



Urgent Field Safety Notice

GE Healthcare

Healthcare Systems
9900 Innovation Drive
Wauwatosa, WI 53226
USA

GE Healthcare Ref: FMI 40846

October 2012

To: Managers of Nuclear Medicine
Hospital Administrators / Risk Managers
Managers of Radiology/Cardiology

RE: **Table pallet product issue on Discovery NM/CT 670 and Discovery NM 630.**

GE Healthcare has recently become aware of a potential safety issue associated with the table pallet of your Discovery NM/CT 670 and/or Discovery NM630 system which may impact operation safety. **Please ensure that all potential users and service personnel in your facility are made aware of this safety notification and the recommended actions.**

Safety Issue At scan setup, during gantry rotation towards scanning position, a potential contact between the table-pallet-edge and the detector was identified. Such occurrence may damage the pallet front-edge and raises concern over potential detector-patient contact.

Safety Instructions At scan set-up, use the handheld controller to pull the table pallet out before pressing [SET]. Always ensure the patient's body parts are not protruding out of table pallet limits.

Affected Product Details GE Healthcare Discovery NM/CT 670 and/or Discovery NM630, all configurations.

Product Correction A GE Healthcare Service representative will perform the required software update on each affected system. This activity will be performed at no cost to you.

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 this notice has been notified to the appropriate Regulatory Agency.

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.

Sincerely,



Vice President QARA
GE Healthcare Systems



Chief Medical Officer
GE Healthcare