



TECHNICAL MANUAL



Site-Rite® 6 Ultrasound System
Manufactured for:

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

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Customer Service: (800) 545-0890
Technical/Clinical Support: (800) 443-3385
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An issued or revision date for these instructions is included for the users information. In the event two years have elapsed between this date and product use, the user should contact Bard Access Systems, Inc. to see if additional product information is available.

Revision date: July, 2007

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BARD

ACCESS SYSTEMS

REF | 9770100

SITE  RITE[®] 6))
ULTRASOUND SYSTEM

TECHNICAL MANUAL



TECHNICAL MANUAL

Site  **Rite** 
*
ULTRASOUND SYSTEM





Do not operate in the presence
of flammable anesthetics



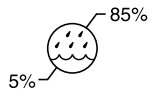
BF Type Equipment



Dangerous Voltage



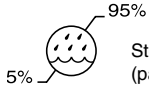
Warning: Refer to
Manual Before Use



Operating Humidity Parameters
Storage Humidity Parameters
(unpackaged)



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



Storage Humidity Parameters
(packaged)

R_x ONLY

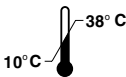
Federal (U.S.A.) law restricts
this device to sale by or on the
order of a physician



Keep Dry



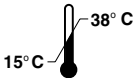
Fragile



Storage Temperature Parameters



Ultrasound Probe



Operating Temperature Parameters



Do not dispose with ordinary municipal waste



Direct Current



Federal Communications Commission



Manufacturer





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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 during such period 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* 6 Ultrasound System.

The following actions void the warranty of the Site~Rite* 6 Ultrasound System:

- Opening or servicing the scanner or the probe housing by anyone other than Bard Access Systems authorized service personnel.
- 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* 6 Ultrasound System scanner to any power source other than the Site~Rite* 6 Ultrasound System combination A/C adapter and battery pack.
- Connecting the Site~Rite* 6 Ultrasound System scanner to any A/C adapter other than the one provided with the scanner.
- Connecting the Site~Rite* 6 Ultrasound System to any unauthorized accessory.

TO THE EXTENT ALLOWABLE BY APPLICABLE LAW, THIS LIMITED PRODUCT WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

IN NO EVENT WILL **Bard Access Systems** BE LIABLE TO YOU FOR ANY INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM YOUR HANDLING OR USE OF THIS PRODUCT.

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

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* 6 Ultrasound System scanner. Hazardous voltages exist at several points within the system.
- Warning:** Do not operate the Site~Rite* 6 Ultrasound System or the Site~Rite* 6 Ultrasound System 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* 6 Ultrasound System may result in damage to the equipment or personal injury.
- Warning:** Use only the combination Site~Rite* 6 Ultrasound System A/C adapter and battery charger to charge Site~Rite* 6 Ultrasound System. Use of any other device to charge Site~Rite* 6 Ultrasound System battery packs may damage the battery packs and will void your warranty.
- Warning:** Only connect a Site~Rite* 6 Ultrasound System combination A/C adapter and battery charger to the Site~Rite* 6 Ultrasound 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* 6 Ultrasound System 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


- Warning:** Do not attempt to sterilize the Site~Rite* 6 Ultrasound System 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 environmental hazard.
- Warning:** Only qualified personnel should attempt to service this equipment. The Site~Rite* 6 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 the warranty of the Site~Rite* 6 Ultrasound System and/or may result in patient injury or equipment damage:
- Opening or servicing the scanner or the probe housing by anyone other than Bard Access Systems authorized service personnel.
 - 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* 6 Ultrasound System scanner to any power source other than the Site~Rite* 6 Ultrasound System combination A/C adapter and battery pack.
 - Connecting the Site~Rite* 6 Ultrasound System scanner to any A/C adapter other than the one provided with the scanner.
 - Connecting the Site~Rite* 6 Ultrasound System 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 should not be used with this system. Failure to comply could result in increased patient risk.

Warnings

- Warning:** Maximum shelf load on the VAD bedside roll stand is 22 lbs. Exceeding this weight may damage the roll stand.
- 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.
- Warning:** The keyboard tray and arm are designed to support the keyboard weight only. Additional weight may cause the stand 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* 6 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 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:** Inspect the keyboard prior to each use. If damage is noted, do not use the keyboard.
- 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 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 increase patient risk and/or 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.
- 

Precautions

- 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.
- 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* 6 Ultrasound System Description

The Site~Rite* 6 Ultrasound System contains three major components. (See Figure 1)

- Power Source External Battery
- Scanner Assembly (Site~Rite* 6 Ultrasound System External Battery or Site~Rite* 6 Ultrasound System A/C Adapter/Battery Charger)
- Transducer Assembly

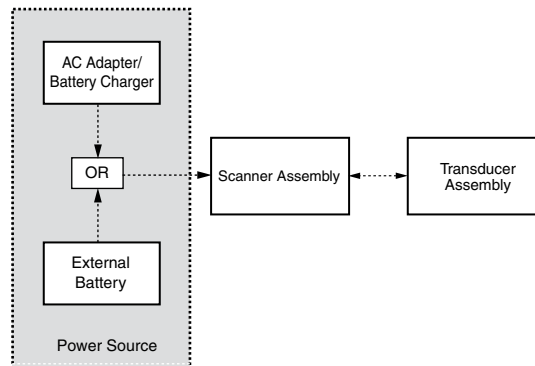


Figure 1. Site~Rite* 6 Ultrasound System Block Diagram

3.1 Power Source

The power source supplies 15 volts direct current (VDC) nominal to the Scanner Assembly. Power source options include the Site~Rite® 6 Ultrasound System A/C adapter/battery charger and the Site~Rite® 6 Ultrasound System external battery. The Site~Rite® 6 Ultrasound System external battery 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.

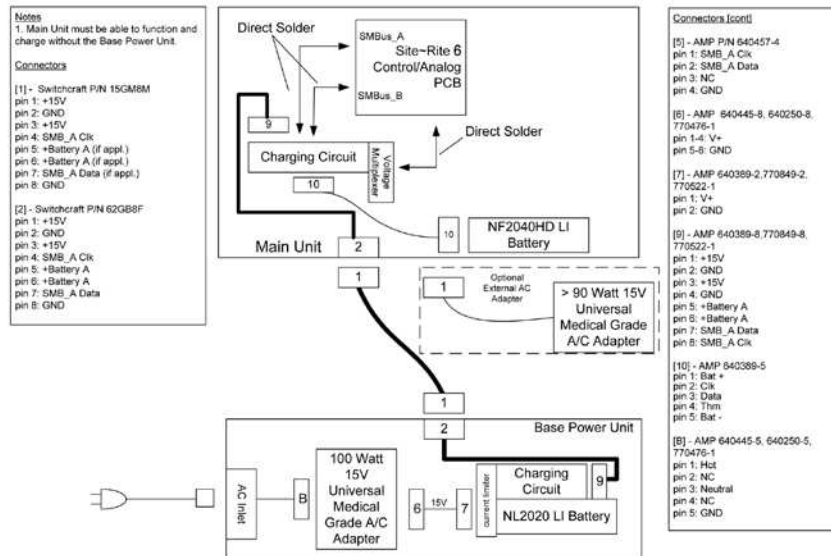
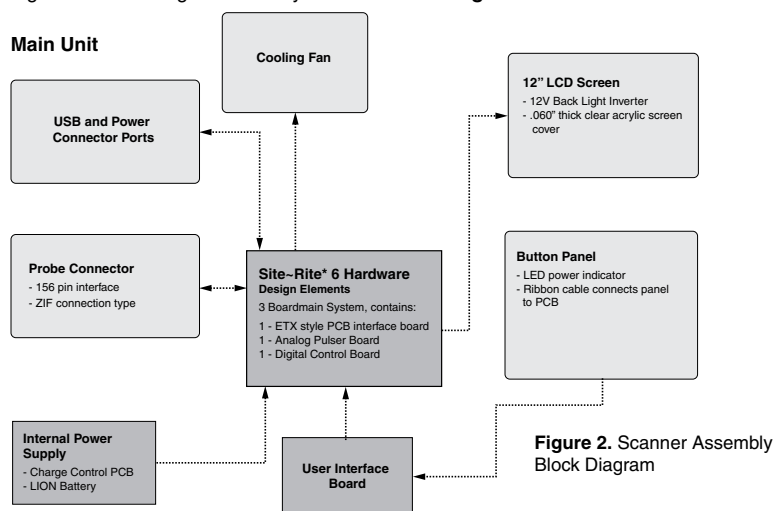


Figure 2. Site~Rite® 6 Ultrasound System Power Architecture

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**.



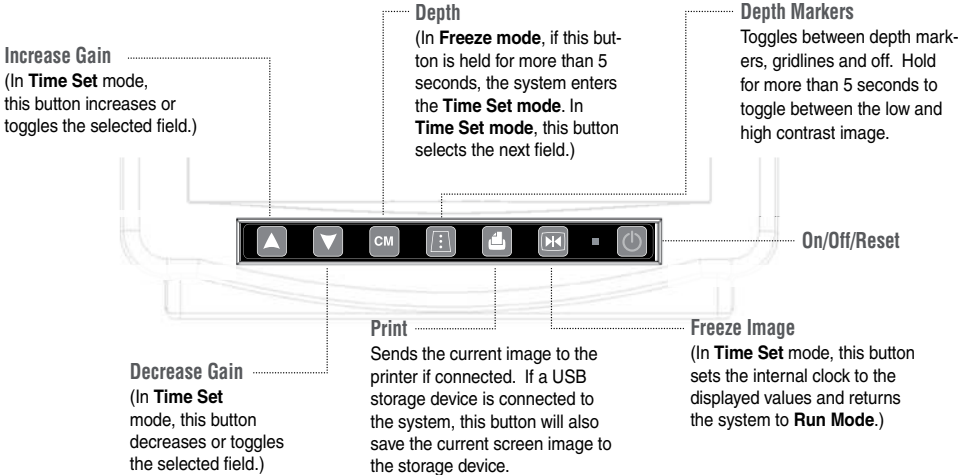
NOTE: The Scanner Assembly is NOT field serviceable. If a problem is found with the Scanner Assembly please contact Bard Access Systems at (800) 443-3385.

3.3 Transducer Assembly

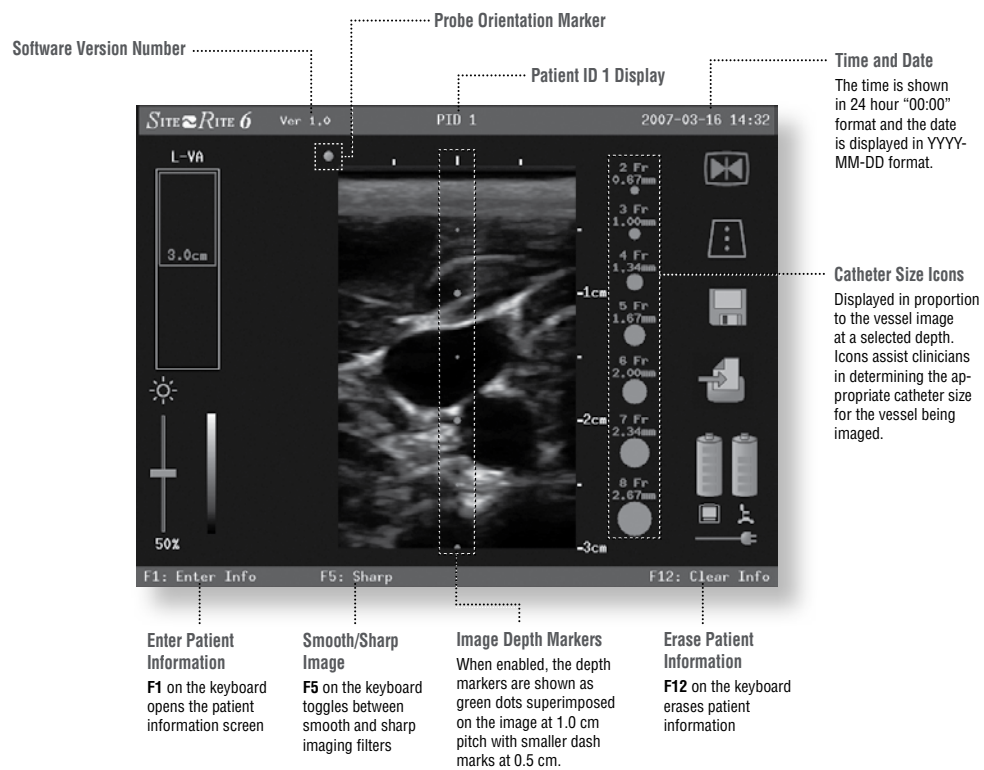
The Transducer Assembly converts electrical signals to acoustic pulses that are transmitted into the body. The pulses reflect off the target and return to the transducer, which converts the acoustic data back into electrical data. The electrical data is then transmitted to the scanner assembly where 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

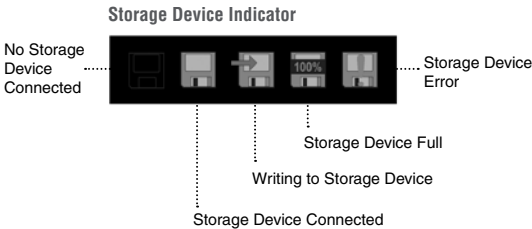
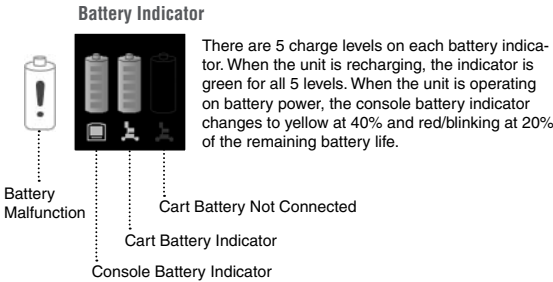
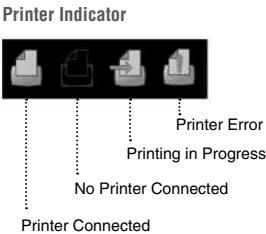
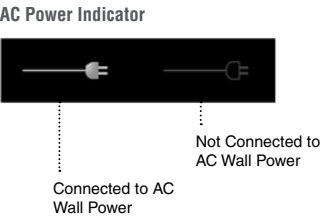
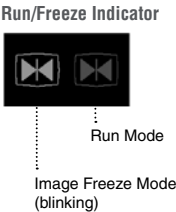
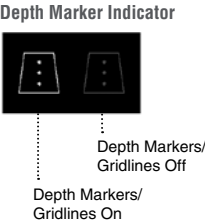
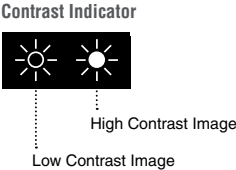
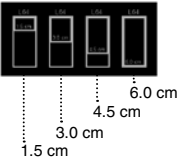


3.5 Display Screen Information

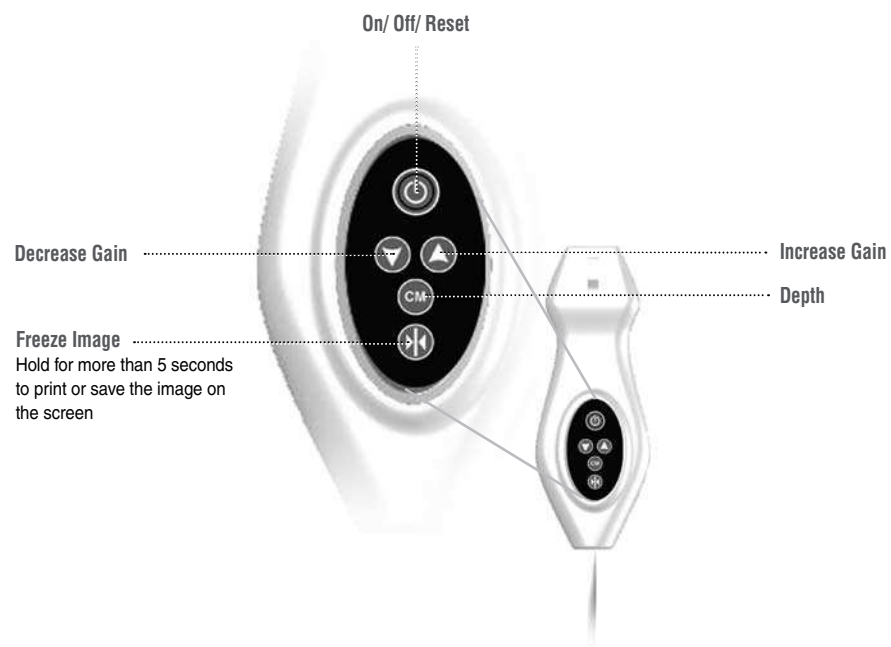


Display Screen Information

Probe Depth Indicator
Indicates current image depth



3.6 Probe Controls



4 Settings

4.1 Date, Time and Image Size

To modify date, time and image size settings:

1. Press the Freeze button (▶|◀) to pause the system.
2. Press and hold the Depth button (**cm**) for more than 5 seconds until the year field is highlighted. Release the Depth button.
3. Press the Depth button (**cm**) to select the desired date or time field to be modified.
4. Press the Gain buttons (▼, ▲) to change the selected date or time values.
5. After setting the date and time, press the Depth button (**cm**) to enter the image size field. The current image size will be highlighted.
6. Press the Gain buttons (▼, ▲) to select the desired image size.
7. Press the Freeze button (▶|◀) to store the updated settings and resume normal operation.

4.2 Image Parameters

The Site~Rite* 6 Ultrasound System image may be changed from the factory default settings.

Contrast

To toggle between the high and low contrast image settings, press and hold the Depth Marker button (/:\) for five seconds.

Smooth/Sharp

To toggle between a smooth and sharp image, press the F5 key.



4.3 Sizing Tools

Gridlines can be viewed over the ultrasound image to provide an effective tool to estimate vessel diameter. To toggle the image gridlines on and off, press the Depth Marker button (/:\).

Catheter size icons are displayed in proportion to the vessel image at a selected depth. These icons assist clinicians in determining the appropriate catheter size for the vessel being imaged. To toggle the catheter size chart on and off, press the F9 key.

4.4 Image Depth

The Site~Rite* 6 Ultrasound System image depth may be changed to image structures at different depths. Adjusting the depth also adjusts the focus of the ultrasound. Adjusting the depth to place the structure of interest at the appropriate focus will improve the ultrasound image.

Image Depth Setting (cm)	Focal Depth (cm)
1.5 cm	0.6 cm
3.0 cm	1.5 cm
4.5 cm	3.0 cm
6.0 cm	5.0 cm

1. To change the depth setting, press the depth button (cm) on the front panel or probe.
2. Select the image depth that has the focal depth closest to that of the target structure.

4.5 Image Gain

The image gain can be adjusted to amplify the signal returned to the ultrasound machine.

Adjusting the gain effects the entire image. Increasing gain will amplify the signal from the target structure along with non-targeted structures.

1. To change the gain, press the gain up or down buttons (▲▼) on the front panel or probe.
2. Select the gain that provides the best ultrasound image for the targeted structure.



5 Upgrading Software

The Site~Rite* 6 Ultrasound System allows the software to be upgraded 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 the USB drive containing the software upgrade into one of the USB connectors located on the rear of the Site~Rite* 6 Ultrasound System 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* 6 Ultrasound System will automatically upload the software from the attached USB drive.

Note: The screen may appear blank and/or inactive during part of the software installation process.

6. When the system displays a message that the software update is successful, power off the Site~Rite* 6 Ultrasound System scanner.
7. Disconnect the USB drive.
8. Power on the Site~Rite* 6 Ultrasound System scanner.
9. Verify that the correct software version appears on the upper left hand corner of the screen.
10. Resume normal operation.



6 Calibrating the Rechargeable Batteries

The Site~Rite* 6 Ultrasound System batteries may occasionally require calibration to ensure the battery power meter is accurate. The following icon indicates that a Site~Rite* 6 Ultrasound System rechargeable batteries require calibration.



To calibrate the Site~Rite* 6 Ultrasound System Rechargeable Batteries:

1. Disconnect the Site~Rite* 6 Ultrasound System from A/C power.
2. Power on the Site~Rite* 6 Ultrasound System scanner and operate on battery power until the system powers off.
3. Connect the Site~Rite* 6 Ultrasound System to A/C power to recharge the batteries.








Note: At least five hours of charge time is recommended to fully charge the Site~Rite* 6 Ultrasound System batteries.

4. Disconnect the Site~Rite* 6 Ultrasound System from A/C power.
5. Power on the Site~Rite* 6 Ultrasound System and operate on battery power until the system powers off.

Note: The batteries are now calibrated.

6. Connect the Site~Rite* 6 Ultrasound System to A/C power to recharge the batteries and continue normal use.

7 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® 6 Ultrasound System 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: Storage device error. Solution: Replace storage device.
Printer Device Indicator		Cause: Printer device error. Solution: Check paper or refer to printer instructions for use.
Poor Image Quality		Cause: Incorrect settings. Solution: Refer to Section 5. Cause: Scanner is not operating within normal parameters. Solution: Return to authorized repair facility.



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 alternate buttons on the probe or scanner 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 alternate buttons on the probe or scanner 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.

8 Site~Rite* 6 Ultrasound System Technical Specifications

8.1 Operating and Storage Conditions

- Operating Temperature: 59°F to 100°F (15°C to 38°C)
- Storage Temperature: 50°F to 100°F (10°C to 38°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)

8.2 Scanner Specifications

- Dimensions: 12" W x 13" H x 5" D
- Weight: 10 lbs.
- Power Sources: AC adapter, Internal and External DC Battery Pack
- Power Consumption: 84 Watts Maximum
- Monitor Size: 12.1" diagonal
- IEC 60601- 1: Class I, Type BF Applied Part, Continuous Operation, Internally Powered Equipment, Not Category AP or APG Equipment, Not protected against ingress of water.



8.3 Probe Acoustic Output Specifications

Description of Probe	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
L-VA	B	49.003mW/cm ²	Peripheral Vessel < 720 m W/cm ² Cardiac < 430 mW/cm ² Fetal Imaging & Other** < 94 mW/cm ²	.885	Peripheral Vessel < 1.9 Cardiac < 1.9 Fetal Imaging & Other** < 1.9

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

All measurements were conducted in accordance with the measurement procedures of the NEMA Standard Publications UD-2 and UD-3, and following the calibration procedures given in Appendices B, C, D and E of the 1985 FDA 510(k) Guide, and Part A, Sections III-IV, and Appendices A, B, C and D of the 1989 FDA 510(k) Guide, and the Track 1 and Track 3 reporting requirements of the September 30, 1997 Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers

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* 6 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.

8.4 Probe Specifications

L-VA : Linear Vascular Access Probe

Frequency: 5 -10 MHz

Elevation Focus: 1.8 cm

Maximum Scan Depth: 6.0 cm

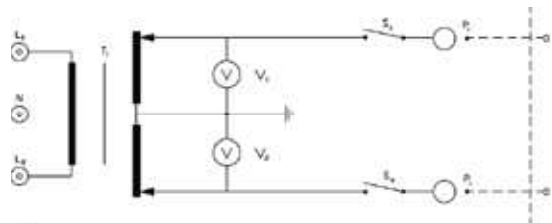
Scan Width: 1.9 cm

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

8.5 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): 2 Amps	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): 1.7 Amps	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



9 Standards Information

The Site~Rite* 6 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
- CAN/CSA - C22.2 No. 601.1-M90, Medical Electrical Equipment - Part 1: General Requirements for Safety
- IEC 60601-1:1988, Medical Electrical Equipment - Part 1: General Requirements for Safety
- EN 60601-1: 1990, Includes Amendments A1:1993, A11:1993, A12:1993, A2:1995 and A13:1996, 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 Standard: Safety Requirements for Medical Electrical Systems
- IEC 60601-1-2: 2001, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests
- IEC 60601-2-37: 2004, Medical Electrical Equipment - Part 2-37: Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment
- IEC 60601-1-4: 2000, Medical Electrical Equipment - Part 1-4: General Requirements for Safety - Collateral Standard: Programmable Electrical Medical Systems
- 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: 1998, Group 1, Class A - Industrial, Scientific, and Medical (ISM) Radio-Frequency Equipment - Radio Disturbance Characteristics-Limits and Methods of Measurement

10 Disposal Information

To return the Site~Rite* 6 Ultrasound 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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