

URGENT MEDICAL DEVICE NOTIFICATION

Site~Rite® 8 Ultrasound System

November 4, 2019

Product Description	Catalog No.	Serial Number
Site~Rite® 8 Ultrasound System	9770500	All
Refurbished, Site~Rite® 8 System	9770500R	All
Site~Rite® 8 Ultrasound System	9770501	All
Refurbished Site~Rite® 8 System	9770501R	All
Site~Rite® 8 Ultrasound System	9770550	All
Site~Rite® 8 Ultrasound System	9770552	All
Site~Rite® 8 Ultrasound System	9770553	All
Site~Rite® 8 Ultrasound System	9770554	All
Site~Rite® 8 Ultrasound System	9770555	All
Site~Rite®8 Ultrasound System Console with Connector	9770600	All
Site~Rite®8 Ultrasound System Console with Connector, Refurbished	9770600X	All
Site~Rite®8 Ultrasound System Console with Connector (Remanufactured)	9770600Y	All

For the Attention of: Medical Director, Risk Manager, Medical Device Safety Officer, Nurse Manager

Description of the problem and associated health hazard(s):

BD has become aware of an issue affecting the Battery Status Indicator on Site~Rite® 8 Ultrasound Systems through an increase in complaints. The indicator may show available charge when the battery is close to depletion. As a result, the Site~Rite® 8 has the potential to abruptly shut down, without advance warning to the user, when running on battery power only. This issue will not occur when the unit is plugged into an AC power source, as specified in the Instructions for Use.

Based on statistical analysis, the probability of battery depletion (and therefore abrupt shutdown) increases on systems that have been in service more than 19 months. No adverse events or injuries have been reported.

An abrupt shutdown of the Site~Rite® 8 Ultrasound System may result in an unsuccessful insertion attempt, which would require removal and replacement of the catheter.

BD is currently working on a solution that will enhance the Battery Status Indicator in order to accurately characterize the remaining battery life that will be available by June 2020. Until the issue is resolved, it is recommended that all Site~Rite® 8 Ultrasound Systems be operated using AC power at all times during use in a clinical procedure.

If use of AC power is not practical for your clinical setting, we recommend the use of an external rechargeable battery. The following batteries have been qualified for use with the Site~Rite® 8 Ultrasound System and are available for purchase through common retailers.

Battery Description	Model No.
Vorally - Portable Generator Power Station 173Wh 300W Rechargeable Lithium Battery Pack	ES-300B
Battery Backup Power - Portable Rechargeable Battery Backup UPS 120VAC/400W 12VDC/Solar/CAR 5VDC/2.1A/USB 12V/30AH Capacity	850-0536
CHAFON - Portable Generator 288WH UPS Battery Backup Pack	CF-UPS008

YOU NEED TO TAKE THE FOLLOWING ACTIONS:

1. If you have experienced an abrupt shutdown, please contact 1-800-296-4146 Opt. 1 to coordinate with BD to replace your battery or provide you with an external battery.
2. Please share this medical device notification with all users of the Site~Rite® 8 Ultrasound System at your facility to ensure they are also aware of the issue.
3. Complete the attached Customer Response Form and return to the BD contact noted on the form so that BD may acknowledge your receipt of this notification.
4. If you choose to purchase one of the above batteries independently, please contact BD Customer Service at capital_support@bardaccess.supportsystem.com. Please include a copy of the purchase receipt, BD account number and serial number of affected unit to arrange for reimbursement.
5. If the above batteries are not available, please contact BD Customer Service for additional battery options.

Contact Information:

If you have questions or require further assistance, please contact BD Customer Service:

Contact Information
1-800-290-1689 Monday – Friday between 8:00am and 5:00pm (EST) in the United States.

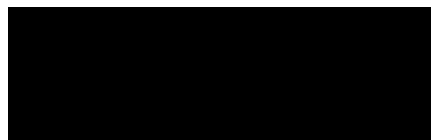
Any adverse health consequences experienced with the use of this product should be reported to BD and may be reported to the FDA's MedWatch Adverse Event Reporting program.

- Web: MedWatch website at www.fda.gov/medwatch
- Phone: 1-800-FDA-1088 (1-800-332-1088)
- Mail: MedWatch, HF-2, FDA, 5600 Fisher's Lane, Rockville, MD 20852-9787

Sincerely,



VP Global Medical Affairs
BD Medication Delivery Solutions



Gail Griffiths
Sr. Director Corporate Regulatory Compliance
BD US Region

Customer Response Form

Site~Rite® 8 Ultrasound System

Please assist BD by promptly returning this form to:

BD
Email: BDRC2@bd.com
Fax No.: 312-949-0227

Facility: _____
Please use full, current facility name. Do not use initials.

Street Address: _____

City: _____ **State:** _____ **Zip:** _____

Contact Person: _____

Telephone No.: _____ **Email Address:** _____

Fax No.: _____

Name:	
Title:	
Signature/Date:	

I have read and understood the contents of this Urgent Medical Device Notification and confirm that all users of the Site~Rite® 8 Ultrasound System in my facility have been informed.

To further assist BD in ensuring that these notices are delivered correctly to individuals in your facility, please indicate if there is a centralized function who is responsible for managing recalls.

No, there is no centralized function responsible for managing recalls

Yes, there is a centralized function responsible for managing recalls

Function/Department Name _____

Contact Person _____

Telephone # _____ Email Address _____