



GE Healthcare

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**

February 14, 2008

FMI 15082

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

Subject: Product Safety Issues

Affected Products: OEC® 7700, OEC® 7600

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

- OEC® 7700
- OEC® 7600

GE Healthcare Surgery has identified a potential safety issue with the systems listed above.

If your facility is receiving this notification, our records indicate that your OEC®7700 or OEC® 7600 may be affected this issue.

The design of the OEC 7600 and some OEC 7700s may have resulted in a compromising of the primary barrier at the rear of the camera portion of the unit on your system. A potential exists for insufficient stray radiation control measures, this could result in additional unwanted x-ray exposure to the operator and/or staff in the immediate vicinity of the imaging assembly.

- The system may be non compliant with the maximum primary barrier leakage radiation provisions of 21CFR 1020.32 (a)

Internal testing by GEHC Surgery has determined that while the system may be non-compliant to 21CFR 1020.32 (a), this non-compliance would have minimal impact on the radiation exposure to the operator, staff or patient and does not result in a significant additional radiation hazard to the operator, staff or patient. **At this time GEHC Surgery is not recommending that this device be removed from service.**

Solution:

GEHC Surgery is working on a corrective solution at this time. Once a solution is available, it will be provided at no charge to your facility. GEHC Surgery will be contacting your facility as soon as the correction is available to arrange for installation.

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
GE Healthcare Surgery



Maria Frame
Vice President Quality and Regulatory Affairs
GE Healthcare Surgery