



URGENT FIELD SAFETY NOTICE

GE Healthcare

3000 N. Grandview Blvd. - W440
Waukesha, WI 53188, USA

<Date of Letter Deployment>

GEHC Ref# 74077, 74078, 74079

To: Hospital Administrators /Risk Manager
Biomedical Engineering
Head of Primary Care Ultrasound Department

RE: **Increased temperature in the probe-head surface with LOGIQ P5 Model BT06/BT08 and LOGIQ A5 BT08 scanners when used in specific types of scans and with specific probes.**

This document contains important information for your product. Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions. Please retain this document for your records.

Safety Issue In rare instances, if a certain component fails, there is a potential of increased temperature in the probe-head surface when using these scanners with specific probes. This could result in a burn to the patient in specific types of scans.

Safety Instructions To mitigate this potential risk, GE recommends discontinuing scanning patients in Endocavitary (transvaginal and transrectal), Surgical, and Neonatal exams. In addition, discontinue use of E8C, ERBC, ERBL, 4DE7C, BE9C, 4D8C, 8C, 7S, 9L, 10L, 12L, 5S and 5Sp probes.

You can continue to use your scanner with all other probes in non-affected applications

Affected Product Details LOGIQ P5 Model BT06/BT08 and LOGIQ A5 BT08 systems

Product Correction GE Healthcare will correct all affected products 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 Service or your local Service Representative.

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 immediately per the contact information above.

Sincerely,

A handwritten signature in black ink, appearing to read "JDennison".

James W. Dennison
Vice President - Quality Assurance
GE Healthcare

A handwritten signature in black ink, appearing to read "JHersh".

Jeff Hersh, PhD MD
Chief Medical Officer
GE Healthcare



**FIELD SAFETY NOTICE 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 Ref# 74077, 74078, 74079.

Customer/Consignee Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Email Address: _____

Phone Number: _____

We acknowledge receipt and understanding of the accompanying Medical Device Notification, and that we have taken and will take appropriate actions in accordance with that Notification.

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

Signature: _____

Printed Name: _____

Title: _____

Date (DD/MM/YYYY): _____

Please return completed form to FAX NUMBER: +82-(0)31-740-6435, or scanning or taking a photo of the completed form e-mailing to: GEUK.recall@ge.com

You may obtain this e-mail address through the QR code below:

