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URGENT RECALL NOTICE

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

April 2, 2007
FMI 15046

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 one or more of 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. The details and symptoms of these issues, as well as the associated interim solutions are outlined below.

1. Navigation Tracking Inaccuracy:

Affected Products: FluoroTrak Spinal Navigation Application on the OEC® 9900 Elite^{NAV}

An issue has been discovered with the FluoroTrak Spinal Navigation Application on the OEC®9900 EliteNAV that could result in an incorrect position of the navigated instrument(s) versus the displayed reference image. **This issue could result in an injury to the patient due to incorrect anatomical location of the instrument during a procedure.**

This issue arises when the patient is positioned for a cross-table image and is far from the image intensifier of the C-arm (i.e., close to the x-ray source).

Solution:

- The patient should be positioned so that the image intensifier is as close to the patient as is practical.
- Utilize x-ray control shots in both AP and Lateral cross table views to correlate instrument position.
- Take notice of any instrument tip depth discrepancies in the lateral cross table view.
- Stop use if any directional inaccuracies are outside safety limits.
- Please refer to the Instructions for Use document for General navigation and specific instrument use.

The accuracy issue identified for the 9900 Elite^{Nav} in this letter is different than the previously identified issue addressed in the customer letter dated November 8, 2006. Per that letter, customers should not use their 9900 Elite^{NAV} navigation system until the software version 6.15.3 has been successfully installed on their system. Once the 6.15.3 upgrade is done the system can be used provided the user adheres to the above instructions.

Your 9900 systems may be used as a standard C-Arm provided that your facility reviews the additional issues affecting the 9900 EliteNav described below, and in the previous letter of November 8, 2006

2. Loss of navigations settings on incorrect shutdown:

Affected Products: OEC® 9900 Elite^{Nav}

Your 9900 EliteNAV system is equipped with a feature that retains the current settings if the FluoroTrak application is exited and restarted. We have become aware of two settings that are not retained upon restart. These settings are:

- Extended trajectory settings will reset to their default values.
- If using the Accuracy verification mode, any stored verification points will be lost.

Interim Solution:

Users are advised to verify all settings upon restart of the FluoroTrak application until a corrective solution has been identified and successfully implemented on your system(s).

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