



IMPORTANT PRODUCT INFORMATION

GE Healthcare

3000 N. Grandview Blvd. - W440
Waukesha, WI 53188, USA

< Date of Letter Deployment >

GEHC Ref# 25482

To: Hospital Administrators / Risk Managers
Managers of Radiology/Cardiology
Radiologist/Cardiologist
Chairman Medical Board
Relevant Head of Departments for hospital

RE: GE Healthcare Revolution CT SmartStep Localization Error

Please ensure that all potential users in your facility are made aware of this notification and the recommended actions.

**Defect Description
and Related
Hazards**

GE Healthcare has become aware of a localization error on Revolution CT systems equipped with the SmartStep Option. The Z location displayed on image annotation and on the gantry display may not be the actual location of the table. This can occur if:

1. The table has been moved all the way out of the gantry using the 'Out' button on the gantry control or the 'Unload Pedal'. (See Figure 1)
2. The table is then moved back into the gantry using the 'Move to start location' button on the Hand Held Controller.

In this situation, if a scan is initiated by the user, the scan may be acquired in the wrong location. An additional scan may be necessary.

Figure 1: 'Unload Pedal' On Left



Safety Instructions

To avoid this issue, only use the 'In' button on the gantry controls and follow this required workflow:

1. Move the table back into the gantry using the 'In' button on the gantry controls. (See Figure 2)
2. Verify that the needle position is aligned using the internal laser alignment light.



Figure 2: Gantry Control Panel 'In' Button

Affected Product Details

Revolution CT Systems with SmartStep Option.
You have received this notification because your system is equipped with the SmartStep option.

Product Correction

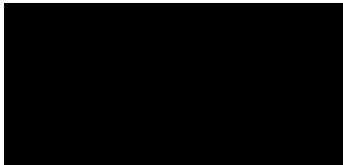
GE Healthcare will correct all affected products at no cost to you. A GE Healthcare representative will contact you to arrange for the correction.

Contact Information

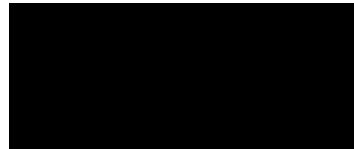
If you have any questions or concerns regarding this notification, please contact GE Healthcare Service at 1-800-437-1171 or your local Service Representative.

Please be assured that maintaining a high level of safety and quality is our highest priority. If you have any questions, please contact us immediately per the contact information above.

Sincerely,



James W. Dennison
Vice President - Quality Assurance
GE Healthcare



Jeff Hersh, PhD MD
Chief Medical Officer
GE Healthcare