



GE Healthcare

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URGENT SAFETY ADVISORY NOTICE

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FMI 15037

GE OEC ***InstaTrak™ 3500 Plus System***

Subject: Product Safety Issues
Affected Products: GE OEC *InstaTrak™ 3500 Plus System*

Dear Valued Customer:

Our records indicate that your healthcare facility has purchased a GE OEC ***InstaTrak™ 3500 Plus System*** with ***Software version 5.2***, the Surgical Navigation & Visualization Application.

For this software version 5.2, GE Healthcare has determined the existence of the following two system (software related) issues:

- **System Issue 1:** A trajectory is inadvertently generated for an angled or bent tool (such as an angled aspirator) if a button on an instrument (that is connected to the system but not tracked) is inadvertently pressed. Erroneous use of such trajectories that are not valid for bent tools might result in patient injury.
- **System Issue 2:** The proper workflow during use of the Image Fusion feature in software version 5.2 consists of loading the datasets (CT and MR) followed by Image Fusion, Surgical Planning and Navigation on the datasets. If after loading the two datasets (CT and MR), Surgical Planning is carried out before Image Fusion, the Surgical Planning is displayed inaccurately during Navigation. This may erroneously be interpreted as a tracking related inaccuracy that may lead to patient injury during surgery.

GEHC OEC has a software correction available that addresses these issues. GEHC OEC will contact your facility to verify the current software version installed at your site. If this issue affects your facility the upgrade to the corrected software will be provided at no cost.

Users are advised to exercise caution when using the ***InstaTrak™ 3500 Plus System*** in the above-described clinical scenarios until the 5.2.1 software upgrade is completed.

Please convey this information to your OR management along with all users of the GE OEC **InstaTrak™ 3500 Plus System**. Please contact GE Healthcare Customer Service at 1-800-874-7378, option 1 or 1-801-536-4688, option 1 for any questions.

Thank you,

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