



GE Healthcare

Surgery

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URGENT FIELD SAFETY NOTICE

January 15, 2013

Ref: 15109

To: Hospital Administrator
Director/Manager of Radiology

Subject: Completion of a Medical Device Correction for the OEC® Uroview 2800

Affected Products: All OEC® UroView 2800

Our records indicate that your facility has one or more of the above mentioned products.

GE Healthcare Surgery has finalized the corrections to remedy the issues we initially advised you of in letters in 2007 and 2009 (reminder). Specifically, these corrections will address issues involving system lock-ups, incorrect image display, system stalls during the boot cycle, and failure of the system to display the International standard quantity, air kerma, to describe the radiation output.

Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.

Safety Issue

The system may lock-up during system usage; the system may stall during the boot cycle; when the image directory is accessed and thumbnail images are used to recall patient images, incorrect images may be displayed or there may be an inability to locate images on the system; failure of the system to display the International standard quantity, air kerma, to describe the radiation output.

Affected Product Details

All OEC® UroView 2800

Safety Instructions

- You may continue to use your 2800 UroView until this field action is performed.
- Should your OEC system experience a lock-up or failure to boot, restarting (rebooting) the system should restore system functionality. When restarting the system, it is important to place the power switch in the OFF position and wait 10 seconds. Instructions for restarting the system are located in the Operators Guide.
- To reduce the occurrence of data loss/data mix, users should always follow the correct power down procedure, which is described in the Operators Guide.

Product Correction

In the near future, your GE Healthcare Surgery field service representative will be contacting you to arrange for installation of corrections at no charge.

Contact Information

Should you have any questions or concerns regarding these corrections, please do not hesitate to contact your local Service representative for further information.

GE Healthcare confirms that this notice has been notified to the appropriate Regulatory Agency.

Please be assured that maintaining a high level of safety and quality is our highest priority. If you have any questions, please contact us immediately.

Thank you,



President and CEO
GE Healthcare, Surgery



Executive, Quality Assurance and Regulatory Affairs
GE Healthcare, Surgery