



URGENT MEDICAL DEVICE CORRECTION

GE Healthcare

Healthcare Systems
9900 Innovation Drive
Wauwatosa, WI 53226
USA

November 2013

GEHC Ref# 76135

To: Hospital Administrators / Risk Manager
Biomedical Engineering
Managers of Radiology / Managers of Cardiology

RE Vivid E9 keyboard response time

GE Healthcare has recently become aware of a potential safety issue where the keyboard response time on the system may increase, and possibly eventually result in the system being locked up. Note that the safety concern only relates to Vivid E9 4D systems of specific software versions within serial numbers in the range given below, and only when used together with the 4D TEE (6VT-D) probe for certain types of procedures. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Safety Issue During procedures where the 4D TEE (6VT-D) probe is used over an extended period of time, the Vivid E9 Scanner may gradually become unresponsive with the result that the Vivid E9 Scanner must be rebooted. This event may lead to possible risk to patients, when performing Transesophageal echocardiography (TEE).

Safety Instructions If you observe an increase in the system response time and the system becomes unresponsive, please reboot the scanner. The approximate reboot time is 2 minutes.

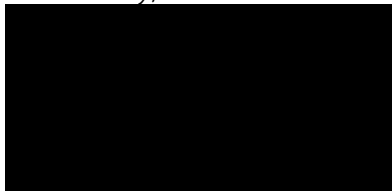
Affected Product Details Vivid E9 with software versions 112.1.0, 112.1.1, and 112.1.3 with affected serial numbers between VE94165 and VE95415, using a GE transesophageal echocardiography probe under the operating condition mentioned above, are affected.

Product Correction GE Healthcare will provide a correction that will be installed by a GE service engineer. This correction will be provided at no cost to you.

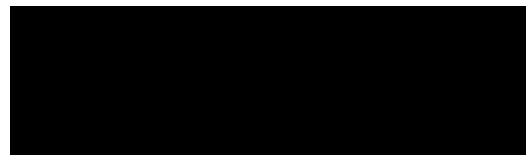
Contact Information If you have any questions or concerns regarding this issue, please contact your local GE Healthcare service representative

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,



Vice President QARA
GE Healthcare Systems



Chief Medical Officer
GE Healthcare