



URGENT MEDICAL DEVICE CORRECTION

GE Healthcare

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

<Date of Letter Deployment>

GEHC Ref# 70219

To: Chairman Medical Board and relevant Head of Departments
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.

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 & Regulatory
GE Healthcare



Jeff Hersh, PhD MD
Chief Medical Officer – Medical Safety
GE Healthcare