TECHNICAL MANUAL

BARD

Site~Rite* 5 Ultrasound System
Manufactured by:

Bard Access Systems, Inc.
Salt Lake City, UT 84116
U.S.A.

(801) 595-0700
Customer Service: (800) 545-0890
Technical/Clinical Support: (800) 443-3385
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www.bardaccess.com

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

Revision date: May, 2006.

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TECHNICAL MANUAL

SITE RITE 5

VASCULAR ACCESS ULTRASOUND SYSTEM

BARD

SITE RITE* 5

VASCULAR ACCESS

ULTRASOUND SYSTEM

TECHNICAL MANUAL

Do not operate in the presence of flammable anesthetics

Dangerous Voltage

BF Type Equipment

Do Not Dispose of Battery Pack In Fire

Humidity Parameters

Dot Markers Active

Warning: Refer to Manual Before Use

Power/Stand-by

Medical Electrical Equipment Classified by ETL with respect to Electric Shock, Fire, and Mechanical Hazards only in accordance with UL60601-1 and CAN/CSA C22.2 No. 601.1

AC Adapter

Class II Equipment

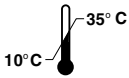
Freeze Image

℞ ONLY

Prescription Only

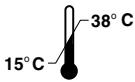
Battery Pack

Fragile



Storage Temperature Parameters

Ultrasound Probe



Operating Temperature Parameters

cm

Depth (In Centimeters)

Gain

Do not dispose with ordinary municipal waste

Table of Contents

Section

1 Warranty

The manufacturer, Bard Access Systems, warrants this product against defects in material and workmanship for a period of one year from the date of original purchase, and agrees to repair, or at Bard Access Systems' discretion, replace any defective unit free of charge. The warranty on the repaired or replaced unit continues from the purchase date of the original unit. This warranty does not cover damages resulting from misuse, abuse, modification, or alteration of the Site~Rite* 5 System.

The following actions void the warranty of the Site~Rite* 5 System:

- Opening or servicing the scanner or the probe housing.
- Removal of system labels by anyone other than by Bard Access Systems authorized service personnel.
- Opening or servicing the battery pack or the combination A/C adapter and battery charger by anyone other than Bard Access Systems authorized service personnel.
- Connecting the Site~Rite* 5 scanner to any power source other than the Site~Rite* 5 combination A/C adapter and battery pack.
- Connecting the Site~Rite* 5 scanner to any A/C adapter other than the one provided with the scanner.
- Connecting the Site~Rite* 5 System to any unauthorized accessory.

2 Warnings, Precautions and Notes

Warnings

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

Warning: Do not remove outer protective covers from the Site~Rite* 5 scanner. Hazardous voltages exist at several points within the system.

Warning: Do not operate the Site~Rite* 5 Ultrasound System or the Site~Rite A/C adapter and battery charger 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* 5 System may result in damage to the equipment or personal injury.

Warning: Use only the combination Site~Rite A/C adapter and battery charger to charge Site~Rite* 5. Use of any other device to charge Site~Rite* 5 battery packs may damage the battery packs and will void your warranty.

Warning: Only connect a Site~Rite* 5 combination A/C adapter and battery charger to the Site~Rite* 5 System. Use of any other A/C adapter may cause intermittent or unpredictable operation, may damage the system and will void your warranty.

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

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

Warning: Use only Bard Access Systems probes with this system. Use of unapproved probes may result in patient injury or equipment damage.

Warning: When using Site~Rite Needle Guides on the Site~Rite probe, use only sterile plastic probe covers that are 1 mil (0.001 inch or 0.0254 mm) thick.

Warning: Do not allow liquid to enter the scanner, combination A/C adapter and battery charger, probe connector or probe port. Damage to equipment may occur.

Warnings (continued)

Warning: Do not attempt to sterilize the Site~Rite* 5 scanner or probes with ethylene oxide or heat sterilization methods. Damage to the equipment may occur.

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

Warning: Only qualified personnel should attempt to service this equipment. The Site~Rite* 5 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 the warranty of the Site~Rite* 5 System.

- Opening or servicing the scanner or the probe housing.
- Removal of system labels by anyone other than by Bard Access Systems authorized service personnel.
- Opening or servicing the battery pack or the combination A/C adapter and battery charger by anyone other than Bard Access Systems authorized service personnel.
- Connecting the Site~Rite* 5 scanner to any power source other than the Site~Rite* 5 combination A/C adapter and battery pack.
- Connecting the Site~Rite* 5 scanner to any A/C adapter other than the one provided with the scanner.
- Connecting the Site~Rite* 5 to any unauthorized accessory.

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

Warning: Verify that all accessories attached to the system comply to 60601 safety standards. Non-compliance may result in increased patient risk.

Warning: Use only IEC or ISO approved safety devices outside the patient environment. Failure to do so may damage the equipment.

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

Warning: Maximum shelf load on the VAD bedside roll stand is 22 lbs. Exceeding this weight may damage the roll stand.

Warnings (continued)

Warning: Do not overtighten screws when attaching to the VESA roll stand mount. Doing so may damage the scanner.

Warning: Use only screws provided in packaging. Ensure the unit is secure against the VESA roll stand mount. Failure to do so may cause the scanner to disconnect from the VESA roll stand mount.

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

Warning: Do not pull on probe cable. Doing so may cause the system to tip.

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* 5 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 pull the cable to disconnect the probe connector from the scanner. Pulling the cable may damage the cable, cable connection or scanner.

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

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.

Precautions (continued)

Caution: Use water or rubbing 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 to allow 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 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. Bard Access Systems distributes sterile probe covers and needle guide kits that do not contain latex.

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

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.

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

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

Caution: Unapproved extension cords should not be used with this system. Doing so may damage the system.

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

Caution: To avoid unnecessary strain on the user, use the device in a comfortable manner.

Caution: Attach 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.

Precautions (continued)

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

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

Notes

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

Note: For 240 V applications use only center tapped 240 VAC single phase power.

3 Site~Rite* 5 Ultrasound System Description

The Site~Rite* 5 Ultrasound system contains three major components. **(See Figure 1)**

- Power Source (External AC Adapter or Base Unit Battery System/AC Adapter)
- Scanner Assembly
- Transducer Assembly

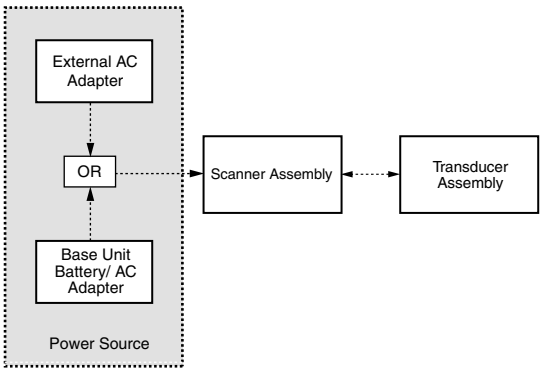


Figure 1. Site~Rite* 5 System Block Diagram

3.1 Power Source

The power source supplies 15 volts direct current (VDC) nominal to the Scanner Assembly. Power source options include an External AC Adapter or a Base Unit Battery Assembly. The Base Unit Battery assembly contains a battery and built-in AC Adapter that permits portable system operation. Both power supply options provide power to the scanner and charge the internal battery simultaneously.

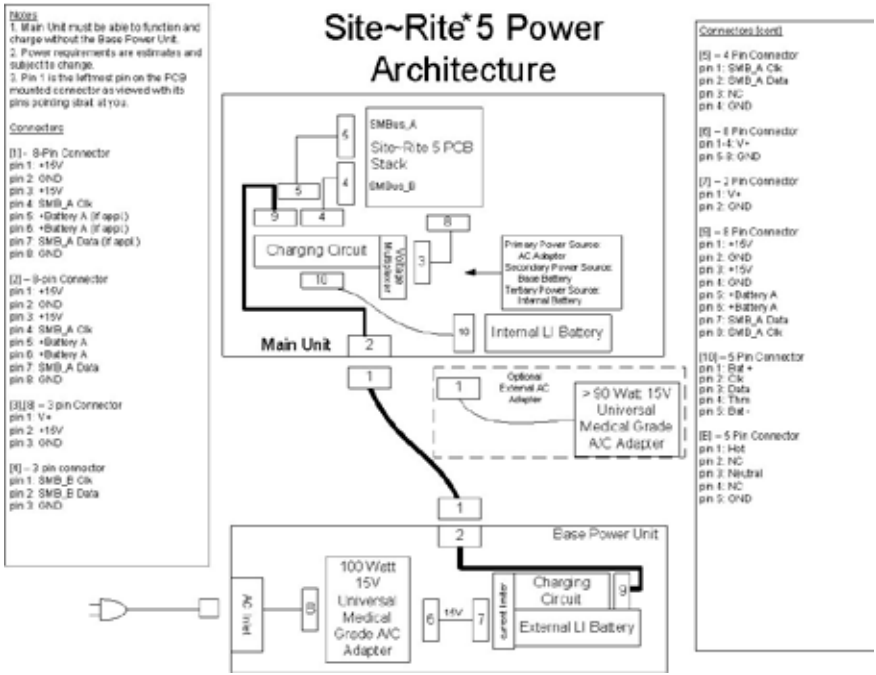


Figure 2. Site~Rite* 5 Power Architecture

3.2 Scanner Assembly

The Scanner Assembly transmits and receives electrical ultrasound data that is used to form a coherent image. A high-level block diagram of the system is shown in **Figure 2**.

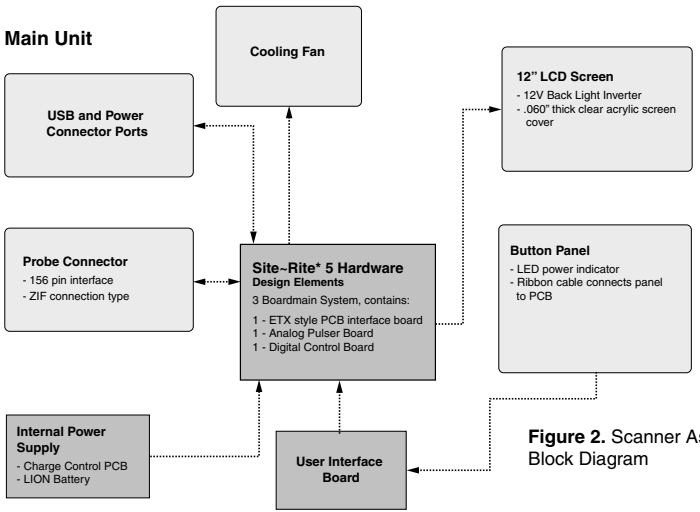


Figure 2. Scanner Assembly Block Diagram

NOTE: The Scanner Assembly is NOT field serviceable. If a problem is found with the Scanner Assembly please contact Bard Access Systems at (800) 443-3385.

3.3 Transducer Assembly

The Transducer Assembly converts electrical signals to acoustic pulses that are transmitted into the body. The pulses reflect off the target and return to the transducer, which converts the acoustic data back into electrical data. The electrical data is then transmitted to the scanner assembly where an ultrasonic image is generated from multiple pulse echo frames.

NOTE: The transducer assembly is NOT field-serviceable. If a problem is found with the transducer please contact Bard Access Systems at (800) 443-3385.

3.4 Front Panel Controls

Increase Gain
(In **Time Set** mode, this button increases or toggles the selected field.)

Depth Markers
Toggles depth markers on/off.

Print
Sends the current image to the printer if connected. If a USB storage device is connected to the system, this button will also save the current screen image to the storage device.

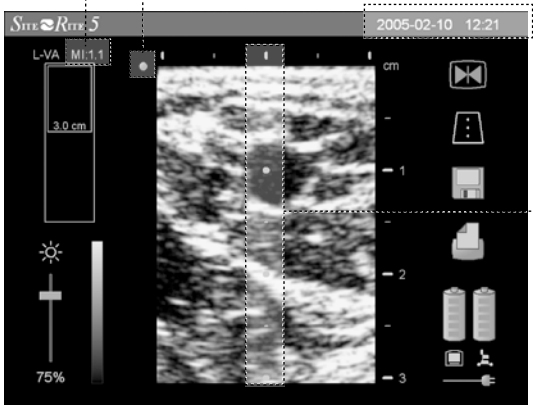
Decrease Gain
(In **Time Set** mode, this button decreases or toggles the selected field.)

Depth
(In **Freeze mode**, if this button is held for more than 5 seconds, the system enters the **Time Set mode**. In **Time Set mode**, this button selects the next field.)

Freeze
(In **Time Set** mode, this button sets the internal clock to the displayed values and returns the system to **Run Mode**.)

On/Off/Reset

3.5 Display Screen Information



Mechanical Index
The mechanical index is shown in increments of 0.1 with an accuracy of +/- 0.09.

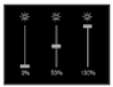
Probe Orientation Marker

Time and Date
The time is shown in 24 hour "00:00" format and the date may be displayed in MM/DD/YY or DD.MM.YY format.

Image Depth Markers
When enabled, the depth markers are shown as green dots superimposed on the image at 1.0 cm pitch with smaller dash marks at 0.5 cm.

Probe Depth Indicator
Indicates current image depth.

Depth Marker Indicator
When depth markers are enabled, the indicator is highlighted in light green.



Gain Indicator
Shows gain levels from 0-100%.

Run/Freeze Indicator
When the system is in freeze mode, the indicator is shown in red and blinks briefly every second.

Storage Device Indicator
When a storage device is connected, the indicator icon is shown in solid grayscale. When the storage device is full or has errors, the indicator is displayed with a red "**!**" overlay.

Printer Indicator
When a printer is connected, the indicator is shown in solid grayscale. If the printer has an error condition, the indicator is displayed with a red "**!**" overlay.

Display Screen Information (continued)

AC Power Indicator

The indicator is shown in solid grayscale when connected to AC wall power and is shown as a dark gray outline when disconnected.

Battery Indicator

The 5 charge levels for the batteries are displayed as shown. When the unit is recharging, the indicator is green for all 5 levels. When the unit is under battery power, the console battery indicator changes to yellow at 40% and red/blinking at 20% of remaining life. If a battery malfunction is detected, the system will show the battery with a red "**!**" overlay.

4 Installing Site~Rite* 5 Software

The Site~Rite* 5 Ultrasound System allows software installation through the USB connectors located on the rear of the scanner.

To install software:

1. Press the Freeze button (▶|◀) to pause the system.
2. Insert a USB drive into one of the USB connectors located on the rear of the Site~Rite 5 scanner.
3. Wait until the storage device icon is illuminated before proceeding.
4. Simultaneously press and hold the Gain buttons (▲▼) until the configuration screen appears.
5. When the configuration screen appears, simultaneously press and hold the Depth button (**cm**) and Depth Marker button (**/:**) until the software installation process begins.

   Note: The Site~Rite 5 System will automatically upload the software from the attached USB drive.

   Note: The screen will appear blank and/or inactive during the software installation process.
6. When a blinking cursor appears, power off the Site~Rite 5 scanner.
7. Disconnect the USB drive.
8. Power on the Site~Rite 5 scanner.
9. Verify that the correct software version appears on the upper left hand corner of the screen.
10. Resume normal operation.

5 Calibrating the Internal Battery

The Site~Rite 5 internal battery may occasionally require calibration to ensure the battery power meter is accurate. The following icon indicates that the Site~Rite 5 battery requires calibration.

To calibrate the Site~Rite 5 Internal Battery:

1. Disconnect all Site~Rite 5 power sources.
2. Power on the Site~Rite 5 scanner and operate on internal battery power until the system powers off.
3. Connect the Site~Rite 5 scanner to the Site~Rite 5 combination A/C adapter and battery charger to recharge the internal battery.

   Note: At least six hours of charge time is recommended to fully charge the Site~Rite 5 internal battery.
4. Disconnect all Site~Rite 5 power sources.
5. Power on the Site~Rite 5 Ultrasound System and operate on internal battery power until the system powers off.
   Note: The internal battery is now calibrated.
6. Connect the Site~Rite 5 scanner to the Site~Rite 5 combination A/C adapter and battery charger to recharge the internal battery and continue normal use.

6 Troubleshooting & Error Screens

Missing/ Invalid Probe

Cause: Scanner does not recognize or identify a probe or probe not attached.
Solution: Ensure that a Site-Rite 5 probe is properly connected to the system.

System Malfunction

Cause: Scanner is not operating within normal parameters.
Solution: Discontinue use immediately. Return to authorized repair facility.

Display Malfunction

Cause: Display malfunction.
Solution: Most display malfunctions can easily be corrected by resetting the system. To do so, power off the device, wait 60 seconds, then power the system back on. If the display malfunction is not resolved by resetting the system, discontinue use and return to authorized repair facility.

Battery Empty

Cause: Battery empty.
Solution: Connect system to AC outlet for operation and battery recharge.

Battery Malfunction

Cause: Battery malfunction.
Solution: Send system to authorized repair facility for battery replacement.

Storage Device Indicator

Cause: When a storage device is connected, the icon is shown in solid grayscale. If the storage device is full or has errors, the icon is displayed with a red “!” overlay.
Solution: Replace storage device.

Printer Indicator

Cause: When a printer is connected, the icon is shown in solid grayscale. If the printer has an error condition, the icon is displayed with a red "**!**" overlay.
Solution: Check paper or service printer.

6 Troubleshooting & Error Screens Continued…

Troubleshooting Guide

Problem	Possible Cause	Solution
The system will not power on. (Power LED is not illuminated, fan is not running, and no information is displayed.)	Did not press power button long enough	Press the power button for at least 1 second.
	Battery is discharged	Plug the unit into a known working AC outlet to operate system and charge the battery.
	AC Adapter is defective	Plug the unit into a known working AC outlet. Verify power LED on Scanner Assembly is blinking. If not, remove AC Adapter and measure voltage levels on the DIN connector. The DIN Shield is GND. Pin 1 & 3 should read ~15VDC.
Gain up and gain down buttons on scanner or probe do not work	System is in freeze mode	Press the freeze button.
	Button pad is defective	Use scanner buttons until unit can be returned for service.
Depth buttons on scanner or probe do not work	System is in freeze mode	Press the freeze button.
	Button pad is defective	Use scanner buttons until unit can be returned for service.
Image is poor or penetration is inadequate	Not enough acoustic coupling gel is being used.	Use more coupling gel.
	Fold or seam of sheath on the acoustic window of the probe.	Smooth out sheath over the acoustic window.
Scanner Assembly powers on momentarily then shuts off	Battery is discharged	Plug the unit into a known working AC outlet to operate system and charge the battery.

7 Site~Rite 5* System Specifications

7.1 Operating and Storage Conditions

Operating Temperature:	59°F to 100°F (15°C to 38°C)
Storage Temperature:	50°F to 95°F (10°C to 35°C)
Operating Humidity:	5% to 85% Relative Humidity (non-condensing)
Storage Humidity (packaged):	5% to 95% Relative Humidity (non-condensing)
Storage Humidity (unpackaged):	5% to 85% Relative Humidity (non-condensing)

7.2 Scanner Specifications

Dimensions:	12" W x 12" H x 5" D
Weight:	10 lbs.
Power Sources:	AC adapter, Internal and External DC Battery Pack
Power Consumption:	82 Watts Maximum
Monitor Size:	12.1” diagonal
IEC 60601- 1:	Class II, Type BF Applied Part, Continuous Operation, Internally Powered Equipment, Not Category AP or APG Equipment, Not protected against ingress of water.

7.3 Probe Specifications

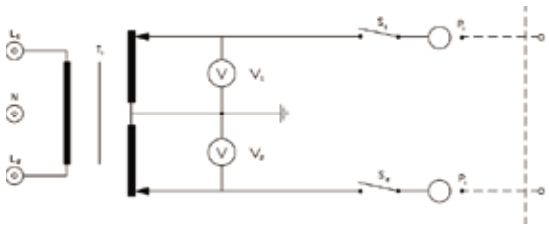
L-VA:	Linear Vascular Access Probe
Frequency:	5 -10 MHz
Elevation Focus:	1.8 cm
Maximum Scan Depth:	6.0 cm
Scan Width:	1.9 cm

Lateral Foci:

Image Depth	Focal Depth
1.5 cm	0.6 cm
3.0 cm	1.5 cm
4.5 cm	3.0 cm
6.0 cm	5.0 cm

7.4 Power Supply Specifications

Note: For 240 V applications use only center tapped 240 VAC single phase power as shown below.



A/C Adapter Specifications

Input Voltage:	100-240 VAC, 50/60 Hz.	**Output Voltage:**	15 VDC
Input Current (Max):	1 Amp	**Output Current (Max):**	6 Amps

Internal Battery Pack Specifications

Battery Chemistry:	Lithium Ion	**Output Power (Full Charge):**	52 Wh
Nominal Output Voltage:	10.8 VDC	**System Run Time on Full Charge:**	1.0 Hours
Output Current (Max):	6 Amps	**Charge Time (Full):**	1.75 Hours

Combination A/C Adapter Auxiliary Battery Specifications

Input Voltage:	100-240 VAC, 50/60 Hz.	**Battery Output Current (Max):**	6 Amps
Input Current (Max):	1 Amp	**Battery Chemistry:**	Lithium Ion
A/C Adapter Output Voltage:	15 VDC	**Output Power (Full Charge):**	95 Wh
A/C Adapter Output Current (Max):	7 Amps	**System Run Time on Full Charge:**	2.5 Hours
Nominal Battery Output Voltage:	10.8 VDC	**Battery Charge Time (Full):**	3 Hours

8 Standards Information

The Site~Rite* 5 Ultrasound System is designed to comply with applicable sections of the following International Standards:

- UL 60601-1: 2003, Medical Electrical Equipment, Part 1: General Requirements for Safety
- IEC 60601-1: 1988, Medical Electrical Equipment - Part 1: General Requirements for Safety
- IEC 60601-1-1: 2000, Medical Electrical Equipment - Part 1-1: General Requirements for Safety - Collateral Stanard: Safety Requirements for Medical Electrical Systems
- IEC 60601-1-2: 2004, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Stanard: Electromagnetic Compatibility - Requirements and Tests
- IEC 60601-2-37:2005, Medical Electrical Equipment - Part 2-37: Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment
- NEMA UD-2:2004, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
- NEMA UD-3:2004, Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- EN 55011:2000 Class A - Industrial, Scientific, and Medical (ISM) Radio-Frequency Equipment -Radio Distrubance Characteristics-Limits and Methods of Measurement

9 Disposal Information

To return the Site~Rite* 5 System for end of life recycling, please contact your nearest Bard sales or distributor office in the country of purchase.

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

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Site~Rite® Needle Guides Distributed by:

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