GE Healthcare

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Certified Mail Return Receipt Requested

URGENT RECALL NOTICE

PLEASE TAKE ACTION TO INFORM ALL USERS OF THE RELEVENT SYSTEM(S) OF THESE ISSUES AND HOW TO ADDRESS THEM

April 13, 2007

To: **Hospital Administrator**
Director/Manager of Radiology

Subject: **Product Safety Issues**

Affected Products: **OEC® 9900 Elite, OEC®, 9900 Elite*MD* Motorized C-arm System, OEC® OEC® 9900 Elite*NAV* , FlexiView 8800 Mobile C-Arm, OEC® Miniview 6800, OEC® UroView 2800, OEC® 9800, OEC® FluoroTrak 9800 Plus, OEC® 9800 Plus, OEC® 9800MD Motorized C-arm System**

Our records indicate that your facility has one or more of the following GEHC OEC products:

- OEC® 9900 Elite
- OEC® 9900 Elite*MD* Motorized C-arm System
- OEC® 9900 Elite*NAV*
- FlexiView 8800 Mobile C-Arm
- OEC® Miniview 6800
- OEC® UroView 2800
- OEC® 9800
- OEC® FluoroTrak 9800 Plus
- OEC® 9800 Plus
- OEC® 9800*MD* Motorized C-arm System

GE Healthcare previously identified and communicated intermittent potential safety issues that may occur with the products listed above. The details and symptoms of these issues, as well as the associated interim solutions, were described in the Recall Notification dated November 8, 2006. **As the result of the investigation of a reported incident, we are updating item 3 of that notification as follows:**

Incorrect Image Display:

Affected Products: OEC® 9900 Elite, OEC®, 9900 Elite*MD* Motorized C-arm System, OEC® OEC® 9900 Elite*NAV* , FlexiView 8800 Mobile C-Arm, OEC® Miniview 6800, OEC® UroView 2800, OEC® 9800, OEC® FluoroTrak 9800 Plus, OEC® 9800 Plus, OEC® 9800MD Motorized C-arm System

When the image directory is accessed and thumbnail images are used to recall patient images, incorrect images may be displayed or there may be an inability to locate images on the system. The actual images may display **incorrect** patient information and may be located within another patient's file.

Interim Solution:

Solutions to eliminate this issue are under investigation by GEHC OEC. To reduce the occurrence of this issue, users should follow the correct power down procedure. The power down procedure is described in the Operators Guide and on the supplemental stickers previously sent to your facility in November 2006.

Users are advised to exercise caution in using the system by verifying that the image displayed is consistent with current examination and patient being reviewed until a comprehensive and permanent solution has been developed.

GEHC OEC is actively working on solutions that will permanently resolve this issue. When a solution becomes available GEHC OEC will contact you and without charge, remedy this issue.

If you have any questions or concerns regarding these issues, please do not hesitate to contact the service team for further information at 800-874-7378 option 8. Information is available at this number 24 hours per day, 7 days a week.

Thank you,

Pete McCabe
President and CEO