



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

## URGENT FIELD SAFETY NOTICE

<Date of Letter Deployment>

GEHC Ref# 40880

To: Director of Clinical/Radiology  
Risk Manager/Hospital Administrator  
Director of Biomedical Engineering  
Chairman Medical Board and relevant Head of Departments

**RE: Discovery NM 530c, Ventri Missing Safety Field Action FMI 40847**

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

### **Safety Issue**

GE Healthcare has identified that a small number of Nuclear Medicine systems are operating without currently updated software. In a recent event, a patient's finger was injured during the Unload process while the automatic Unload feature was being used; the software on the system was not current.

The relevant software update, Field Action 40847, released in 2013, issued a mandatory software update to disable the automatic Unload motion feature. Requiring Unload table motions to be done manually (via Remote Control Unit) necessitates that the operator remain in close proximity to the patient during the Unload process. Appropriate operator monitoring while unloading the patient helps ensure that the patient arms and hands do not protrude from the table.

### **Safety Instructions**

Monitor the patient and the system during the entire scan procedure. At scan completion and throughout during the unloading process, continue to monitor the patient and verify that patient's limbs do not protrude from the table pallet.

### **Affected Product Details**

GE Healthcare **Discovery NM 530c** and **Ventri** Nuclear Medicine system using Premium (automatic) table and with MS Windows Operating System configuration.

### **Product Correction**

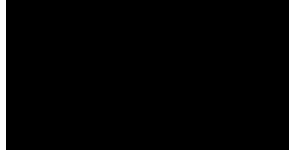
A GE Healthcare Service representative will inspect all affected systems to verify the proper software is installed on your system. This activity will be performed at no cost to you.

### **Contact Information**

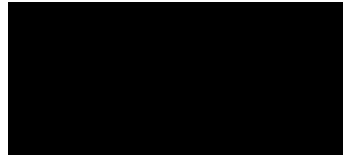
If you have any questions or concerns regarding this notification, please contact your local Service Representative at 800 1012882 (Toll free).

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