



GE Healthcare

GE Healthcare, Surgery
384 Wright Brothers Drive
Salt Lake City, Utah 84116
U.S.A.

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**

January 8, 2008
FMI: 15057; 15087

To: Director/Manager of Radiology
Subject: Product Safety Issues

Affected Products: OEC® 9900 Elite, OEC® 9900 EliteMD Motorized C-arm; OEC® 9900 EliteNAV

Our records indicate that your facility has one or more **OEC® 9900** Elite fluoroscope products:

- **OEC® 9900 Elite**
- **OEC® 9900 EliteMD Motorized C-arm**
- **OEC® 9900 EliteNAV**

GE Healthcare Surgery has identified a potential safety issue with these of these fluoroscopic units.

If your facility is receiving this notification our records indicate that your OEC®9900 Fluoroscope may be affected.

Changing the Anatomical Profile:

A software design defect in the 9900 Elite fluoroscope results in the failure to apply the EER (Entrance Exposure Rate) mA limits calibration to the automatic exposure rate control system when the anatomical profile mode is changed from the default selection to another selection. (Manual technique modes are not affected.) In a small number of fluoroscopic units, this can result in a failure to comply with the 20 R/minute limit in High Level Fluoroscopic operation, by a small margin, as regulated by 21CFR 1020.32 (d) (federal regulation). The maximum EER is typically less than 5% above this limit on the affected systems.

GEHC Surgery has determined that this noncompliance has marginal impact on the amount of radiation to the user or patient and does not pose a significant increase to patient or user radiation exposure hazards.

Interim Solution:

The number of OEC 9900 C-arms affected by this defect is very limited. The user can ensure the application of the Entrance Dose Limits profile by selecting the LOW DOSE mode on the C-arm control panel, and then returning to STANDARD DOSE mode after the **Anatomical Profile** is changed. This will restore the Entrance Dose Limits profile. This procedure should be repeated each time an anatomical profile is changed after system startup.

NOTE: It is not necessary to perform this step if imaging profiles (anatomical profiles) are not changed after system Start-up.

Permanent 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 Assurance and Regulatory Affairs
GE Healthcare, Surgery