

# URGENT FIELD SAFETY NOTICE



Date of Letter Deployment

GE HealthCare Ref. # 87012

To: Head of Surgical Operations  
Head of Ultrasound Department  
Hospital Administrator / Risk Managers  
Head of Clinical / Biomedical Engineering

RE: **bk3500, bk3000, bk5000 & bkActiv 2300 Ultrasound Devices with battery option**

## Safety Issue

BK Medical, a GE HealthCare company, has become aware of an issue where the internal power connections at the power inlet of the device can come loose for bk3500, bk3000, bk5000 & bkActiv 2300 ultrasound devices with the battery option. In the unlikely event that this goes unnoticed, there is the potential for excessive heat, which could lead to a thermal event or the device becoming inoperable.

There have been no injuries reported as a result of this issue.

## Actions to be taken by Customer/ User

You can continue to use your device by following the instructions below:

Until GE HealthCare implements a permanent correction on your device for this issue, please inspect the power cord connection at the power inlet to the ultrasound device (See Figure 1).

- If a cord retaining bracket is not present, ensure the power cord is fully pushed into the power inlet before each use and while the ultrasound device is charging.
- If a cord retaining bracket is present, no further action is required.



Figure 1: Cord Retaining Bracket

Please ensure all potential staff in your facility are made aware of this safety notification and the recommended actions.

Please complete and return the attached acknowledgement form to [recall.fmi87012@gehealthcare.com](mailto:recall.fmi87012@gehealthcare.com).

Please retain this document for your records.

**Affected  
Product  
Details**

All bk3500, bk3000, bk5000 & bkActiv 2300 Ultrasound Devices with battery option  
GTIN = 05704916000264

INTENDED USE:

The system is a diagnostic ultrasound imaging system used by qualified and trained healthcare professionals for ultrasound imaging, human body fluid flow analysis and puncture and biopsy guidance.

**Product  
Correction**

All affected products will be corrected at no cost to you. A GE HealthCare representative will contact you to arrange for the correction.

**Contact  
Information**

If you have any questions or concerns regarding this notification, please contact GE HealthCare or your local Service Representative at [BKsupport.dk@Gehealthcare.com](mailto:BKsupport.dk@Gehealthcare.com).

GE HealthCare confirms that this notice has been notified to the appropriate Regulatory Agency.

Please be assured that maintaining a high level of safety and quality is our highest priority. If you have any questions, please contact us per the contact information above.

Sincerely,



Laila Gurney  
Chief Quality & Regulatory Officer  
GE HealthCare



Scott Kelley  
Chief Medical & Safety Officer  
GE HealthCare



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**MEDICAL DEVICE NOTIFICATION ACKNOWLEDGEMENT  
RESPONSE REQUIRED**

**Please complete this form and return it to BK Medical a part of GE HealthCare, promptly upon receipt and no later than 30 days from receipt. This will confirm receipt and understanding of the Medical Device Correction Notice.**

Facility Name: \_\_\_\_\_  
Street Address: \_\_\_\_\_  
City/State/ZIP/Country: \_\_\_\_\_  
Customer Email Address: \_\_\_\_\_  
Customer Phone Number: \_\_\_\_\_

By signing this form, we acknowledge receipt and understanding of the accompanying Medical Device Notification, and that we have informed all potential staff and have taken and will take appropriate actions in accordance with that Notification.

**Please provide the name of the individual with responsibility who completed this form.**

Signature: \_\_\_\_\_  
Printed Name: \_\_\_\_\_  
Position/Job Title: \_\_\_\_\_  
Date (DD/MM/YYYY): \_\_\_\_\_

**Please return completed form by scanning or taking a photo of the completed form and email to: [recall.fmi87012@gehealthcare.com](mailto:recall.fmi87012@gehealthcare.com)**  
**You may obtain this e-mail address through the QR code below:**

