



Fax-Back Acknowledgement Requested

IMPORTANT ELECTRONIC PRODUCT RADIATION WARNING

PLEASE TAKE ACTION TO INFORM ALL USERS OF THE RELEVANT SYSTEM(S) OF
THIS ISSUE AND HOW TO ADDRESS

November 6, 2009

FMI 15100

To: Hospital Administrator
Director/Manager of Radiology

Subject: Radiation Regulatory Compliance Issue

Affected Products: OEC® 9900 ESP and OEC 9900 GSP

Our records indicate that your facility currently has an **OEC® 9900 ESP** or an **OEC 9900 GSP** C-arm that may be affected by the issue described below.

Displayed Air Kerma Rate

A software defect has been discovered that may result in a FALSE indication and warning on the OEC 9900 Workstation and C-arm display that the X-Ray tube Anode is over-heated (The 5 Minute Exposure Timer will Alarm prematurely and ANODE HOT - 179% Warning will intermittently flash on the C-Arm LED Display).

This will also cause the displayed cumulative air kerma to be inaccurate. The Dose Summary Screen will also display an inaccurate calculation of the patient's cumulative X-ray exposure.

This is in violation of 21CFR1020.32 (k)(6) that states:

The displayed AKR and cumulative air kerma shall not deviate from the actual values by more the +/-35% over the range of 6mGy/min and 100 mGy to the maximum indication of AKR and cumulative air kerma, respectively. Compliance shall be determined with an irradiation time of greater than 3 seconds.

Interim Solution:

If the software defect occurs (as described above), the cumulative air kerma may be reset by beginning a new exam or by re-booting the system. Always follow normal power-down procedures.

Permanent Solution:

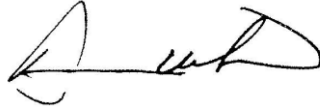
Your GEHC OEC service representative will be contacting you in the near future to arrange for the installation of the corrective software at no charge to you. Until your system has had the corrective software installed, please exercise caution in monitoring the cumulative air kerma when using your system.

If you have any questions or concerns regarding this issue, 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
GE Healthcare, Surgery



Doug Uelmen
Vice President, Quality Assurance and Regulatory Affairs
GE Healthcare, Surgery