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President and CEO  
GE Healthcare, Surgery  
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**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

August 20, 2007

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

**Subject:** Product Compliance Issue

**Affected Product:** OEC® 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 us at the toll-free number + 800 41 14 14 41 or + 33 (0) 1 30 83 11 42 if not applicable to your country. Information is available at this number from 9 a.m. to 5 p.m. (Central European Time) Mondays to Fridays.**

Thank you,

[Redacted signature]

[Redacted name]

President and CEO