



Urgent Field Safety Notice

GE Healthcare

Healthcare Systems
9900 Innovation Drive
Wauwatosa, WI 53226
USA

GE Healthcare Ref: FMI # 13704

2011-06-02

To: Hospital Administrators / Risk Managers
Managers of Radiology/ Nuclear Department
Radiologists/ Physicist

RE: **System time drift on Discovery VCT, Discovery RX VCT, Discovery STE, Discovery RX and Discovery ST systems with Dimension console.**

GE Healthcare has become aware of system time drift on the operator's console of some Discovery VCT, Discovery RX VCT, Discovery STE, Discovery ST and Discovery RX systems. If unchecked, or not connected to a network time server, system time can drift. This issue may impact patient safety. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Safety Issue Due to an issue in the system time adjustment feature, the system time can drift. If unchecked, or not connected to a network time server, system time can drift, impacting Standardized Uptake Value (SUV) measurements. A fifteen minute difference between system time and the dose calibrator clock impacts SUVs by 10%. Discovery ST systems without Dimension consoles are not affected.

No injury has been reported related to this issue.

Safety Instructions Service will schedule time with your site to perform this service action described in the Product Correction section below.

Your site should be aware that time synchronization between your dose calibrator clock and the scanner clock is important and the time of your system should be checked, as defined in the Operator's Manual.

If time drift becomes a concern, please contact your service personnel. Your service personnel have the procedures to accurately set the time and prevent potential future system time drift on the products. Setting the time incorrectly can introduce greater drift over time.

Having service personnel configure your system to use a network time server is the best method for synchronizing your system's time.

Affected Product Details Discovery VCT, Discovery RX VCT, Discovery STE, Discovery RX and Discovery ST systems with Dimension console. Discovery ST systems without Dimension consoles are not affected.

NOTE: It is recommended that your service representative install the latest software for your product.

Product Correction GE Healthcare will correct all affected systems by providing a one time field service action at no cost to you. A GE Healthcare service representative will contact you to arrange for this correction.

A GE Healthcare service representative will assist your site in correcting for system time drift.

- At your request, service personnel can configure a network time server to automatically synchronize times to a network time source.

- Service will provide software modifications to correct and prevent further system time drift. This action will be performed at all affected sites.

**Contact
Information**

If you have any questions regarding this Field Safety Notice or the identification of affected items, please contact your local Sales/Service representative.

GE Healthcare confirms that the appropriate Regulatory Agencies have been notified.

Please be assured that maintaining a high level of safety and quality is our highest priority.

Sincerely,



James Dennison
Vice President QARA
GE Healthcare Systems



William Denman, M.D., FRCA
Chief Medical Officer
GE Healthcare