

Patient Safety Alert

Veterans Health Administration Warning System
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AL14-08

August 11, 2014

Item: Table Tipping Risk with GE Healthcare Infinia Nuclear Medicine Imaging Systems

NOTE: The Specific Incident and General Information sections below reference a specific model of GE Healthcare Infinia system; however, this Patient Safety Alert APPLIES TO ALL GE HEALTHCARE INFINIA NUCLEAR MEDICINE IMAGING SYSTEMS.

Specific Incident: A VA medical center experienced a major equipment failure involving a GE Healthcare Infinia Hawkeye 4 single photon emission computed tomography and computed tomography (SPECT/CT) system. The exam table, weighing approximately 900 pounds, spontaneously tipped over after a patient exam. No patient was in the room at the time of the failure and no injuries occurred as a result of this incident; however, this issue could have resulted in serious injury or death to a patient or staff member.

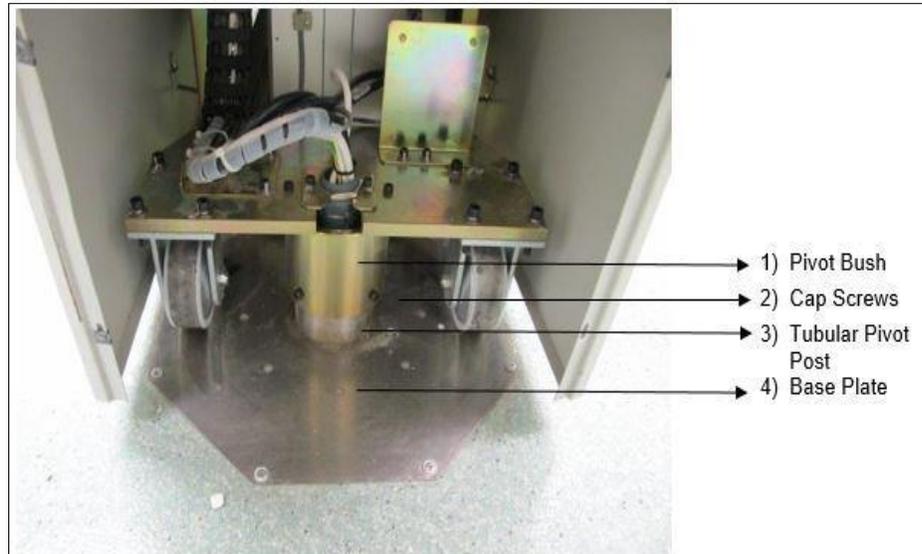
General Information: After a nuclear medicine study was completed using a GE Healthcare Infinia Hawkeye 4 SPECT/CT system, the UNLOAD button on the handle control pad was pressed to return the exam table to its home position, thus automatically lowering the table. As the table finished lowering, it tipped over completely onto its side.

The exam table involved in the incident was secured to the floor by a pivot bush/pivot plate assembly. This assembly has a metal sleeve, referred to as the bush (pivot bush) that fits onto a cylindrical post (tubular pivot post) that is welded to a base plate. The pivot bush has cap screws (set screws) that, when properly engaged, prevent the pivot bush from lifting off of the post. A third party incident investigation revealed the causes of the incident were that the pivot bush on the table was bolted to the bottom of the table frame 180 degrees out of rotation, from the specification in the installation manual, and the cap screws were not properly engaged.

Actions:

1. By Close of Business (COB) August 13, 2014, the **Medical Center Director (or designee)** shall ensure that the Chief of Nuclear Medicine and Chief of Biomedical Engineering are made aware of this Patient Safety Alert AL14-08.
2. By COB August 18, 2014, the **Chief of Nuclear Medicine and Chief of Biomedical Engineering (or designees)** shall review this Patient Safety Alert and determine if your facility has **any** GE Healthcare Infinia nuclear medicine imaging systems. If so, proceed to Action 3. If not, proceed to Action 4 and mark this alert as 'not applicable' to your facility, including your justification.
3. By COB September 19, 2014, **Chief of Biomedical Engineering (or designee)** shall ensure that the pivot bush/pivot plate assembly has been installed correctly using the following steps:
 - Inspect the pivot bush/pivot plate assembly of all GE Healthcare Infinia nuclear medicine imaging systems' imaging tables to determine if the pivot bush/pivot plate assembly has been installed correctly. To do this, remove the plastic front upper cover and metal front lower cover at the head end of the table (the end furthest from the gantry) to expose the pivot bush/pivot plate assembly (see Figure). Then verify that the pivot bush is installed so that the **heads** of the bush cap screws are facing outward toward the observer and that all cap screws are present.
 - If the pivot bush is installed correctly (i.e., the pivot bush is installed so that the heads of the bush cap screws are facing outward toward the observer and all cap screws are present), Biomedical Engineering staff shall tighten the bush cap screws until the cap screw heads are flush and secure against the pivot bush.
 - If the pivot bush/pivot plate assembly is not installed correctly, remove the system from use, immediately notify the contacts listed on page 4, and have GE Healthcare or other qualified personnel correctly reinstall the pivot bush/pivot plate assembly. The system can only be placed back into service once the problem is corrected (by GE Healthcare or other qualified personnel) and Biomedical Engineering has verified that the pivot bush/pivot plate assembly was corrected and that the bush cap screws are flush and secure against the pivot bush.

Figure: GE Healthcare Infinia nuclear medicine imaging system pivot bush/pivot plate assembly, showing correct assembly with cap screw heads facing outwards.



4. By COB September 26, 2014, the **Patient Safety Manager** shall document on the VHA Alerts and Recalls Web site that medical center leadership has reviewed and implemented these actions. Facilities that do not have GE Healthcare Infinia nuclear medicine imaging systems may mark this Alert as 'not applicable', including their justification.

NOTE: When closing out this Patient Safety Alert on the VHA Alerts and Recalls Web site, please include the following information:

- When entering in the “estimated number of devices affected” field, sites shall enter the number of GE Healthcare Infinia nuclear medicine imaging systems in which the pivot bush/pivot plate assembly required any correction by Biomedical Engineering staff, GE Healthcare, or other qualified personnel.
- When entering in the “estimated number of patients affected per month” field, sites shall enter the average number of patients per month within their facility that would be imaged on GE Healthcare Infinia nuclear medicine imaging systems that required any correction.

Source: Patient Safety Report submitted by a VA medical center

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Contacts: The National Center for Patient Safety (NCPS) at (734) 930-5890