



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



URGENT RECALL NOTICE

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

March 28, 2007

FMI 15038

To: Director/Manager of Diagnostic Imaging

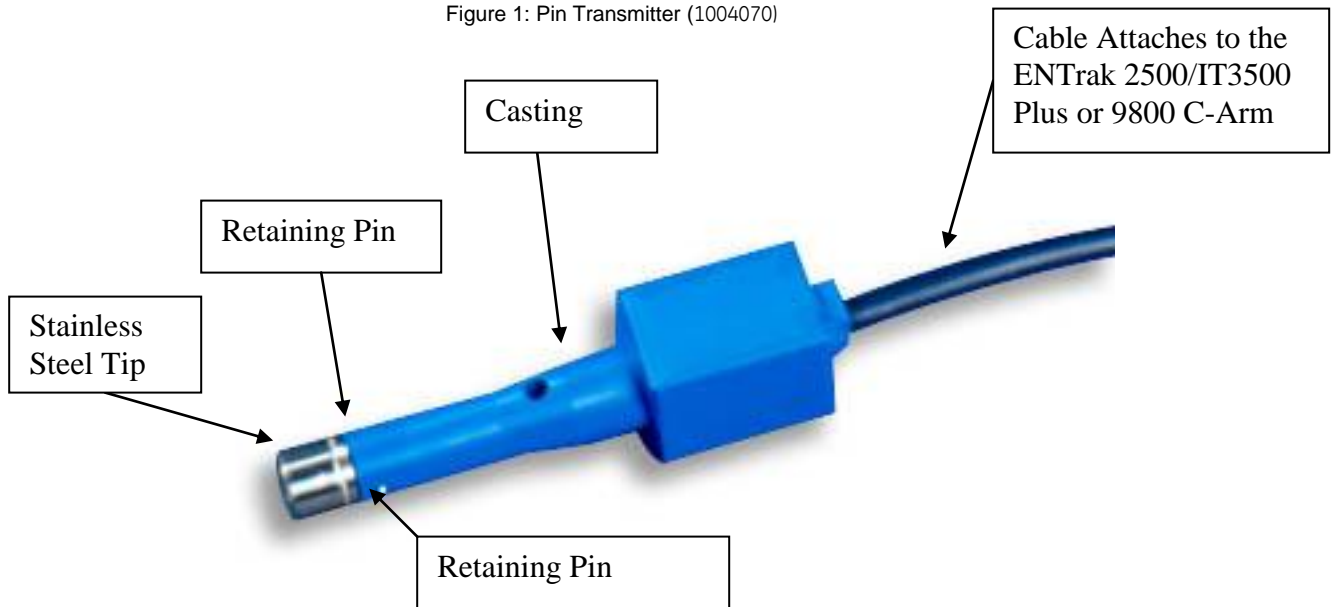
Subject: Product Safety Issues

Affected Products: OEC® ENTrak 2500 Plus, OEC® IT 3500 Plus and OEC® 9800 C-Arm Navigation Systems

It has come to our attention that there is a potential safety concern associated with the GE Healthcare Navigation Pin Transmitter (GE P/N 1004070) that you may own. Because patient safety is of paramount concern to GEHC, we ask your immediate attention to help us resolve this matter.

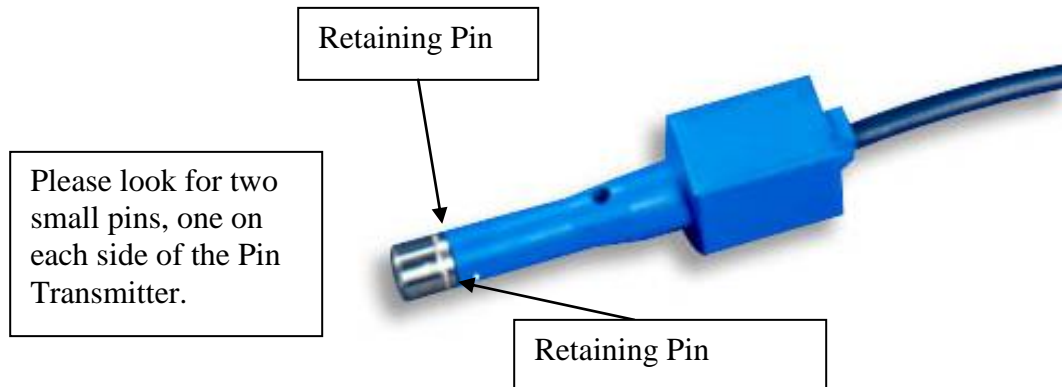
GE Healthcare Navigation Pin Transmitter: (PN: 1004070) [See Figure 1 Below]

Figure 1: Pin Transmitter (1004070)



The housing of the Pin transmitter consists of two main parts: the casting (plastic) and the stainless steel tip that attaches the housing to the clamp/pin that is affixed to the patient (See Figure 1). The design is intended to have a small pin through each sidewall of the casting to secure the stainless steel tip with two pins. In a few cases, we have seen that the stainless steel tip of the Pin Transmitter has disconnected from the casting because only one pin of the transmitter was secured. In these cases, there is a potential for this small, unattached retaining pin to fall into the surgical field.

Figure 2: Pin Transmitter (1004070)



Please perform a visual inspection of your GE Healthcare Surgical Navigation Pin Transmitter (PN: 1004070) to make sure that your Pin Transmitter is pinned on both sides of the transmitter (See Figure 2) and follow the instructions below:

If you have a defective Pin Transmitter (pin on one side only):

- 1) Please discontinue the use of the Pin Transmitter and contact GE Healthcare by completing the attached form and FAX it to GE Healthcare Regulatory Affairs to arrange for a part replacement of the Pin Transmitter.
- 2) Please convey this information to your OR management along with all users of the ENTrak 2500 Plus, InstaTrak 3500 Plus, or 9800 C-Arm Navigation Systems.

If you have a Pin Transmitter that is not defective (pinned on both sides):

You may continue to safely use this device. We simply ask that you contact GE Healthcare by completing the attached form and FAX it to GE Healthcare Regulatory Affairs to confirm your inspection with us at your first available opportunity.

GE Healthcare

If you have an affected Pin Transmitter, we will replace it as soon as possible at no cost to you. A GE Surgery Field Service Engineer will be contacting you to arrange for a part replacement which will enable you to continue using your ENTrak 2500 Plus, IT 3500 Plus and 9800 C-Arm Navigation Systems.

GEHC appreciates your awareness and cooperation in order to remedy this potential health concern. Should you have any questions or require additional information regarding this notice please contact your local Canadian Regulatory Affairs contact at: (905) 567-2172.

Sincerely,

Pete McCabe
President and CEO

Pin Transmitter Fax Back Form

Part Replacement: GE Healthcare Surgical Navigation Pin Transmitter (PN: 1004070)

Customer Facility Name:

Customer Contact Name:

Please select **one** of the following:

I have inspected my GE Healthcare Surgical Navigation Pin Transmitter (PN: 1004070) and it **requires** replacement.

I have inspected my GE Healthcare Surgical Navigation Pin Transmitter (PN: 1004070) and it **does NOT** require replacement.

Customer Signature: _____

Date: _____

Please FAX to: (905) 567-2115

Attention: Paul Atkins
GE Healthcare
Regulatory Affairs
2300 Meadowvale Blvd
Mississauga, Ontario
L5N 5P9