URGENT MEDICAL DEVICE CORRECTION

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

<Date of Letter Deployment>

GEHC Ref# 70220

To: Hospital Administrators /Risk Manager
Biomedical Engineering
Head of Primary Care Ultrasound Department
Chairman Medical Board and Relevant Head of Departments for hospital

RE: **LOGIQ E10 Ultrasound Systems combined with TEE probes**

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

Safety Issue	LOGIQ E10 ultrasound systems shipped between April and July 2018 have the potential for an undetected over temperature condition on the trans-esophageal (TEE) probe, leading to a possible burn injury. No TEE probes have shipped with the impacted LOGIQ E10 systems. To date there have been no injuries reported due to this issue.
Safety Instructions	Do not use a TEE probe (GE model 6Tc-RS) from another device on the LOGIQ E10 system until your LOGIQ E10 is corrected. You may scan normally with any other probes.
Affected Product Details	LOGIQ E10 ultrasound systems installed between April and July 2018.
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.

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,

[redacted]

James W. Dennison
Vice President - Quality Assurance
GE Healthcare

[redacted]

Jeff Hersh, PhD MD
Chief Medical Officer
GE Healthcare