

URGENT FIELD SAFETY NOTICE



Date of Letter Deployment

GE HealthCare Ref. # 87013

To: Hospital Administrators / Risk Managers
Biomedical Engineering
Head of Surgical Ultrasound Department

RE: Flex Focus, bkSpecto, bk3000, bk3500, bk5000, and bkActiv Ultrasound Systems with battery

Safety Issue GE HealthCare has become aware that the Instructions for Use within the user guide and service manual do not adequately state the required battery replacement intervals, end-of-life handling procedures, or general battery safety precautions. This lack of guidance could result in delayed battery replacement, improper handling, or continued use of degraded batteries, potentially increasing the risk of a system malfunction or in rare cases smoke or fire.

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:

1. Review and follow the applicable addendums to the Instructions for Use and the updated Service Manuals. The Addendums and Service Manuals are available for download at: <https://www.gehealthcare.com/support/manuals>
 - a. Enter the addendum number or service manual number applicable to your product in the search bar:

| Ultrasound System Type | Addendum Number | Service Manual Number |
|---|-----------------|-----------------------|
| 1202 Flex Focus carts models UA1214 & UA1814 | 5996949 | 5997076 |
| 1300 Ultrasound System, bkSpecto w/battery | 5996950 | 5997076 |
| bk3000 Ultrasound System w/battery bk3500 Ultrasound System w/battery bk5000 Ultrasound System w/battery 2300 Ultrasound System, bkActiv w/battery | 5996948 | 5997076 |

Table 1 – Electronic User Guide Addendums

- b. Filter by language
 - c. Click 'Download' to open the file in your browser.
2. Follow the conditions defined within the addendum and Service Manual applicable to your product for further instructions.
3. Place the applicable addendum and Service Manual with your existing product Instructions for Use.

4. If you have difficulty accessing the documentation or require a printed copy of the applicable addendum or Service Manual, please contact a GE HealthCare Service Representative for assistance.

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

Please retain this document for your records.

Please complete and return the attached acknowledgement form to recall.fmi87013@gehealthcare.com.

Affected Product Details

The following six Ultrasound Systems with batteries are affected:

1. 1202 Flex Focus cart models UA1214 (GTIN 05704916001056) and UA1814 (GTIN 05704916001087) used with:

- Flex Focus 200
- Flex Focus 300
- Flex Focus 400
- Flex Focus 500
- Flex Focus 700
- Flex Focus 800

Note: 1202 Flex Focus cart models UA1210, UA1283 and UA1810 are not affected.

See Figure 1 below for how to identify that your Flex Focus system is equipped with batteries.

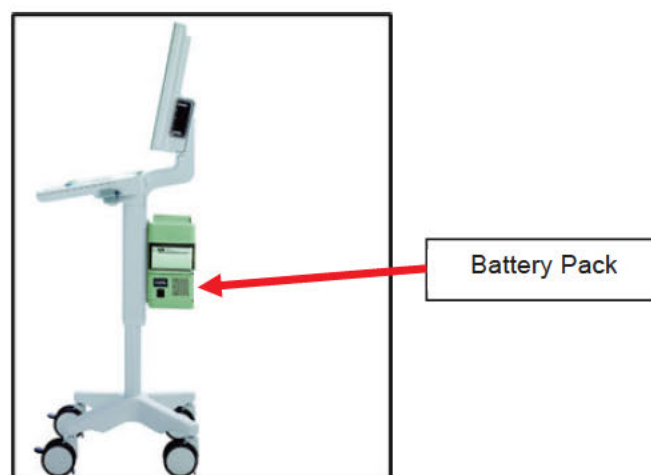


Figure 1 – Battery Pack on 1202 Flex Focus cart models UA1214 and UA1814

2. 1300 Ultrasound System, bkSpecto w/battery
(Model No. 1300-21 or 1300-S1, GTIN 05704916001285)

See Figure 2 for how to identify that your system is equipped with batteries. Locate the 1300-21 or 1300-S1 model number (3) on the system label placed on the rear monitor.

Additional information includes Ref. type number (1), serial number (2), production date (4), GTIN (5), production date (6) and serial number (7).

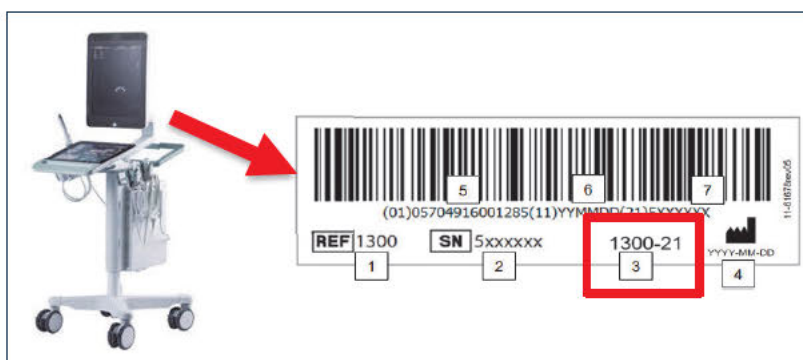


Figure 2 – 1300 Ultrasound System, bkSpecto w/battery, Product Label

3. bk3000 Ultrasound System w/battery

See Figure 3 for how to identify that your system is equipped with batteries (Model No. 2300-11, GTIN 05704916000264)

4. bk3500 Ultrasound System w/battery

See Figure 3 for how to identify that your system is equipped with batteries (Model No. 2300-41, GTIN 05704916000264)

5. bk5000 Ultrasound System w/battery

See Figure 3 for how to identify that your system is equipped with batteries (Model No. 2300-61, GTIN 05704916000264)

6. 2300 Ultrasound System, bkActiv w/battery

See Figure 3 for how to identify that your system is equipped with batteries (Model No. 2300-66, GTIN 05704916000264)



Figure 3 – bk3000, bk3500, bk5000, bkActiv

Intended Use:

These systems are diagnostic ultrasound imaging systems used by qualified and trained healthcare professionals for ultrasound imaging, human body fluid flow analysis and puncture and biopsy guidance.

Product Correction GE HealthCare is providing updated Instructions for Use addendums and updated Service Manuals with specific instructions regarding battery safety.

Contact Information If you have any questions or concerns regarding this notification, please contact GE HealthCare or your local Service Representative.

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,



**MEDICAL DEVICE NOTIFICATION ACKNOWLEDGEMENT
RESPONSE REQUIRED**

Please complete this form and return it to 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.

There are two options for your convenience:

- 1) Electronic response form (this page)

OR

- 2) Manual filled and scanned response form (next page)

Electronic response form

Please scan the QR code or follow the link below to complete the form

<https://buildsmart.capgemini.com/esurveys/takesurvey/18446744073712236296>



Manual filled and scanned response form

GE HealthCare Ref. # 87013

Alternatively, if the workflow on the previous page is not possible, please complete this form and return it to 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 users 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.fmi87013@gehealthcare.com
You may obtain this e-mail address through the QR code below

