

## **URGENT MEDICAL DEVICE CORRECTION**

**GE** Healthcare

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

<Date of Letter Deployment>

**GEHC Ref# 70219** 

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.

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.

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,