



Certified Mail Return Receipt Requested

URGENT RECALL NOTICE

PLEASE TAKE ACTION TO INFORM ALL USERS OF THE RELEVANT SYSTEM(S) OF THESE ISSUES AND HOW TO ADDRESS THEM

February 22, 2008
FMI 15086

To: Hospital Administrator
Director/Manager of Radiology

Subject: Product Safety Issues:
Vertical Lift Column Failure (PS3 Power Supply failure)

Affected Products: OEC® 9900 Elite, OEC®, 9900 Elite^{MD} Motorized C-arm System, OEC® 9900 Elite^{NAV}, OEC® 9800, OEC® FluoroTrak 9800 Plus, OEC® 9800 Plus, OEC® 9800MD Motorized C-arm System, OEC® 8800 Flexiview

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

- OEC® 9900 Elite
- OEC® 9900 Elite^{MD} Motorized C-arm System
- OEC® 9900 Elite^{NAV}
- OEC® 9800
- OEC® FluoroTrak 9800 Plus
- OEC® 9800 Plus
- OEC® 9800^{MD} Motorized C-arm System
- OEC® 8800 Flexiview

GE Healthcare has received reports from some customers of the vertical lift function of the C portion of the device failing on the above listed products. Failure of this functionality could result in the user experiencing difficulty in positioning the device.

Interim Solution:

To reduce the potential occurrence of this issue, users are advised to avoid activating both the up and down directional movement buttons on the mainframe at the same time. Should the user note that the vertical lift is slow to respond, or intermittently fails to respond to an up or down command, the user should contact the OEC Service Department at GEHC Surgery for a replacement of the failing power supply (PS3).

In addition, users should verify that the standby key switch is in the full ON position prior to attempting to use the vertical lift feature, as this was also identified as a potential cause for vertical lift column failure.

GEHC OEC is actively working on a solution that will permanently resolve this issue. When a solution becomes available GEHC OEC will contact you and at no cost resolve this issue.

If you have any questions or concerns regarding this issue, 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



Maria Frame
Vice President Quality and Regulatory Affairs