



SECOND NOTICE

URGENT SAFETY ADVISORY NOTICE

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

We have not received a Fax-Back confirmation from your facility for the original Notice sent July 22, 2009 and sent to your Facility Administrator and Director of Radiology

PLEASE ACKNOWLEDGE THIS NOTICE WITH THE ENCLOSED FAX-BACK

November 6, 2009
FMI 15097

To: Director of Surgery

Subject: Product Safety Issues: Navigation Headset Operator's Manual Update

Affected Products: OEC® IT3000; IT2500 (EnTrak); IT2500 Plus (EnTrak Plus); IT3500 (InstaTrak); IT3500 Plus (InstaTrak Plus); ConneCTstat; ConneCTstat Plus

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

- OEC® NAV IT3000
- OEC® NAV IT2500 (EnTrak)
- OEC® NAV IT2500 Plus (EnTrak Plus)
- OEC® NAV IT3500 (InstaTrak)
- OEC® NAV IT3500 Plus (InstaTrak Plus)
- OEC® NAV ConneCTstat
- OEC® NAV ConneCTstat Plus

GE Healthcare is advising all users of the systems noted above to not use the ENT registration Headset in the inverted position for any CT scans or surgical procedures.

Permanent Solution:

Do not use the registration Headset in the inverted position (Upside Down) for any CT scans or surgical procedures. Please remove all references in your Navigation System Operator's Manual that discuss an inverted headset placement, and replace with the enclosed updated instructions for the Navigation System Operator's Manual.

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.

Pete McCabe
President and CEO
GE Healthcare Surgery

Doug Uelmen
Vice President Quality and Regulatory Affairs
GE Healthcare Surgery