



**Important
Electronic Product
Radiation Warning**

GE Healthcare

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

< Date of Letter Deployment >

GEHC Ref# 25487

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 scan issues potentially causing additional low dose exposure

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 two potential issues on Revolution CT Scanners that could cause additional low dose radiation exposure.

The first issue could delay the transition from the monitor to diagnostic scan phase during a Smart Prep procedure. In this case, the system would acquire additional monitor scans and result in extra radiation delivered to the patient. In some cases, this may also necessitate a re-scan of the patient.

The second issue is that scout images could become rotated if the foot pedals are used to reposition the patient instead of the gantry controls. This could mean another scout image must be acquired thereby delivering additional X-Ray radiation.

Safety Instructions

You can continue using your system.

Recommended workaround instructions to use until the correction is provided:

- To prevent a potential Smart Prep transition delay, the RTS (Real Time Systems) function should be disabled. This function collects system health related data but was found to interfere with the Smart Prep transition timing. Please contact your local Service Representative if you would like GE Healthcare to disable this function on your system.
- When performing a scout scan use only the gantry controls to reposition the patient as indicated in the operator manual.

**Affected Product
Details**

Revolution CT

Product Correction

GE Healthcare will, without charge, remedy the defect or bring the product into compliance with each applicable Federal standard in accordance with a plan to be approved by the Secretary of Health and Human Services, the details of which will be included in a subsequent communication to you or through a GE Healthcare field engineer site visit.

**Contact
Information**

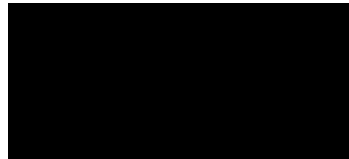
If you have any questions or concerns regarding this notification, please contact GE Healthcare Service at 1-800-437-1171 or your local Service Representative.

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