

# Site~Rite Prevue™ Ultrasound System and Site~Rite Prevue+™ Ultrasound System Technical Manual





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## 1 Statement of Purpose

This Technical Manual is intended to provide technical specifications for the Site~Rite Prevue™ Ultrasound System and Site~Rite Prevue+™ Ultrasound System. For service requests, call Bard Access Systems' Technical/Clinical Support at (800) 443-3385. Please refer to the IFU for all indications, contraindications, hazards, warnings, cautions, adverse events and indications for use.

## 2 System Overview

### 2.1 Controls and Connections

The hardware is composed of user accessible features on the unit and ultrasound probe connection at the back.

#### 2.1.1 Front/Side Panel

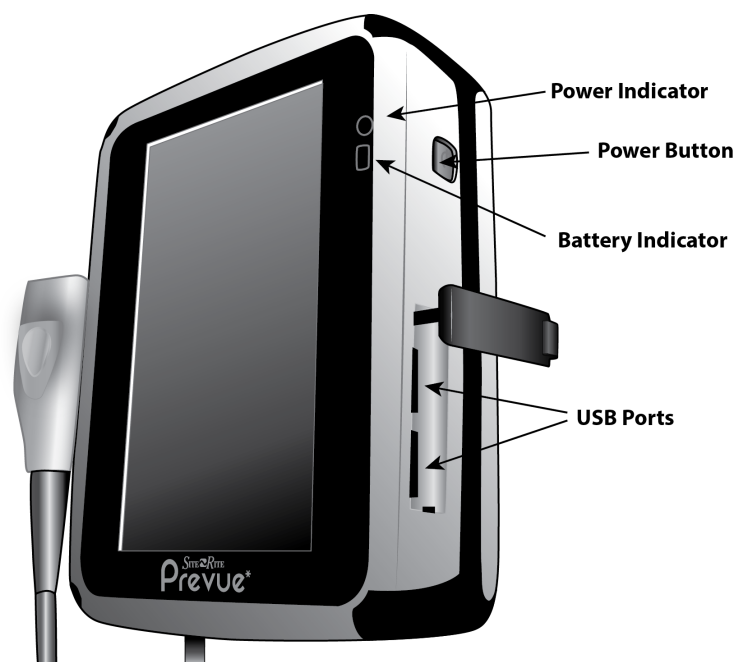


Figure 2.1.1 Front/Side Panel

Press and hold the power button on the display for three seconds to turn the system on or off. The power LED indicates that the system is on when lit. Insert USB flash drive and A/C power adapter into designated ports on the ultrasound display as shown in Figure 2.1.1.

**Note:** In standby mode the system remains powered and battery life will be depleted. Standby mode allows the system to power up into ultrasound imaging more quickly than returning from a full shutdown.

**Note:** Holding the Power Button down for 8 seconds can be used to power the system down via a “Hard” shutdown. Powering the system down in this manner may cause system malfunction and should only be used when appropriate shutdown methods are unavailable.

### 2.1.2 Back Panel

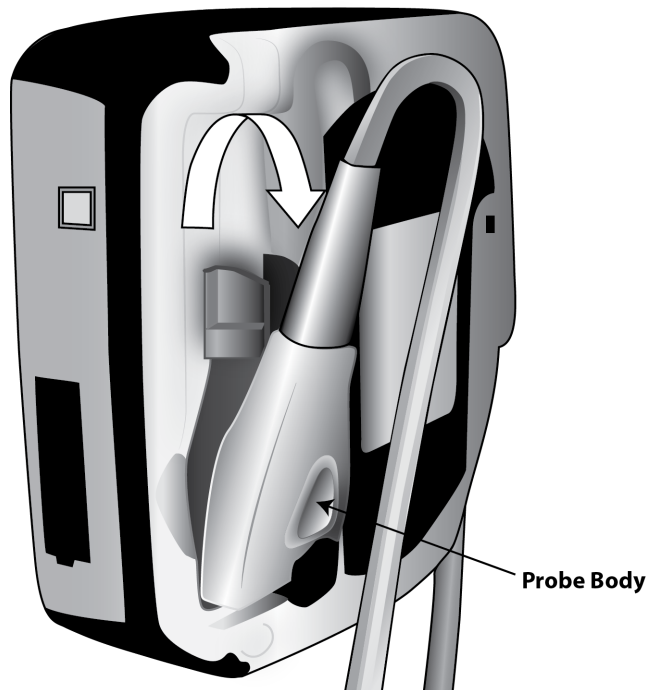


Figure 2.1.2 Back Panel

Hold probe body for insertion/removal as shown in Figure 2.1.2. Do not pull the cable.

## 2.2 Hardware

## 2.2.1 Component Overview

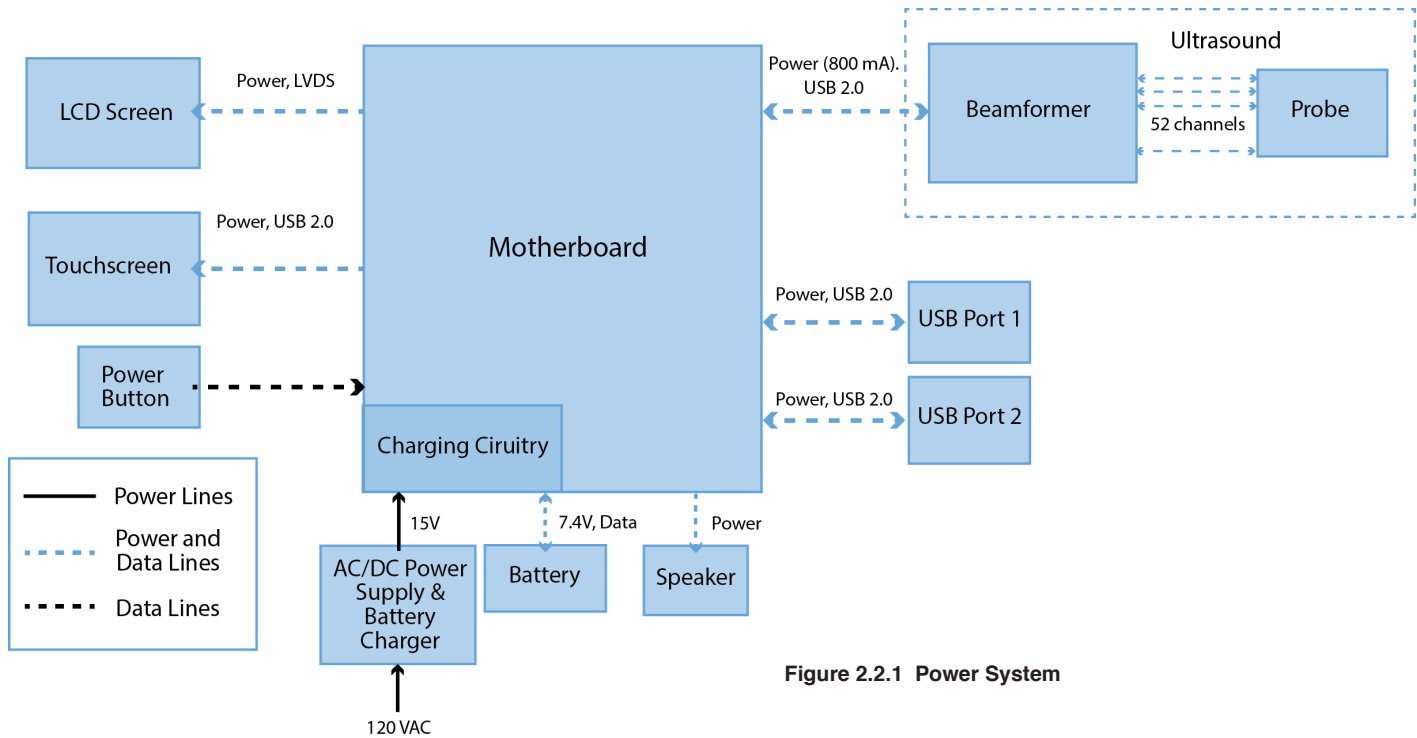


Figure 2.2.1 Power System

The Ultrasound System is composed of several major components as depicted in Figure 2.2.1. See Table 2.2.1 for a functional description.

Table 2.2.1 Major Components of the Ultrasound System

Component	Functional Description	Location
Plastic Housing (Cyclopy Resin)	Contain parts, mechanical support, aesthetics	Exterior
Charging Circuitry	Power management and distribution, battery charging	Within plastic housing. Part of motherboard assembly.
USB Module	USB 2.0	Within plastic housing. Part of motherboard assembly.
Lithium Ion Battery	Power storage, charge status	Within plastic housing, rear enclosure.
Motherboard and Beamformer Platform	Processing, display data, provide user interface, application management	Within plastic housing
Power Button	On / off signal	Switch is directly mounted on the mother board assembly
Touch Screen	Resistive touch	Outermost layer of screen. Mounted on front enclosure.
Probe	52 element 7.5 MHz	PCB board to board connector to the beamformer assembly.

### 2.2.2 System Hardware

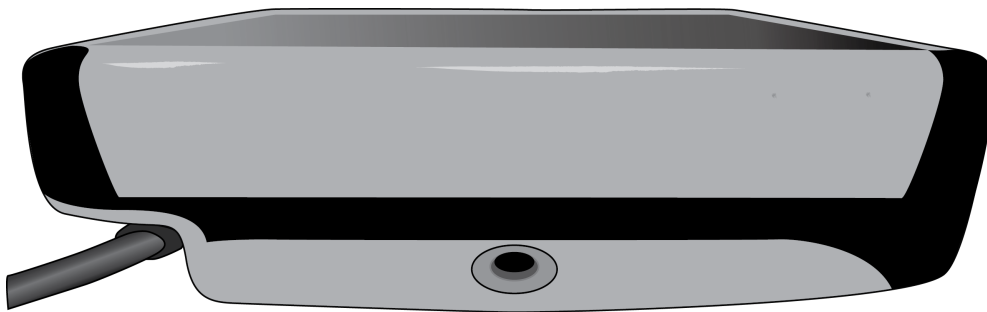
The software needs to interface to the beamformer hardware via USB 2.0 interface to receive the beam formed ultrasound data. The system also supplies power to the beamformer via an internal USB port. The beamformer electronics drive the ultrasound probe. The ultrasound system monitors and displays the remaining battery charge level as well as if the battery is actively charging. The external USB ports interface and power USB flash drives.

### 2.3 Software:

The system runs on a Linux® based operating system. The software consists of an application, the resident platform operating system, and firmware to interface with the hardware. The application software may be updated by following the upgrade directions in the instruction for use.

## 3 Mounting Hardware

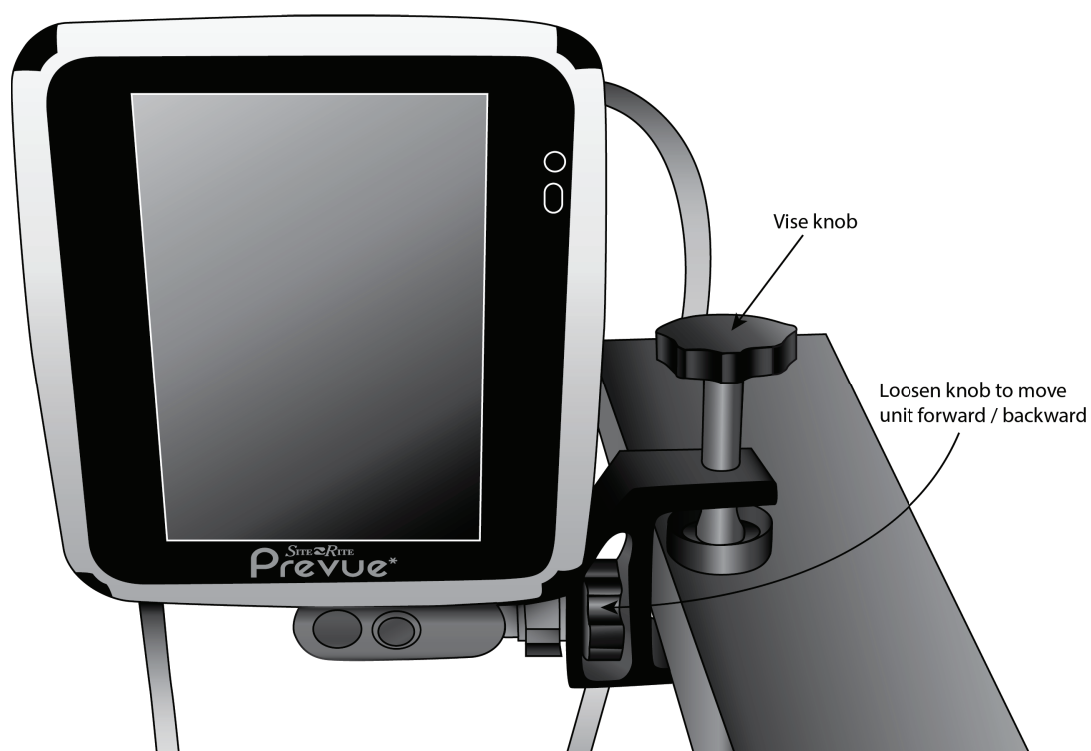
### 3.1 Tripod/Clamp Attachment



Step 1. Locate female attachment location



Step 2. Insert tripod and extend legs for proper balance



OR: Insert clamp and tighten vise for proper balance



## 4 Cleaning and Disinfection

### 4.1 Cleaning Procedure

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

**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 System. Damage to the equipment may occur.

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

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 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.

## 5 Technical Specifications

### 5.1 General Specifications

#### 5.1.1 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)
Dimensions:	5.9" x 4.6" x 2.0" (149 x 117 x 52 mm)
Weight:	2 lbs (0.9 kg)
Power Sources:	Internal battery, AC adapter
Power Consumption:	45 Watts Max
IEC 60601-1:	Class II, Type BF Applied Part, Continuous Operation, Internally Powered Equipment, Not Category AP or APG Equipment, IPX1

### 5.1.2 A/C Adapter Specifications

Manufacturer:	SINPRO
Model Number:	MPU60B-106
Input Voltage:	100-240 VAC, 50/60 Hz
Input Current (Max):	1.60A
Output Voltage:	15V
Output Current (Max):	4.2A

### 5.1.3 System Battery Specifications

Battery Chemistry:	Lithium Ion
System Run Time on Full Charge:	3.0 Hours
Charge Time (Full):	4.0 Hours

## 5.2 EMC Tables

The ultrasound system is intended for use in the electromagnetic environment specified below. The customer or user of the ultrasound system should ensure that it is used in such an environment.

Guidance and Manufacturer's Declaration - Emissions		
Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF Emissions CISPR 11	Group 1	The ultrasound system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.  The 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.
RF Emissions CISPR 11	Class A	
Harmonics IEC 61000-3-2	Class A	
Flicker IEC 61000-3-3	Complies	

**Note:** The 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 ultrasound system or shielding the location.

Guidance and Manufacturer's Declaration – Immunity			
The ultrasound system is intended for use in the electromagnetic environment specified below. The customer or user of the ultrasound system should ensure that it is used in such an environment.			
Immunity Test	EN/IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
ESD EN/IEC 61000-4-2	±6kV Contact ±8kV Air	±6kV Contact ±8kV Air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the relative humidity should be at least 30%.
EFT EN/IEC 61000-4-4	±2kV Mains ±1kV Input/Output Lines	±2kV Mains ±1kV Input/Output Lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN/IEC 61000-4-5	±1kV Differential ±2kV Common	±1kV Differential ±2kV Common	Mains power quality should be that of a typical commercial or hospital environment.
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 ultrasound system requires continued operation during power main interruptions, it is recommended that the ultrasound system be powered from an uninterruptible power supply or battery.
Power Frequency 50/60 Hz Magnetic Field EN/IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

Guidance and Manufacturer's Declaration – Emissions			
The ultrasound system is intended for use in the electromagnetic environment in which radiated disturbances are controlled. The customer or user of the ultrasound system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment and the ultrasound system as recommended below, according to the maximum output power of the communications equipment.			
Immunity Test	EN/IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Conducted RF EN/IEC 61000-4-6  Radiated RF EN/IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz  3 V/m 80 MHz to 2.5 GHz	3 Vrms  3 V/m	Portable and mobile communications equipment should be separated from the ultrasound system by no less than the distances calculated/ listed below:  $D = 1.2 (\sqrt{P})$ $D = 1.2 (\sqrt{P})$ 80 to 800 MHz $D = 2.3 (\sqrt{P})$ 800 MHz to 2.5 GHz  where P is the max power in watts and D is the recommended separation distance in meters.  Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels.  Interference may occur in the vicinity of equipment containing a transmitter.






Recommended Separation Distances between portable and mobile RF Communications equipment and the ultrasound system			
Max Output Power (Watts)	Separation (m) 150 kHz to 80 MHz $D = 1.2 (\sqrt{P})$	Separation (m) 80 to 800 MHz $D = 1.2 (\sqrt{P})$	Separation (m) 800 MHz to 2.5 GHz $D = 2.3 (\sqrt{P})$
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



## 6 Repair and Troubleshooting

There is no periodic or preventive maintenance required for the Site~Rite Prevue™ Ultrasound System or Site~Rite Prevue+™ Ultrasound System, probe or approved accessories. For service information or to return your 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 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.

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.

Power Problem	System will not turn on or powers on but immediately turns off.	<ol style="list-style-type: none"><li>1. Connect system to an A/C outlet for operation and battery recharge.</li><li>2. Press and hold the power button for at least 3 seconds to power on.</li></ol> <p>Note: If error persists, call Customer Service at 1-800-545-0890.</p>
A/C adapter indicator does not change states 	Connection error	<ol style="list-style-type: none"><li>1. Shutdown the system.</li><li>2. Unplug the A/C adapter and plug it back in.</li><li>3. Turn the system on.</li></ol> <p>Note: If error persists, call Customer Service at 1-800-545-0890.</p>
	Can't save an image	<p>The USB Storage device may be full or not an approved USB Storage Device. Replace the USB Storage Device.</p> <p>Note: If error persists, call Customer Service at 1-800-545-0890.</p>
Poor image		<ol style="list-style-type: none"><li>1. Refer to Image Settings, Section 5 of the Instructions for use.</li><li>2. Apply sterile saline to both surfaces of the Pinpoint* Gel Cap.</li><li>3. If error persists, call Customer Service at 1-800-545-0890.</li></ol>

## 7 Disposal Information

To return the ultrasound system for end of life recycling, please contact your nearest Bard 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.



Manufacturer:  
Bard Access Systems, Inc.  
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Salt Lake City, UT 84116 U.S.A.  
(801) 522-5000  
Customer Service: (800) 545-0890  
Technical/Clinical Support: (800) 443-3385  
Fax: (801) 522-4948  
[www.bardaccess.com](http://www.bardaccess.com)

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

Revision date: January 2014

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