URGENT FIELD SAFETY NOTICE

GE HealthCare

Date of Letter Deployment

GE HealthCare Ref. # 87010

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

RE: **Dual Live Compare Measurement Error on bkActiv 2300 Ultrasound Systems**

Safety Issue

BK Medical, a GE HealthCare company, has become aware of an issue with the Dual Live Compare feature on the bkActiv system which could result in a measurement error. If the scanning depth on the Live image is different than the Stored image, an error could result when making measurements with the system.

This issue was found during internal testing. There have been no reports of injury as a result of this issue.

Actions to be taken by Customer/ User

You can continue to use your ultrasound system.

Before using the Dual Live Compare, consult the bkActiv User Manual 16-0126278, Chapter 6 – Working with the Image. When performing measurements using this feature, ensure that the scanning depth in the Live image is the same as in the Stored image as described in Figure 1.

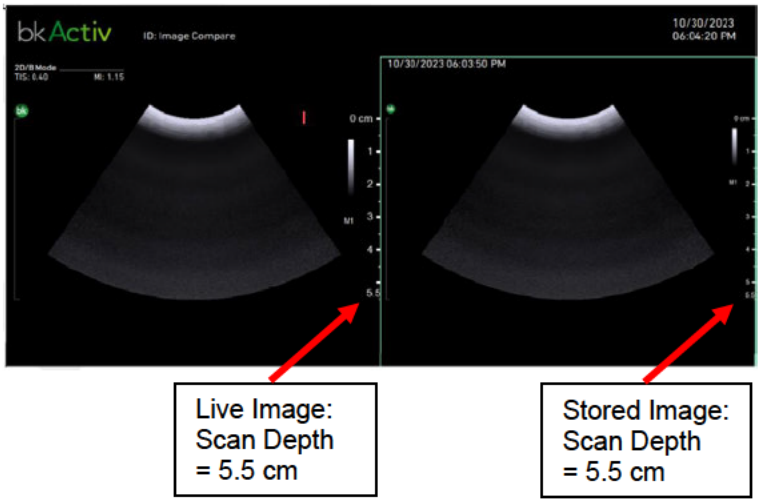

Figure 1. bkActiv screen during Dual Live Compare. Same scanning depth is used on Live image (left panel) and Stored image (right panel)

Ensure all potential users in your facility are made aware of this correction notification and the recommended actions.

Complete and return the attached acknowledgement form to FMI.87010@ge.com. Please retain this document for your records.

Affected Product Details

All bkActiv (2300-56 and 2300-66) Ultrasound systems. See attached appendix for a list of affected serial numbers.

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

BK Medical, a GE HealthCare company, will correct all affected products at no cost to you. A BK Medical representative will contact you to schedule a service visit to correct this issue.

Contact Information

If you have any questions or concerns regarding this notification, please contact your local BK Medical Representative at bkservice.uk@ge.com.

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,

GE HealthCare

GE HealthCare Ref. # 87010

MEDICAL DEVICE NOTIFICATION ACKNOWLEDGEMENT
RESPONSE REQUIRED

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

*Customer/Consignee Name: _____

Street Address: _____

City/State/ZIP/Country: _____

*Customer Email Address: _____

*Customer Phone Number: _____

☐ We acknowledge receipt and understanding of the accompanying Medical Device Notification, and that we have informed appropriate 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: _____

*Title: _____

*Date (DD/MM/YYYY): _____

*Indicates Mandatory Fields

Please return completed form by scanning or taking a photo of the completed form and email to: FMI.87010@ge.com. **You may obtain this e-mail address through the QR code below:**

APPENDIX

bkActiv (2300-56) Ultrasound systems Affected Serial Numbers						
2000757	2001990	2002262	2002678	2003846	2004489	2004743
2001014	2001991	2002263	2002936	2003858	2004490	2004753
2001016	2001992	2002347	2002938	2003868	2004493	2004755
2001158	2001993	2002348	2002942	2003876	2004495	5016038
2001337	2001994	2002349	2003032	2003882	2004507	5016043
2001338	2001995	2002351	2003159	2003926	2004511	5016045
2001340	2001996	2002353	2003160	2003929	2004512	5016051
2001342	2001997	2002354	2003161	2003937	2004522	5016054
2001344	2002054	2002355	2003164	2003941	2004525	5016055
2001719	2002055	2002356	2003246	2003946	2004538	5016285
2001722	2002056	2002358	2003247	2003951	2004561	5016350
2001723	2002057	2002359	2003248	2003953	2004626	5016362
2001726	2002059	2002360	2003249	2003955	2004653	5016365
2001738	2002061	2002363	2003250	2003964	2004655	5016367
2001739	2002062	2002364	2003251	2003970	2004663	5016369
2001740	2002255	2002669	2003252	2004408	2004694	5016496
2001742	2002257	2002673	2003254	2004469	2004714	-
2001746	2002259	2002674	2003795	2004473	2004729	-
2001747	2002260	2002675	2003840	2004476	2004736	-
2001989	2002261	2002677	2003845	2004488	2004739	-

bkActiv (2300-66) Ultrasound systems Affected Serial Numbers						
2001060	2002113	2002818	2003890	2004407	2004632	2004738
2001061	2002114	2002819	2003893	2004409	2004633	2004745
2001359	2002115	2002820	2003894	2004415	2004636	2004746
2001360	2002116	2003033	2003895	2004447	2004642	2004748
2001362	2002117	2003166	2003896	2004448	2004652	2004749
2001364	2002118	2003167	2003897	2004449	2004654	2004752
2001366	2002119	2003170	2003906	2004450	2004664	2004789
2001368	2002120	2003171	2003909	2004451	2004667	2004957
2001729	2002121	2003172	2003917	2004452	2004670	2004962
2001732	2002122	2003173	2003942	2004456	2004685	2005168
2001733	2002256	2003174	2003957	2004459	2004686	2005192
2001735	2002264	2003175	2003958	2004462	2004692	5016272
2001736	2002361	2003286	2003959	2004474	2004695	5016374
2001737	2002556	2003287	2003962	2004477	2004696	5016415
2001998	2002557	2003288	2003963	2004482	2004700	5016416
2001999	2002558	2003293	2004012	2004485	2004712	5016428
2002000	2002559	2003294	2004053	2004527	2004713	5016429
2002001	2002562	2003295	2004363	2004529	2004719	5016430
2002002	2002563	2003776	2004364	2004539	2004720	5016482
2002003	2002564	2003777	2004365	2004541	2004725	-
2002004	2002565	2003859	2004366	2004559	2004731	-
2002005	2002814	2003862	2004368	2004560	2004732	-
2002006	2002815	2003881	2004387	2004622	2004735	-
2002007	2002816	2003883	2004390	2004627	2004737	-