URGENT MEDICAL DEVICE CORRECTION

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

December 28, 2018

GEHC Ref# 74075, 74076

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

RE: Increased temperature in the probe-head surface with LOGIQ P6 Model BT07 and BT09 scanners when used in specific types of scans and with specific probes.

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

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, E8CS, BE9C, BE9CS, 4DE7C, i12L, 8C, 4D8C, 7S, 5S, and 5Sp probes. You can continue to use your scanner with all other probes in non-affected applications
Affected Product Details	LOGIQ P6 Model BT07 and BT09 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 at 1-800-437-1171 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 immediately per the contact information above.

Sincerely,

James W. Dennison
Vice President - Quality Assurance
GE Healthcare

Jeff Hersh, PhD MD
Chief Medical Officer
GE Healthcare