

January 9th, 2019

URGENT: FIELD SAFETY NOTICE – MDS-19-1657

BARD Site~Rite® 8 Ultrasound System

REF: 9770550 (All Serial Numbers)

Type of Action: Advisory

Attention: Clinical Personnel, Risk Managers, Biomedical Personnel

This letter contains important information which requires your **immediate** attention.

Dear valued Customer,

BD is issuing an advisory Field Safety Notice for the BARD Site~Rite® 8 Ultrasound System (REF: 9770550) due to an issue affecting the Battery Status Indicator on the instrument. According to our distribution records your organisation may have received the impacted product.

Description of the Problem

BD has become aware of an issue affecting the Battery Status Indicator on Site~Rite® 8 Ultrasound Systems (REF: 9770550) through an increase in complaints. The indicator may incorrectly show available charge when the battery is near 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, if there is an issue with the battery source, the AC adapter should be connected for operation

Based on statistical analysis, the probability of battery depletion (and therefore abrupt shutdown) increases on systems that have been in service for more than 19 months. No reports of patient injury have been reported associated with the issue. 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.

Immediate action for customer

It is recommended that all Site~Rite® 8 Ultrasound Systems (REF: 9770550) be operated using AC power at all times during use in a clinical procedure, until the corrective action below is implemented.

Corrective Action by BD

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. BD will contact your facility once the enhancement to the Battery Status Indicator is available.

Actions for Customers to take:

1. Circulate this Field Safety Notice to all those within your organisation that may use the BARD Site~Rite® 8 Ultrasound System (REF: 9770550).
 - It is recommended that all Site~Rite® 8 Ultrasound Systems (REF: 9770550) be operated using AC power at all times during use in a clinical procedure, until the corrective action is implemented.
2. If you have further distributed the product, please identify those users and notify them at once of this advisory.
3. Complete the customer response form on page 3 and return it to BDUKFieldAction@bd.com **as soon as possible or no later than January 30th, 2020.**

There is no requirement for customers to return any BARD Site~Rite® 8 Ultrasound System (REF: 9770550) to BD. These products can continue to be used in accordance with the guidance in this safety notice.

Contact Reference Person

If you have any questions about this or are unable to use the AC power exclusively, please contact your local BD representative or the local BD office on +44-(0)1293-606643 or e-mail BDUKFieldAction@bd.com.

We confirm that the appropriate regulatory agencies have been informed of these actions.

BD is committed to advancing the world of health. Our primary objectives are patient safety and user safety and providing you with quality products. We apologise for the inconvenience this situation may cause you and thank you in advance for helping BD to resolve this matter as quickly and effectively as possible.

Sincerely,



William David
Sr. Director, Quality Compliance,
EMEA Quality Compliance
BD Switzerland Sàrl

Customer Response Form - MDS-19-1657

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Please read in conjunction with Field Safety Notice MDS-19-1657 and return the completed and signed form as soon as possible or **no later than the January 30th, 2020** to BDUKFieldAction@bd.com.

By signing below, you confirm this notice has been read, understood and that all recommended actions have been implemented as required.

Account/Organisation Name:	
Department (if applicable):	
Address:	
Postcode:	City:
Contact Name:	
Job Title:	
Contact Telephone Number:	Contact E-mail Address:
Signature:	Date:

This form must be returned to BD before this action can be considered closed for your account.

If different to above, please provide the best contact for BD to communicate the enhancement to the Battery Status Indicator when it is available (June 2020)

Name	Job Title	Telephone	Email