

IMPORTANT PRODUCT INFORMATION

GE Healthcare

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

<Date of Letter Deployment>

GEHC Ref# 13737

To: Hospital Administrators / Risk Managers
Managers of Radiology/Cardiology
Radiologist/Cardiologist
Chairman Medical Board and relevant Head of Departments

RE: GE Healthcare PET/CT Table Stop Without Stopping X-Ray Exposure

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

Issue GE Healthcare has become aware of an issue on PET/CT Scanners which can allow the patient

table to stop while X-Ray exposure continues until the end of the preset CT exam time. This could result in unintended additional X-Ray radiation in a single anatomical position. This issue occurred at only one site in the GE Healthcare PET/CT installed base, where a unique hardware failure

contributed to the issue.

Instructions You can continue using your system. As indicated in the operator manual, continue to check the

System Readiness Monitor (SRM) regularly, and contact your Service Provider for repair if errors

are indicated.

Affected Discovery PET/CT 610, 710
Product Optima PET/CT 560, 560FX

Details Discovery IQ

Discovery MI, MI DR

Product GE Healthcare will correct all affected products at no cost to you. A GE Healthcare representative

Correction will contact you to arrange for the correction.

Contact If you have any questions or concerns regarding this notification, please contact GE Healthcare

Information Service 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