



URGENT MEDICAL DEVICE CORRECTION

GE Healthcare

9900 Innovation Drive
Mail Stop: RP2130
Wauwatosa, WI 53226
USA

August 17, 2009

To: Hospital Administrators / Risk Managers
Managers of Radiology/Cardiology
Radiologists/Cardiologists

RE: **Innova® 2121^{IQ}, 3131^{IQ}, 2100^{IQ}, 3100^{IQ} and 4100^{IQ} cardiovascular x-ray imaging systems with GE Fluoro UPS 20KVA**

GE Healthcare has become aware of a potential issue regarding Innova systems with GE Fluoro UPS 20KVA that may impact patient safety. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

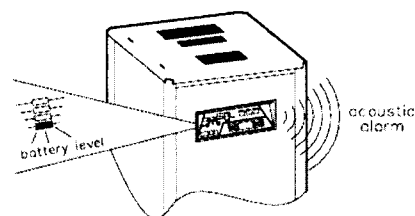
Safety Issue GE Fluoro UPS 20KVA (Uninterrupted Power Supply) is used to maintain fluoroscopy availability for approximately 5 minutes should there be a main power failure. Once power is restored, the equipment power will be returned to the main hospital power.

UPS fluoro battery degradation could occur due to long storage conditions impacting the life expectancy of sealed cell batteries. The fluoro UPS could be potentially unavailable if it is not periodically maintained as prescribed in the service documentation and Operator Manual delivered with the Innova system.

Affected Product Details All GE Fluoro UPS 20KVA associated with Innova 2121^{IQ}, 3131^{IQ}, 2100^{IQ}, 3100^{IQ} and 4100^{IQ} cardiovascular x-ray imaging systems manufactured from November 2005 to June 2009.

Safety Instructions Please verify the battery level and check for the presence of any audible alarm on the UPS front panel. Report any malfunction to a GE Healthcare service representative.

On a monthly basis, please verify the fluoro UPS functionality by turning off the input power and ensuring the availability of fluoroscopy.



As stated in the Operator Manual delivered with the Innova system, the hospital should establish emergency workflow procedures to ensure patient safety should a component stop operating during a patient examination.

- Product Correction**
1. A GE Healthcare service representative will contact you to arrange for the GE Fluoro UPS inspection and correction where necessary at no cost to you.
 2. If your Innova system is under a GE Healthcare service contract, the UPS fluoro preventive maintenance coverage will be added to the contract, if it is not yet included.
 3. If your Innova system is not under a GE Healthcare service contract, please verify that the Fluoro UPS is maintained with a frequency in accordance with the GE Healthcare service documentation and Operator Manual delivered with the Innova system.

**Contact
Information**

Call Center phone numbers:

United States: 800 437 1171, option 4

Japan: 0120 - 055 - 919

For other countries, please contact your local GE Healthcare Service Representative if you have any questions or concerns regarding this notification.

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.

Sincerely,



Senior Executive QARA
GE Healthcare Systems
9900 Innovation Drive
Mail Stop: RP2130
Wauwatosa, WI 53226
USA
_____.@ge.com