URGENT MEDICAL DEVICE CORRECTION

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

GEHC Ref# 70219

<Date of Letter Deployment>

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

RE: Power cord failure and replacement on Vivid and LOGIQ ultrasound systems

Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions. Your safety and the safety of your patients is of our utmost concern.

Safety Issue
The system side of the power cord may break and expose the electrical conductors leading to the risk of shock. This can lead to injuries up to and including cardiac arrhythmia or cardiac arrest. A minor injury has been reported as a result of this issue.

Safety Instructions
You may continue to use your system. If you need to remove the power cord from the rear of the unit (see picture of location below), before doing so be sure to do the following:

1. Turn the system off
2. Unplug it from the wall

If the system end of the power cord (see picture below) is damaged, discontinue use of the system until a replacement cord is provided. If you experience any power issues with your unit, discontinue use of the system and contact GEHC Service.

Location of power cord in rear of unit.

Affected Product Details
LOGIQ 9, LOGIQ E9, Vivid 7, Vivid E7, Vivid E9, Vivid E80, Vivid E90, and Vivid E95 ultrasound systems which have been installed since April 2015 or which have received a power cord replacement since April 2015.
GE Healthcare will correct all affected products at no cost to you. A GE Healthcare representative will contact you to arrange for the correction.

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

8004292222  SaudiArabiaServiceCenter@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 immediately per the contact information above.

Sincerely,

[Signature]

Jeff Hersh,
PhD  MD
Vice President – Quality & Regulatory
Chief Medical Officer – Medical Safety
GE Healthcare