheral Vascular Access System console as short as possible. The maximum operating distance for Bluetooth™ technology is < 10 meters. Bluetooth™ devices generally perform better at shorter distances however, on the order of ~3 meters, with a direct line of sight preferable.

IEEE 802.11b/g/n Wireless Security

To guard against unauthorized access to network resources, ensure that the BD Prevue™ II Peripheral Vascular Access System is connected to a secure network. Use of WPA2 security is preferred over older protocols, such as WEP, as it provides a more secure network. Contact your local IT administrator for more information on which networks can be used and what settings should be used.

Bluetooth™ Security

The BD Prevue™ II Peripheral Vascular Access System employs Bluetooth™ connectivity for use with approved accessories. Bluetooth™ technology does not provide rigorous security measures to prevent unauthorized access, as wifi does. As such, appropriate measures should be taken to ensure that access is limited to approved accessories to be used with the system.

Wireless coexistence issues and mitigations:

There is a potential for wireless conflicts, as 802.11b/g/n and Bluetooth™ both operate on the 2.4 GHz frequency band, as well as interference from other RF devices. If you encounter problems connecting to a network or Bluetooth™ device, remove or separate possible interfering sources as much as possible. Objects and people obstructing line of sight connections between wireless devices can also cause interference. Maintain a clear path between the BD Prevue™ II Peripheral Vascular Access System and paired accessories as much as possible to ensure highest performance.

Manufacturer:
Bard Access Systems, Inc.
605 North 5600 West
Salt Lake City, UT 84116
U.S.A.

Customer Service: 1-800-545-0890
Technical/Clinical Support: 1-800-443-3385
Fax: 1-801-522-4948
www.bardaccess.com

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