



GE Healthcare

Pete McCabe
President and CEO
GE Healthcare, Surgery
384 Wright Brothers Drive
Salt Lake City, Utah 84116
U.S.A.
Pete.mccabe@ge.com

Certified Mail Return Receipt Requested

IMPORTANT- ELECTRONIC PRODUCT RADIATION WARNING

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

July 11, 2007

To: Hospital Administrator
Director/Manager of Radiology

Subject: Product Compliance Issue

Affected Products: OEC® Miniview 6800

Our records indicate that your facility currently has an **OEC® Miniview 6800**.

GE Healthcare has identified an issue affecting the **OEC® Miniview 6800**

The details and symptom of the issue, as well as the associated solution is outlined below.

Incorrect X-ray Source Label:

An issue has been discovered that results in the x-ray source label on the **OEC® Miniview 6800** required by 21 CFR 1020.32(h) (2) being incorrect. This label does not affect the functionality of your system and is for informational purposes only.

Your GEHC OEC service representative will be contacting you in the near future to arrange for installation of the correct label on your system as well as providing an update to the user manual to reflect the revised label.

If you have any questions or concerns regarding these issues, please do not hesitate to contact the GEHC OEC 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