SITE ≈ RITE Prevue+™

ULTRASOUND SYSTEM

BARD

ACCESS SYSTEMS

TABLE OF CONTENTS

1 DEVICE DESCRIPTION

The Site~Rite Prevue +™ Ultrasound System is a portable device that features real-time 2D ultrasound imaging. Additional features include compact size and a simple user interface. The system may incorporate various accessories, including an upright stand, A/C adapter, needle guide, etc. The system includes USB support for storage devices with no external power connections (e.g., USB flash drive).

This manual provides instructions for the proper use of the Site~Rite Prevue +™ Ultrasound System.
For additional information or product training, contact your local Bard Access Systems sales representative.

1.1 Indications For Use

The Site~Rite Prevue +™ Ultrasound System is intended to provide ultrasound imaging of the human body. Specific clinical applications include:

- Adult Cephalic
- Neonatal Cephalic
- Pediatric
- Peripheral Vessel

1.2 Site~Rite Prevue +™ Ultrasound System and Authorized Accessories

Site~Rite Prevue +™ Ultrasound System and Authorized Accessories include:

- Site~Rite Prevue™ Ultrasound System A/C Adapter
- Site~Rite Prevue™ Ultrasound System Line Cord
- USB storage device with no external power connection (e.g., USB flash drive)
- Mounting accessories with a ¼"-20 Camera-mount interface
- Site~Rite Prevue™ Ultrasound System Storage Case
- Site~Rite Prevue™ Ultrasound System Probe Holder
- Site~Rite® Needle Guide Kits and Probe Sheaths
- Pinpoint™ Gel Cap with Guide
- Pinpoint™ Assessment Cap

Contact your Bard Access Systems Sales Representative or Customer Service at (800) 545-0890 to order.

1.3 Warnings, Precautions and Notes

WARNINGS

Warning: This product should only be operated by qualified medical personnel.
Warning: Only qualified personnel should remove the outer housing from the Site~Rite Prevue +™ Ultrasound System device. Hazardous voltages exist at several points within the system.
Warning: Do not operate the Site~Rite Prevue +™ Ultrasound System or the Site~Rite Prevue™ Ultrasound System A/C Adapter in the presence of flammable anesthetics or gases. Explosion may result.
Warning: Do not use for ophthalmic indications. Ophthalmic use may cause patient injury.

Warning: Misuse of the Site~Rite Prevue +™ Ultrasound System may result in damage to the equipment or personal injury.

Warning: Use only the Site~Rite Prevue™ Ultrasound System A/C Adapter to charge the Site~Rite Prevue +™ Ultrasound System. Use of any other device to charge the Site~Rite Prevue +™ Ultrasound System may damage the battery, may cause intermittent or unpredictable operation, may damage the system, may result in injury and will void all warranties.

Warning: If a probe is damaged in any way, discontinue use immediately. Damage to the system may occur.

Warning: Avoid subjecting the system to excessive mechanical shock. Damage to the system may occur.

Warning: Do not allow liquid to enter the system, A/C adapter or connectors. Damage to the system may occur.

Warning: Do not attempt to sterilize the Site~Rite Prevue +™ Ultrasound System. Damage to the system may occur.

Warning: Only qualified personnel should attempt to service this system. The Site~Rite Prevue +™ Ultrasound System contains static sensitive components and circuits. Failure to observe proper static control procedures may result in damage to the system.

Warning: The following actions void all warranties of the Site~Rite Prevue +™ Ultrasound System and may result in injury or system damage:

- Opening or servicing the system or the probe housing by anyone other than Bard Access Systems authorized service personnel.
- Removal of system labels by anyone other than Bard Access Systems authorized service personnel.
- Opening or servicing the A/C Adapter by anyone other than Bard Access Systems authorized service personnel.
- Connecting the Site~Rite Prevue +™ Ultrasound System to any power source other than the Site~Rite Prevue™ Ultrasound System A/C Adapter.
- Installation of unauthorized software on the Site~Rite Prevue +™ Ultrasound system.
- Connecting the Site~Rite Prevue +™ Ultrasound System to any unauthorized accessory. Refer to Section 1.2.

Warning: When using Site~Rite® Needle Guides on the Site~Rite Prevue +™ Ultrasound System Probe, use only sterile legally marketed plastic probe covers that are 1 mil (0.001 inch of 0.0254 mm) thick.

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

Warning: Mounting the Site~Rite Prevue +™ Ultrasound System to any unstable platform may cause the system and platform to tip, resulting in system damage or injury. Ensure the system and platform will remain stable.

Warning: Do not pull the device by the probe cable as this may cause the mounting platform to tip, resulting in system damage or patient injury.

Warning: Avoid patient contact with the console. The console may get warm when it is on for an extended period of time. This may cause patient injury.

Warning: The Pinpoint™ Gel Cap contains potassium metabisulfite and carrageenan which may cause allergic reactions in certain patient populations. Patients with known sensitivity to these ingredients should avoid contact with the gel.

PRECAUTIONS

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 Site~Rite Prevue +™ Ultrasound System acoustic output parameters fall well below all 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 principle of ALARA.

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

Caution: Do not twist or bend the probe cable in excess of that required during normal use of the probe. Excessive twisting or bending of the cable may cause failure, intermittent or unpredictable operation.

Caution: Do not soak the system in any liquid including disinfectants. Doing so may damage the system.

Caution: Only apply commercially available ultrasonic couplant, which has been specifically formulated for use in medical applications, to the acoustic window (or face) of the probe.

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

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

Caution: Do not subject the system to excessive vibration. Vibration may dislodge sensitive components and cause intermittent or unpredictable operation.

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: During use, the A/C wall plug needs to be easily accessible. In case of emergency remove the power cord as soon as possible.

Caution: Get in a comfortable position to avoid unnecessary strain when using the device.

Caution: Attach the power source in such a way as to prevent damage. Improper installation may damage power cords.

Caution: Inspect the probe prior to each use. If damage to the cable or transducer face is noted, do not use the probe. Damage to the system may occur.

Caution: Use only Bard Access Systems cleaning and disinfection procedures and recommended disinfectants. Failure to do so may damage the device.

Caution: Do not use the probe with high frequency surgical equipment. Doing so may damage the device.

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. Bard Access Systems distributes sterile probe covers and needle guide kits that are not made with natural rubber latex.

Caution: Always snap the needle guides on to the probe hook. Do not slide on to the needle guide hook, as the sterile sheath may tear.

Caution: IV Catheter Length in Vessel information should only be used in conjunction with a Pinpoint™ Needle Guide. Length in Vessel information is not valid with "free hand" insertion.

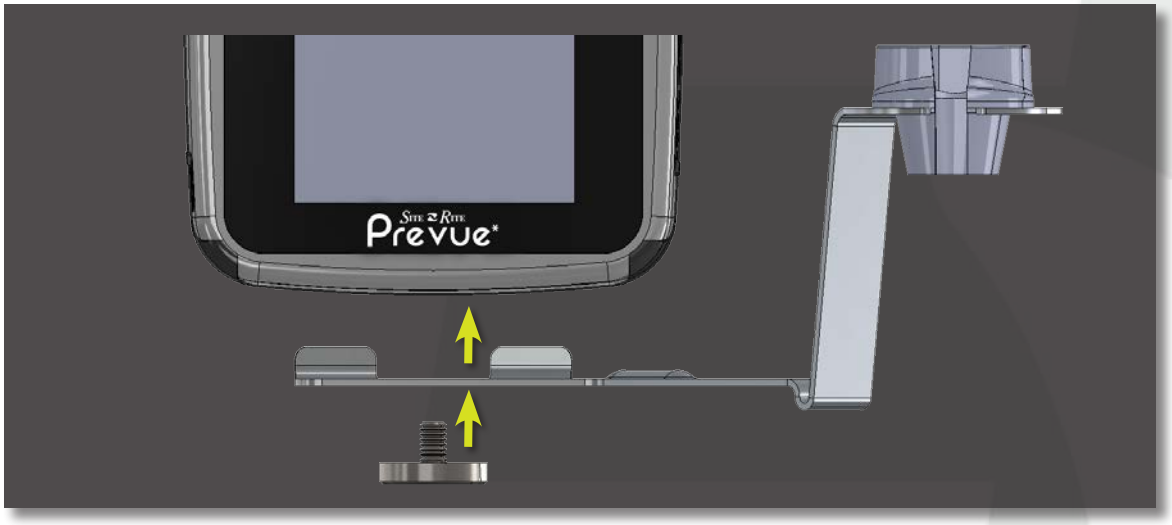
Caution: This system, with its applicable accessories, is intended for use by healthcare professionals only. If used in a domestic environment, this system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures such as re-orienting or relocating the Site~Rite Prevue +™ Ultrasound System or shielding the location.

Caution: The Site~Rite Prevue +™ Ultrasound System is not intended for fetal use.

Note: During normal use, the portable Site~Rite Prevue +™ Ultrasound System should be positioned next to the patient using the provided mounting base, optional clamp mount, or positioned securely on a stable structure to allow for use of both hands throughout the procedure.

2 ASSEMBLING THE SITE~RITE Prevue +™ ULTRASOUND SYSTEM

2.1 Attaching the Probe Holder



2.2 Attaching the Power Source and Charging the Battery

Warning: Use only the Site~Rite Prevue™ Ultrasound System A/C Adapter to charge the Site~Rite Prevue +™ Ultrasound System. Use of any other device to charge the Site~Rite Prevue +™ Ultrasound System may damage the battery, may cause intermittent or unpredictable operation, may damage the system, may result in injury and will void all warranties.

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

Caution: Attach the power source in such a way as to prevent damage. Improper installation may damage power cords.

2.3 Powering On and Off the Site~Rite Prevue +™ Ultrasound System

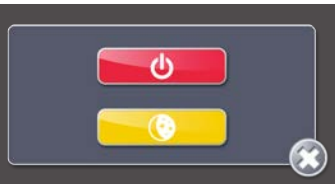
To power on the Site~Rite Prevue +™ Ultrasound System press and hold the Power Button located on the right side of the system for three seconds then release it.

The Power Indicator located on the upper right side of the screen will remain illuminated when powered and will blink when in Standby Mode.

To display the Power Control Window press and release the Power Button while the system is powered on.

The system can be Shut Down or placed in Standby Mode from the Power Control Window

Power Control Window.



To exit without changing the system's power state, select .

The battery indicator located in the upper right side of the screen has the following functionality:

SYSTEM STATUS		BATTERY INDICATOR
System On	AC Mode	Off
	Battery Mode	Off
	Low Battery Mode	Red, blinking
System Off	AC Mode	Green, static when fully charged Green, blinking when charging
	Battery Mode	Off
	Low Battery Mode	Off
System Standby	AC Mode	Green, static when fully charged Green, blinking when charging
	Battery Mode	Off
	Low Battery Mode	Red, blinking

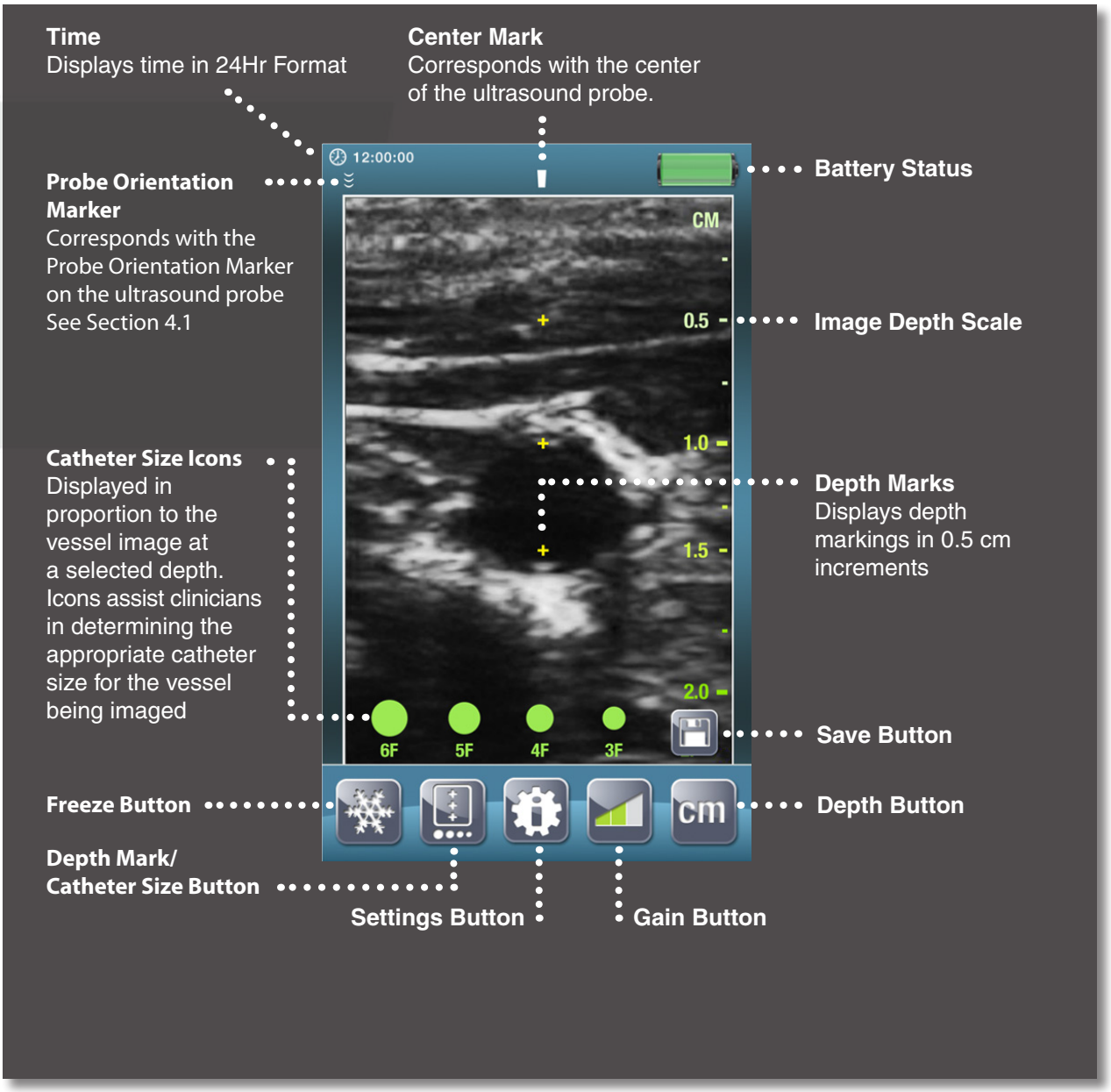
2.4 Probe Storage

Store the probe in the probe holder or the probe pocket when not in use.

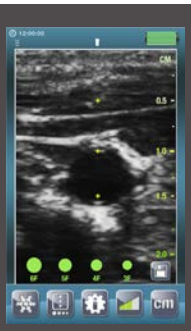
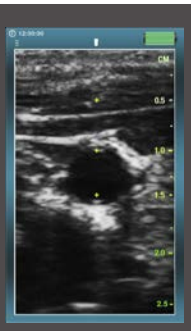
Hold probe body for insertion/removal into the probe pocket.
Do not pull the probe cable.

3 GETTING STARTED

3.1 Display



TITLE AND DESCRIPTION	FUNCTION ICON STATUS
Gain Adjusts the overall image gain to high, medium, and low.	 Low Medium High
Settings Button Opens the Settings Window, see Section 8.	
Save Saves image to USB drive (if attached).	 Save Icon will appear when a USB storage device is attached Saving File Saving Error
Depth Button Adjusts the display image depth.	
Freeze Button Freezes the image	Freeze Mode  (Blinking) Imaging Mode 
Depth Mark/Catheter Size Icons Button Toggles between depth markers, catheter size icons, and off.	

TITLE AND DESCRIPTION	FUNCTION ICON STATUS
Center Mark Toggles between gel cap center mark/ indicator and bar center mark. Note: The presence of a gel cap determines which face is the center front of the probe.	 Center mark (no gel cap detected) OR  Center mark (gel cap present)
Orientation Mark Toggles between gel cap orientation and no gel cap orientation. See section 4.1, probe orientation Note: the presence of a gel cap determines the orientation of the probe.	 no gel cap detected OR  gel cap present
Full Screen Mode Touch the imaging area to hide the control buttons for full screen imaging. Touch the imaging area again to display the control buttons.	 OR 

BATTERY STATUS

81% to 100% battery life.	
61% to 80% battery life.	
41% to 60% battery life.	
21% to 40% battery life.	
A blinking red bar indicates 0% - 20% battery life remains. Connect the system to A/C for operation and battery recharge.	
Battery Error – see Section 10 Troubleshooting and Errors.	
A/C status icon – indicates A/C power is connected and the system is charging.	

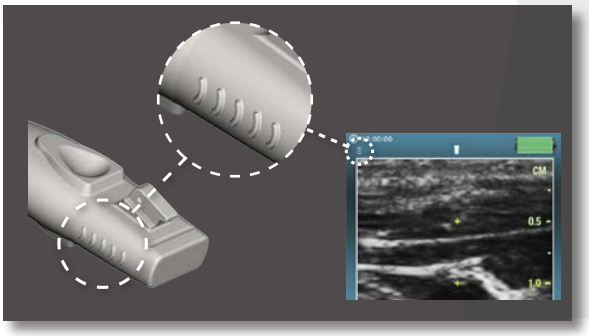

12:00:00
cm
0.5
1
1.5
2
2.5
cm
SiteRite
Prevue*

4 USING THE Site~Rite Prevue +™ ULTRASOUND SYSTEM PROBE

4.1 Probe Orientation

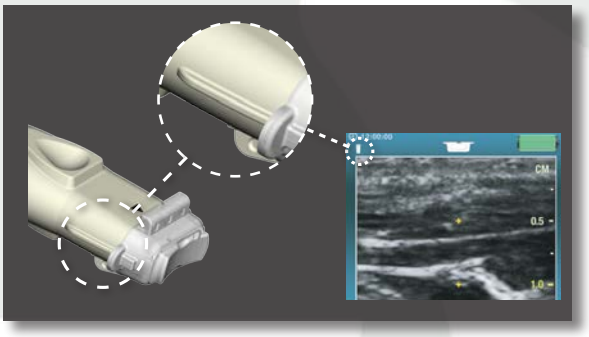
The probe orientation changes when a gel cap is present. The Ultrasound image will adjust so that the orientation mark on the display corresponds to the appropriate orientation mark on the probe.

WITHOUT GEL CAP



OR

WITH GEL CAP



4.2 Draping the Probe for Sterile Use

When using the Site~Rite Prevue +™ Ultrasound 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.

Warning: When using Site~Rite® Needle Guides on the Site~Rite Prevue +™ Ultrasound System Probe, use only sterile, legally marketed plastic probe covers that are 1 mil (0.001 inch or 0.0254 mm) thick.

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. Bard Access Systems distributes sterile probe covers and needle guide kits that are not made with natural rubber latex.

To purchase sterile plastic probe covers, contact Bard Access Systems Customer Service at:
Customer Service: (800) 545-0890
www.bardaccess.com

To drape the probe for sterile use:
1. Place the probe in the side arm probe holder.
2. Apply a layer of non-sterile ultrasound coupling gel on the acoustic window of the probe head.
3. Make sure that the probe cover is fully rolled up.
4. Place the probe cover over the probe head, being careful not to wipe off the coupling gel.
5. Cover the probe and cable with the probe cover.
6. Smooth the probe cover over the acoustic window of the probe head to remove any air bubbles or folds in the sheath.
7. Use the latex free poly-bands to hold the probe cover in place.
8. Apply a layer of sterile coupling gel to the covered acoustic window.

5 IMAGE SETTINGS

5.1 Image Depth 

The depth button toggles between 1.0cm, 2.5cm, and 4.0cm depths. Adjusting the depth also adjusts the focus of the ultrasound. For optimal viewing, adjust the depth so that the structure of interest is centered in the image.

IMAGE DEPTH	FOCAL DEPTH
1.0 cm	0.5 cm
2.5 cm	1.25 cm
4.0 cm	2.00 cm

5.2 Image Gain 

The image gain can be adjusted to amplify the signal which brightens the image. Increasing gain will brighten the target structure along with non-targeted structures.

Press the gain button  to select the gain that provides the best ultrasound image.

5.3 Image Filter 

Press the image filter button 

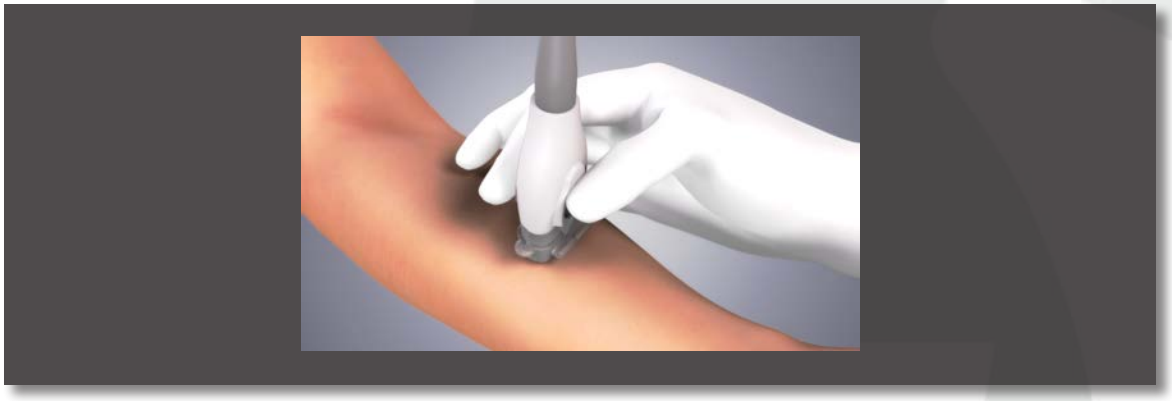
to toggle between a smooth and sharp image. Adjusting the image filter affects the entire image. See Section 8.1 Settings.

6 USING SITE~RITE Prevue +™ ULTRASOUND SYSTEM FOR VASCULAR ACCESS

Note: Always prepare the patient access site and the ultrasound system per appropriate institutional protocol for the procedure being performed. See Section 4.2, Draping the Probe for Sterile Use.

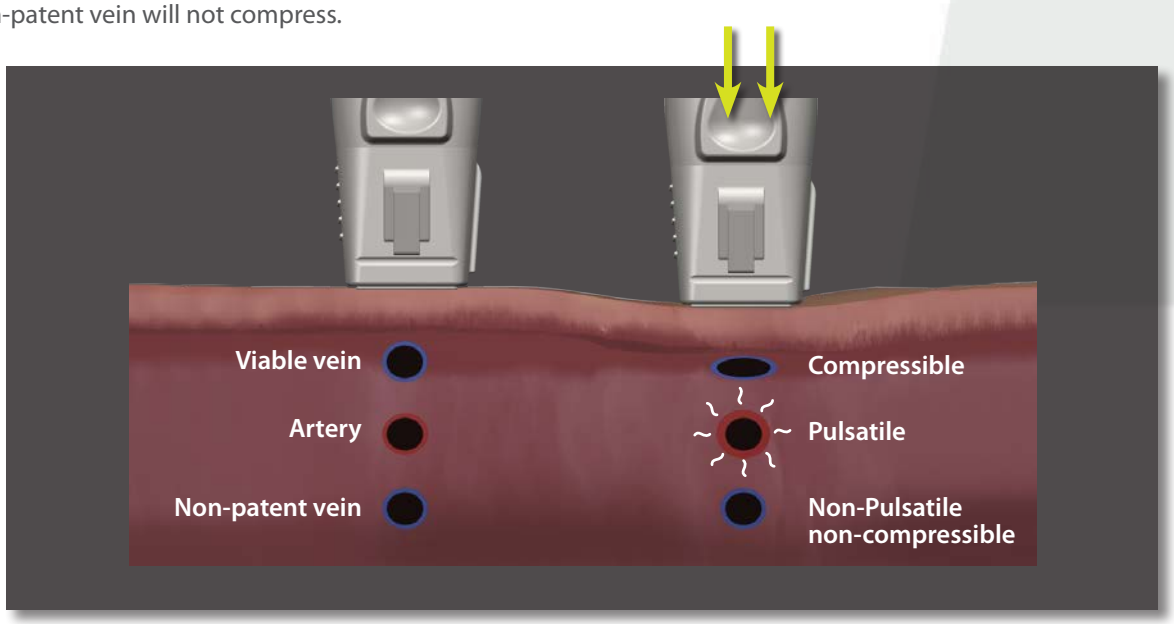
6.1 Scanning Technique

Very lightly scan patient to reduce vessel compression by holding probe with thumb and index finger (C Grip).



6.2 Vessel Identification

Veins can be distinguished from an artery by lightly pressing down on the vessel with the probe. With a viable vein the vessel will compress, with an artery the vessel will usually pulsate (unless low blood pressure), and a non-patent vein will not compress.

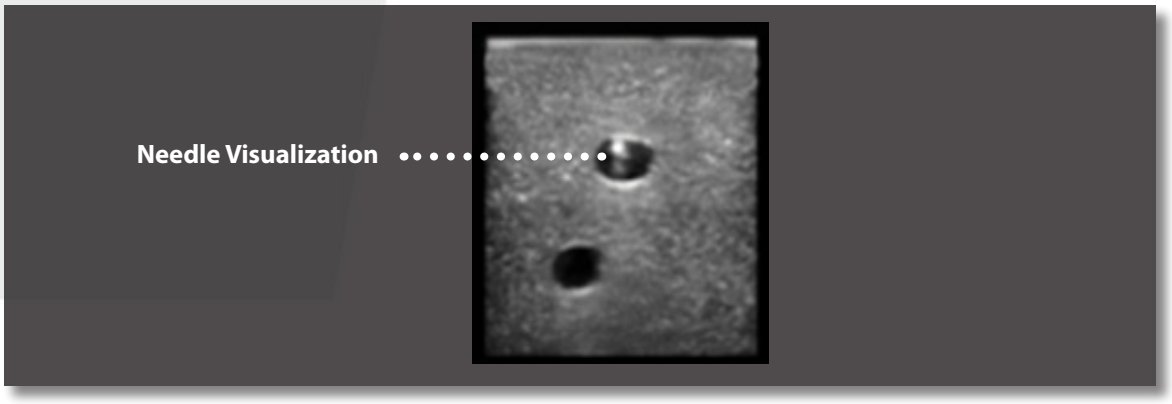


6.3 Vessel Access

Identify vessel access by the anterior vessel wall indenting. Once the puncture occurs the vessel will return to normal shape. Additional indications of vessel access may include needle visualization on the ultrasound image and blood flash.

6.4 Needle Visualization

The needle may be visualized on the ultrasound image once it intersects the ultrasound beam.



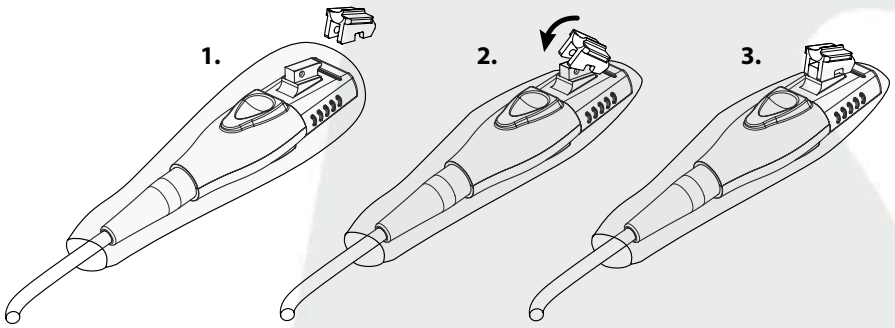
Caution: The adverse biological effects of ultrasound on tissue appear to be threshold effects. When tissue is repeatedly exposed to ultrasound, with intervals in between, there will likely be no cumulative biological effect. If however a certain threshold has been passed, biological effects may occur. While the Site~Rite Prevue +™ Ultrasound System acoustic output parameters fall well below all 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 principle of ALARA.

6.5 Using Site~Rite® Needle Guides and Probe Sheaths

For instructions on proper use of Site~Rite® Needle Guides, refer to Site~Rite® Needle Guide Kits and Ultrasound Probe Cover Kits Instructions for Use.

Warning: When using Site~Rite® Needle Guides on the Site~Rite Prevue +™ Ultrasound System Probe, use only sterile, legally marketed plastic probe covers that are 1 mil (0.001 inch or 0.0254 mm) thick.

Caution: Always snap the needle guides on to the probe hook. Do not slide the needle guide on to the needle guide hook, as the sterile sheath may tear.



To purchase Site~Rite® Needle Guides and sterile Plastic Probe Covers, contact Bard Access Systems

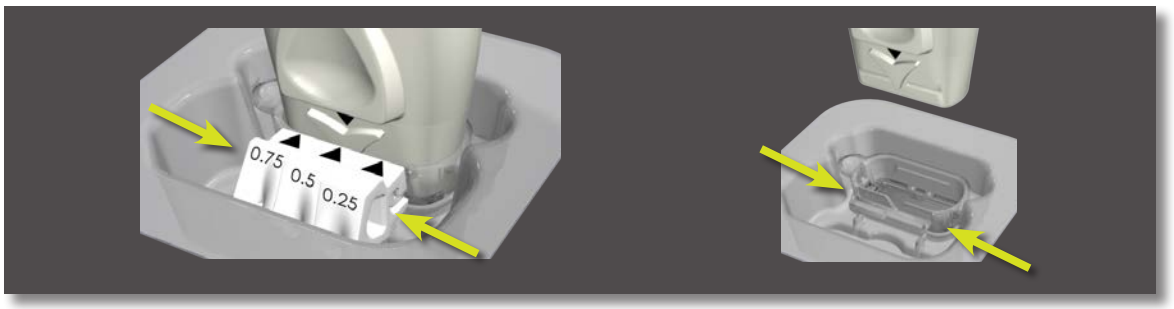
Customer Service: (800) 545-0890 www.bardaccess.com

6.6 Using the Pinpoint™ Accessories

For proper use of Pinpoint™ Accessories, refer to the Pinpoint™ Instructions for Use (IFU).

Warning: The Pinpoint™ Gel Cap contains potassium metabisulfite and carrageenan which may cause allergic reactions in certain patient polulations. Patients with known sensitivity to these ingredients should avoid contact with the gel.

Note: The Site~Rite® Needle Guide hook prohibits attaching the probe to the Pinpoint™ Gel Cap in the provided tray per the Pinpoint™ Gel Cap IFU. The Gel Cap needs to be attached to the probe outside of the tray. To allow for aseptic attachment, remove the cap via the slide or Needle Guide as shown below, then attach to the probe without touching the Gel face or the Needle Guide channels.



7 IV MODE

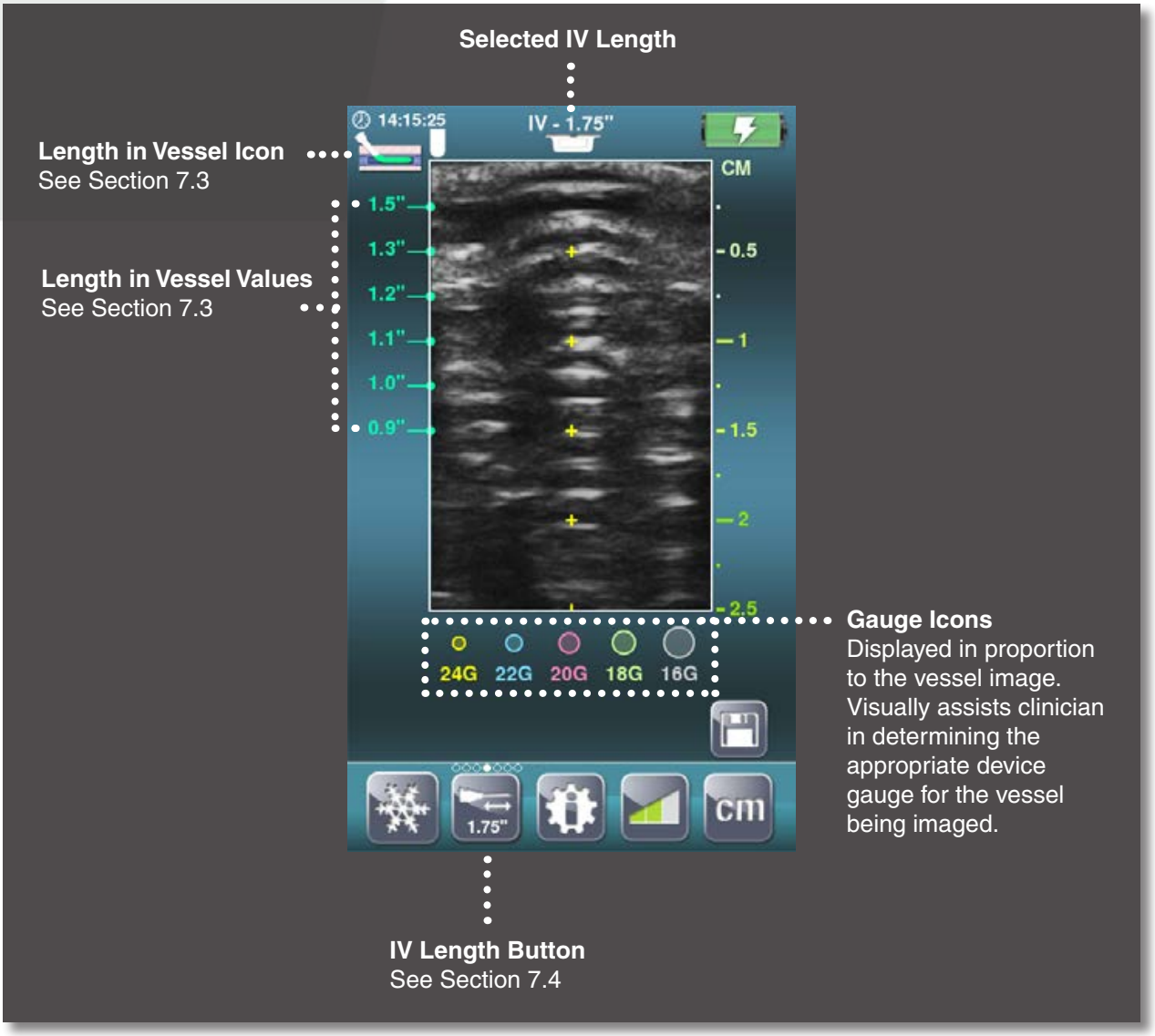
To enable IV mode, select  to open the settings window. Enable IV mode 

. See Section 8.

7.1 IV Mode Display

The IV Mode is designed to assist clinicians in selecting the appropriate IV Catheter length and gauge for a target vessel.

Caution: IV Catheter Length in Vessel information should only be used in conjunction with a Pinpoint™ Needle Guide. Length in Vessel information is not valid with "freehand" insertion.



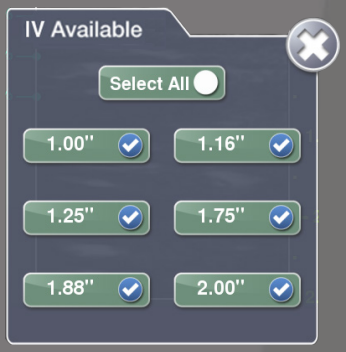
7.2 How to use IV Mode

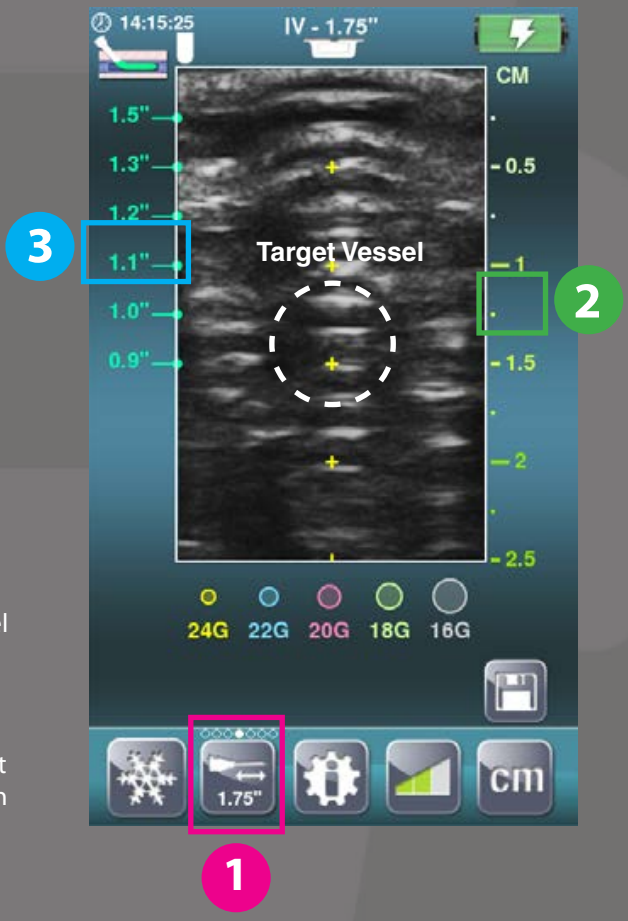
1. Press and hold the Length button 

.

Select available IV Lengths.

Press  to set values.





2. Determine vessel depth. Set the appropriate Pinpoint™ Gel Cap with Guide to this depth.

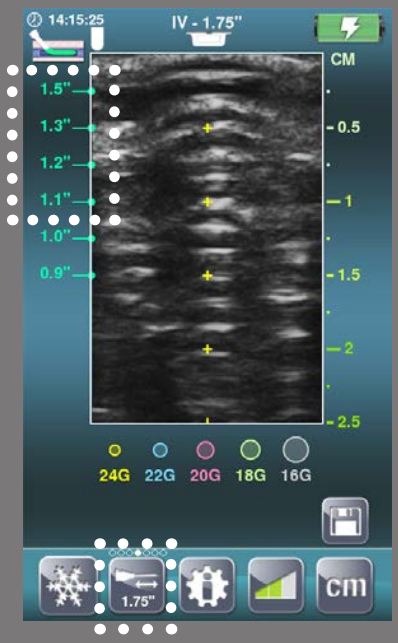
3. Note the estimated length of catheter in vessel at final placement.

Toggle the Length button 

to see the **Length in Vessel** information changes for different catheter sizes. Clinicians can use this information in selecting an appropriate catheter size and vessel.

7.3 Estimated Length in Vessel Values

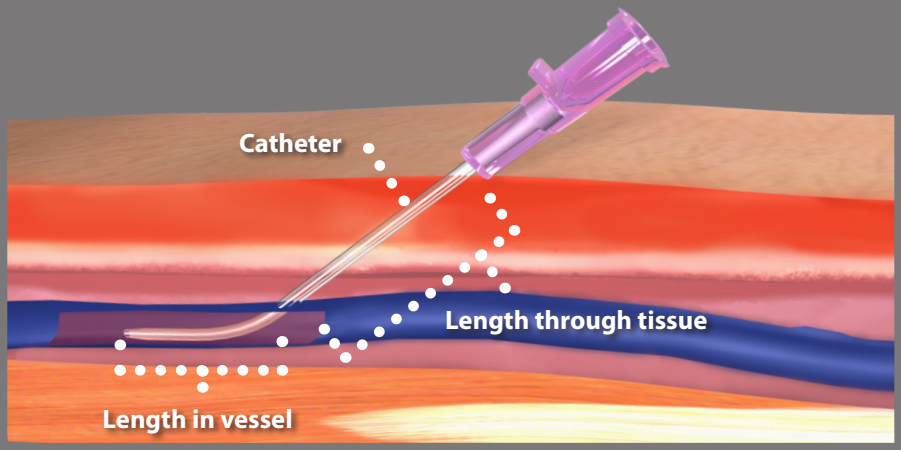
For each selected catheter length, the estimated amount of catheter that will remain in the target vessel at final placement is shown at the left of the ultrasound image. The estimated length in vessel values can be displayed in length or percentage of the selected catheter (see Section 8.2)

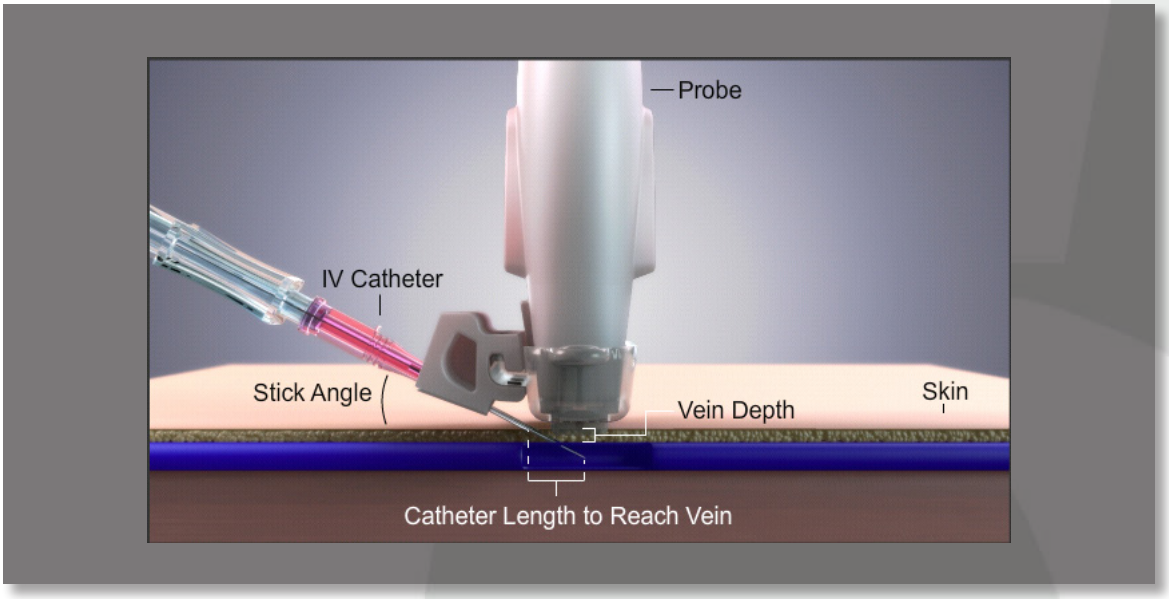


The estimated length will change depending on what catheter length selected.

The image below explains the length in vessel values further. Part of the catheter travels through the tissue to get to the vessel and the rest of the catheter length will remain in the vessel at final placement.

Caution: IV Catheter Length in Vessel information should only be used in conjunction with a Pinpoint™ Needle Guide. Length in Vessel information is not valid with "freehand" insertion.





Note: The length in vessel values are an approximate value. The actual length may vary based on tissue compression, probe angle, and gel height.

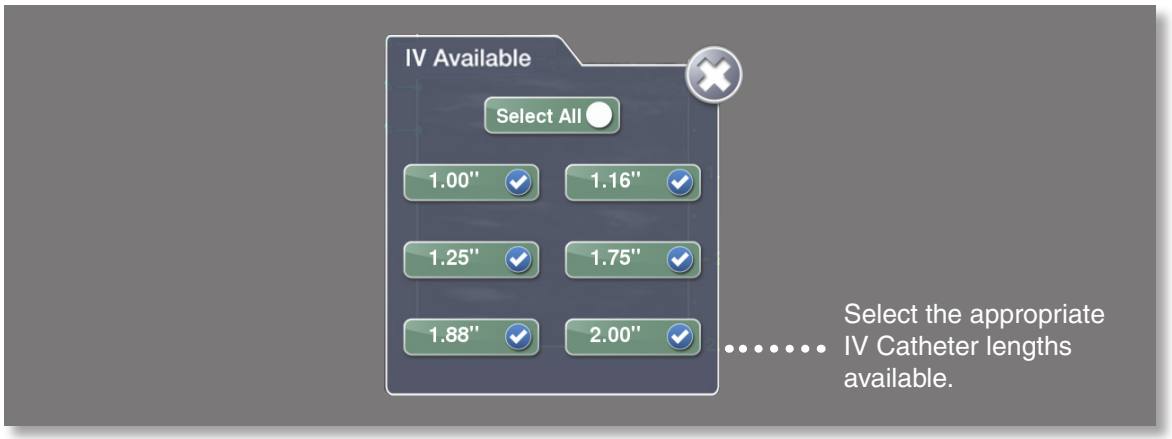
Note: Although a catheter is fully advanced, the entire catheter does not reside in the vessel. A portion of the catheter is left in the tissue and is required to reach the vessel.

Note: Ensure the IV Selected Length on the Site~Rite Prevue +™ matches the actual IV catheter length used during access, otherwise, the Length in Vessel values may be incorrect.

7.4 IV Catheter Length Button

Press and hold the IV Length Button for the IV Available screen to appear.

Select the IV Catheter lengths available and press the to set.



Once the lengths are set, toggle through the selected needle lengths by pressing the length button . This will assist in choosing the appropriate device length for the target vessel.

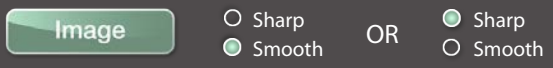
Note: Once the selected IV Catheter Lengths have been set, the system will retain the settings.

8 USING THE SETTINGS WINDOW

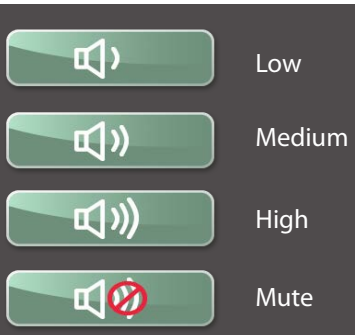
Select  to open the settings window.

8.1 System Settings

Image Button
Toggles the Image Filter between Smooth and Sharp

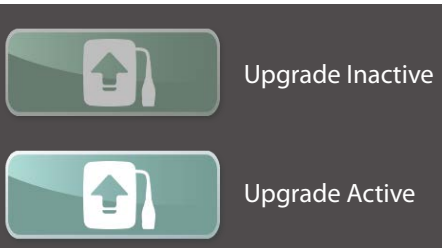


Volume Button
Press the Volume Button to toggle between low, medium, high and mute.



Date/Time Button
Press the Date/Time Button to set the system date and time.

Upgrade Button
The Upgrade Button is inactive unless a USB Storage Device with a software update for the machine is connected to a USB Port. See Section 8.3 regarding how to upgrade a Site~Rite Prevue +™ Ultrasound System.



French/mm Button
Toggles the catheter size icon units between French and mm.

IV Mode Button
Press to enable IV mode features. See Section 7 and 8.2.

Software Package Version Number Displays the current software package version number.	**Ver: 1.0.1**
System Serial Number Displays the System's Serial Number.	**S/N: DTUXXXXX**
Exit Button Saves any settings and exits the Settings window.	

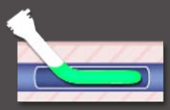
8.2 IV Mode Tab

Contains settings for IV Mode.

IV Available
Set the IV Lengths available.

Also see Section 7.4

Length in Vessel Display Button
Press to toggle the displayed estimated length in vessel values between % and Length. See Section 7.3



Gauge Unit Button
Press to toggle the displayed device gauge units between Gauge and millimeters.

Length Unit Button
Press to toggle the displayed device length units between inches and millimeters.

Exit Button
Saves any settings and exits the Settings window.

8.3 Upgrading the System

Contact your local Bard Access Systems representative for a USB drive with the latest version of Bard Access Systems applications.

1. Insert the USB drive that contains an upgrade into one of the USB ports on the side of the Site~Rite Prevue +™ Ultrasound System.

2. Select Upgrade in the System Settings.

Upgrade Button

3. Follow the onscreen prompts to complete the software upgrade.

Upgrade in Process

Upgrade Successful
After upgrade, restart system

Upgrade Failed
Retry the upgrade. If error persists, call customer service.

Note: Do not attempt to cancel the upgrade procedure, as this may cause the system to malfunction. If an error occurs during the upgrading procedure, reboot the system and repeat the upgrade procedure again. If the error persists, contact technical/clinical support at (800) 443-3385.

9 CLEANING AND DISINFECTION

9.1 Cleaning Procedures

Clean the Site~Rite Prevue +™ Ultrasound System between each procedure.

To clean the console, probe and A/C adapter:

1. Turn off the system.

2. Dampen a nonabrasive cloth with either warm water or isopropyl alcohol.

   For a list of additional disinfectants recommended for use on the Site~Rite Prevue +™ Ultrasound System and probe, contact Bard Access Systems for the "Site~Rite™ Ultrasound System Compatible Disinfectants" document. (800) 545-0890

3. Gently wipe the dampened cloth over the exterior surfaces that require cleaning.

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

Warning: Do not allow liquid to enter the system, A/C adapter, or connectors. Damage to the equipment may occur.
Warning: Do not attempt to sterilize the Site~Rite Prevue +™ Ultrasound System. Damage to the equipment may occur.

Caution: Use only Bard Access Systems cleaning and disinfection procedures and recommended disinfectants. Failure to do so may damage the device.

10 TROUBLESHOOTING & ERRORS

SYMPTOM	DESCRIPTION	SOLUTIONS
Error Code EC: 101 – 108 	Ultrasound Hardware Failure	Reboot the System. **Note:** If error persists, call Customer Service at 1-800-545-0890
Error Code EC: 201 	Software Failure	Call Customer Service at 1-800-545-0890
Error Code EC: 301 	System temperature too high	Shut down the system and allow to cool. **Note:** If error persists, call Customer Service at 1-800-545-0890
System plays a sound every minute 	Low Battery	Connect system to an A/C outlet for operation and battery recharge.
	Battery Error	Connect AC adapter for operation. Note: If error persists, Call Customer Service at 1-800-545-0890

SYMPTOM	DESCRIPTION	SOLUTIONS
Power Problem	System will not turn on or powers on but immediately turns off	1. Press and hold the power button for at least 3 seconds to power on. 2. Connect system to an A/C outlet for operation and battery recharge. **Note:** If error persists, call Customer Service at 1-800-545-0890
A/C adapter indicator does not change states 	Connection error	1. Shutdown the system 2. Unplug the A/C adapter and plug it back in 3. Turn the system on **Note:** If error persists, call Customer Service at 1-800-545-0890
	Can't save an image	The USB Storage device may be full or not an approved USB Storage Device. Replace the USB Storage Device. **Note:** If error persists, call Customer Service at 1-800-545-0890
Poor image		1. Refer to Image Settings, Section 5. 2. Lack of couplant. Apply ultrasound gel, or 3. Apply sterile saline to both surfaces of the Pinpoint Gel Cap. If error persists, call Customer Service at 1-800-545-0890
No control buttons	Can't see/access control buttons	Touch the imaging area to display the control buttons

11 WARRANTY

Bard Access Systems Inc. warrants to the original purchaser that this product will be free from defects in material and workmanship for a period of one (1) year from the date of purchase. If this product proves to be so defective, purchaser may return same to Bard Access Systems Inc. for repair, replacement, refund, or credit at Bard Access Systems Inc.'s option.
All returns must be authorized in advance in accordance with Bard Access Systems Inc.'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 Bard Access Systems Inc. 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 Bard Access Systems Inc. representative.

The following actions void the warranty of the Site~Rite Prevue +™ Ultrasound System:
- Opening or servicing the system or the probe housing by anyone other than Bard Access Systems authorized service personnel.
- Removal of system labels by anyone other than Bard Access Systems authorized service personnel.
- Opening or servicing the A/C adapter by anyone other than Bard Access Systems authorized service personnel.
- Connecting the Site~Rite Prevue +™ Ultrasound System to any power source other than the Site~Rite Prevue™ Ultrasound System A/C adapter.
- Installation of unauthorized software on the Site~Rite Prevue +™ Ultrasound System.
- Connecting the Site~Rite Prevue +™ Ultrasound System to any unauthorized accessory. Refer to Section 1.2.

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.

12 SERVICE AND REPAIR

There is no periodic or preventive maintenance required for the Site~Rite Prevue +™ Ultrasound System, probe or approved accessories. For servicing information or to return your Site~Rite Prevue +™ Ultrasound System for repair, please contact Bard Access Systems Technical / Clinical Support at (800) 545-0890.

Warning: Only qualified personnel should attempt to service this equipment. The Site~Rite Prevue +™ Ultrasound System contains static sensitive components and circuits. Failure to observe proper static control procedures may result in damage to the system.
Warning: Opening or servicing the system, probe, or A/C adapter by anyone other than Bard Access Systems Inc. authorized service personnel will void the warranty and may result in injury or equipment damage.

13 TECHNICAL SPECIFICATIONS

13.1 Operating and Storage Conditions

Operating Temperature: 50°F to 104°F (10°C to 40°C)
Storage Temperature: 0°F to 104°F (-18°C to 40°C)
Operating Humidity: 5% to 90% Relative Humidity (non-condensing)
Storage Humidity: 5% to 95% Relative Humidity (non-condensing)

13.2 System Specifications

Dimensions: 5.9" x 4.6" x 2.0" (149 x 117 x 52 mm)
Weight: 2 lbs (0.9 kg)
Power Sources: A/C adapter, Internal Battery Pack
Power Consumption: 45 Watts Maximum
IEC 60601-1: Class II, Type BF Applied Part, Continuous Operation, Internally Powered Equipment, Not Category AP or APG Equipment, IPX1

13.3 Probe Specifications

PROBE ACOUSTIC OUTPUT SPECIFICATIONS

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
B	20.7 mW/cm^2	Peripheral Vessel < 720 mW/cm^2 Fetal Imaging & Other** < 94 mW/cm^2	0.604	Peripheral Vessel < 1.9 Fetal Imaging & Other** < 1.9

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

Linear Vascular Access Probe
Frequency: 7.5 MHz
Elevation Focus: 1.0 cm
Scan Width: 1.5 cm
Maximum scan depth: 4.0cm

IMAGE DEPTH	FOCAL DEPTH
1.0 cm	0.5 cm
2.5 cm	1.25 cm
4.0 cm	2.00 cm

PROBE ACOUSTIC OUTPUT SPECIFICATIONS

Site~Rite Prevue +™ Ultrasound System **B-Mode**

Acoustic Output			MI	$I_{spta.3}$ (mW/cm^2)	$I_{sppa.3}$ (W/cm^2)
Global Maximum Value			0.604 (statistical maximum)	20.7 (statistical maximum)	75.20
Associated Acoustic Parameter	$p_{r.3}$ (MPa)		0.81 - 1.23		
	W_0 (mW)			0.13 - 3.11	0.13 - 3.11
	f_c (MHz)		6.83 - 7.71	6.83 - 7.71	6.83 - 7.71
	z_{sp} (cm)		1.00 - 1.90		1.00 - 1.90
	Beam dimensions	$x\text{-}_6$ (cm)			0.08 - 0.09
		$y\text{-}_6$ (cm)			0.08 - 0.13
	PD (µsec)		0.15 - 0.27		0.15 - 0.27
	PRF (Hz)		832 - 30100		832 - 30100
	EDS	Az. (cm)		0.24 - 1.56	
		Ele. (cm)		0.40	
Operating Control Conditions	1 cm - 4 cm scan depth				
	8 - 18.1 scans per second				
	104 lines per scan				

13.4 Power Supply Specifications

A/C Adapter Specifications
Input Voltage: 100-240 VAC, 50/60 Hz
Input Current (Max): 1.62 Amps
Output Voltage: 15 V
Output Current: 4.2 A

Internal Battery Pack Specifications
Battery Chemistry: Lithium Ion
Battery Capacity (Full Charge): 4290 mAh
Nominal Battery Output Voltage: 7.4 VDC
Battery Output Current (Max): < 6 Amps

13.5 System Accuracy with Needle Guides

Type	Measurement	Error	Range†
Site~Rite® Needle Guides	Vertical	≤ 1.5 mm	5-35 mm
	Horizontal	≤ 1.5 mm	5-35 mm
Pinpoint™ Needle Guides	Vertical	≤ 1.00 mm	2.5-15 mm
	Horizontal	≤ 1.00 mm	2.5-15 mm

† Available depth range of the referenced type of Needle Guide

14 DISPOSAL INFORMATION

To return the Site~Rite Prevue +™ Ultrasound System for end of life recycling, please contact your nearest Bard Access Systems sales or distributor office in the country of purchase.

Note: Always properly dispose of dead battery packs in accordance with local regulations. Improper disposal may present an environmental hazard.

15 EMC TABLES

Guidance and Manufacturer's Declaration – Emissions

The Site~Rite Prevue +™ Ultrasound System is intended for use in the electromagnetic environment specified below. The customer or user of the Site~Rite Prevue +™ Ultrasound System should ensure that it is used in such an environment.

Emissions Test	Complience	Electronic Envirinment - Guidance
RF Emissions CISPR 11	Group 1	The Site~Rite Prevue +™ Ultrasound System uses RF energy only for its internal function. Therefore, its RF emissions are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	The Site~Rite Prevue +™ Ultrasound 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	

Note: The Site~Rite Prevue +™ Ultrasound System is not classified to be used in a domestic environment.

Caution: This system, with its applicable accessories, is intended for use by healthcare professionals only. If used in a domestic environment, this system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures such as re-orienting or relocating the Site~Rite Prevue +™ Ultrasound System or shielding the location.


12:00:00
cm
0.5
1
1.5
2
2.5
cm
SiteRite
Prevue*

Guidance and Manufacturer's Declaration – Immunity

The Site~Rite Prevue +™ Ultrasound System is intended for use in the electromagnetic environment specified below. The customer or user of the Site~Rite Prevue +™ Ultrasound System should ensure that it is used in such an environment.

Immunity Test	EN/IEC 60601 Test Level	Complience 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.
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 Site~Rite Prevue +™ Ultrasound System requires continued operation during power main interruptions, it is recommended that the Site~Rite Prevue +™ Ultrasound System be powered from an uninterruptible power supply or battery.
Power Frquency 50/60Hz Magnetic Field EN/IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be that of a typical commercial or hospital.

Guidance and Manufacturer's Declaration – Emissions

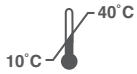
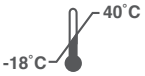
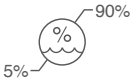
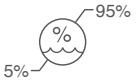
The Site~Rite Prevue +™ Ultrasound System is intended for use in the electromagnetic environment in which radiated disturbances are controlled. The customer or user of the Site~Rite Prevue +™ Ultrasound System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment and the Site~Rite Prevue +™ Ultrasound System as recommended below, according to the maximum output power of the communications equipment.

Immunity Test	EN/IEC 60601 Test Level	Complience 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 Site~Rite Prevue +™ Ultrasound 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 Separations Distances between portable and mobile RF Communications equipment and the Site~Rite Prevue +™ Ultrasound System.

Max Output Power (Watts)	Separation (m) 150 kHz to 80 MHz D = 1.2(√ P)	Separation (m) 80 kHz 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

SITE~RITE Prevue +™ ULTRASOUND SYSTEM — SYMBOLS

	Consult Instructions for Use		BF Type Equipment
	Manufacturer	FC	Federal Communications Commission
	Operating Temperature Limitation		Alternating Current
	Storage Temperature Limitation		Direct Current
	Operating Humidity Limitation		Keep Dry
	Storage Humidity Limitation	IPX1	Drip Proof Equipment
	USB		Power
	Do not dispose with ordinary municipal waste	Ver.	Software Version
	Class II Equipment	SN	Serial Number
REF	Catalog Number	Rx Only	Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

An issued or revision date for these instructions is included for the user's information. In the event two years elapsed between this date and product use, the user should contact Bard Access Systems, Inc. to see if additional product information is available.

Revision date: February 2015

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Salt Lake City, UT 84116 USA

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