GE Healthcare

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

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

January 23, 2008

To:	**Director of Surgery**
	Director/Manager of Radiology
Subject:	**Product Safety Issues**
Affected Products:	**FluoroTrak Spinal Navigation Application on the OEC® 9900 Elite^{NAV}**

Our records indicate that your facility has the product listed above containing the surgical navigation option.

GE Healthcare has identified two intermittent potential safety issues that may occur with this product based upon feedback from some customers.

This notification was originally sent on April 2, 2007 (see enclosed) and this re-notification is to provide an update to the corrective action of these issues. The 9900 Elite NAV system at your facility will have a software modification that will result in the Navigation functions being permanently disabled.

The original notification from April 2, 2007 identified 2 potential safety issues: Navigation Tracking Inaccuracy and Loss of Navigation Settings on Incorrect Shutdown. The specific product affected is the FluoroTrak Spinal Navigation Application on the OEC® 9900 Elite^{NAV} .

Solution:

The 9900 Elite NAV system will have a software modification to the most current version. This will permanently disable the Navigation features. When new 9900 Elite system shipping is resumed, your 9900 Elite NAV system will be replaced with an appropriately configured new 9900 Elite C-arm system. Your 9900 Elite NAV system will be removed and returned to the GE Healthcare Surgery Salt Lake City facility.

The 9900 Elite NAV system can continue to be used for all normal mobile fluoroscopy uses.

A GE Healthcare Surgery Field Service Engineer, at no cost to you, will schedule this software modification.

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
GE Healthcare Surgery

Maria Frame
Vice President QA/RA
GE Healthcare Surgery