El INVIMA informa a los usuarios en general que el Grupo de Tecnovigilancia ha emitido una comunicación relacionada con un Informe de Seguridad asociado a:

NOMBRE DEL DISPOSITIVO MÉDICO	Gammacámaras
NO. IDENTIFICACIÓN RISARH	I1409-364
REFERENCIAS DEL DISPOSITIVO MEDICO	Infinia con Hawkeye 4
REGISTRO SANITARIO	2008EBC-0002241
INDICACIONES Y USO ESTABLECIDOS	Equipo para diagnostico.
NOMBRE DEL FABRICANTE	GE Medical Systems Israel - Functional Imaging GE Medical Systems Scs
DESCRIPCION DEL PROBLEMA	El fabricante afirma que ha detectado que las mesas fabricadas después de noviembre de 2003 pueden inclinarse de lado debido a un pivote instalado incorrectamente, conllevando a que se presenten posibles eventos adversos sobre los pacientes.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	08 de Septiembre de 2014

RECOMENDACIÓN:

En caso de identificar la existencia del producto mencionado anteriormente comuníquese con su proveedor quien determinara las acciones que se llevaran a cabo.

Es importante mantener un estado de alerta, realizando un seguimiento permanente a los productos que se fabrican y/o comercializan en el país, divulgando la información de seguridad respectiva entre los profesionales de la salud que realizan uso de estos recursos tecnológicos.

Para mayor información comuníquese al teléfono 2948700 extensión 3880 en Bogotá, ó al correo electrónico tecnovigilancia@invima.gov.co

S0262 - Normal Priority Medical Device Alert

Medical Device Special Report

Updated: September 4, 2014

UMDNS Terms:
- Scanning Systems, Computed Tomography/Single Photon Computed Tomography [24013]
- Scanning Systems, Gamma Camera, Single Photon Emission Tomography [18444]

Suggested Distribution:
- Clinical/Biomedical Engineering
- Nuclear Medicine

Geographic Regions:
- Worldwide

ECRI Institute User Experience Network—GE Infinia Gamma Camera Table Pivot Assembly May Be Improperly Installed

Product Identifier:
Infinia Tables (manufactured after November 2003) used with Infinia Hawkeye 4 Gamma Cameras *[Capital Equipment]*

Manufacturer:
- GE Healthcare USA9900 Innovation Dr, Wauwatosa, WI 53226,

Problem:
Infinia tables manufactured after November 2003 used with GE Infinia Hawkeye 4 Nuclear Imaging Systems may tip over on their side if not securely anchored to the floor because of an improperly installed pivot assembly. A tipping table could cause serious injury to a patient or staff.

Background
A member hospital reported that while hospital staff were sliding a patient from an Infinia table to a stretcher, significant pulling and pushing was required, and the table was rocked side to side. After the patient had been transferred off the table, the Infinia table was lowered to its home position. When it reached its home position, the table tipped over on its side. Hospital staff report that no objects were wedged under the table that may have caused it to tip over during lowering. This is the only full tip-over event known to GE Healthcare or ECRI Institute.

When GE service personnel visited the facility to set the table back on its pivot assembly, they discovered that the pivot bush/pivot plate assembly had been improperly installed. GE Healthcare Infinia imaging tables, weighing about 900 pounds, are secured to the floor only at the pivot bush/pivot plate assembly at the head of the table. This assembly has an upper metal sleeve (GE refers to it as the "bush") that slides over a beveled topped, tubular post welded to a base plate that is screwed into the flooring substrate (see Figures 1 and 2). The tubular assembly also serves as a wiring conduit through the floor.

Figure 1. The drawing of the pivot bush/pivot plate assembly at the head of the table.

Figure 2. The pivot bush/pivot plate assembly at the head of the table.

When the bush is installed over the post, the overlap of the two is approximately 4 cm, as determined by the height of the casters, which bear the weight of the table (the pivot assembly is not load bearing). The pivot bush has two set screws (GE refers to them as "cap screws") that, when fully tightened, extend into a wide rectangular circumferential notch in the post just below the beveled edge. GE informed ECRI Institute that the cap screws' purpose is to help prevent the forward tipping of the table when subjected to the force of a heavily loaded table with the table top and patient extended into the gantry. In the event that the bush is lifted or tilted, the ends of the screws should catch on the upper lip of the notch and prevent the bush from lifting off or tilting on the post. The bush is intended to be installed so that the cap screws face outward toward the head-end lower cover near the pivot, where they can be seen and are accessible to tighten. However, the bush can be improperly installed with the bush rotated 180°, which causes the cap screws to face inward toward the raising and lowering mechanism of the table out of easy view during installation.

The raising and lowering mechanism of the table pallet is mounted to the lower frame of the table above the pivot bush/pivot plate assembly. Thus, the motorized mechanism that raises and lowers the table pallet does not change the height relationship of the bush with the pivot post, neither of which should normally move in

any respect during raising or lowering the table.

ECRI Institute has investigated the tip over incident for the hospital and found that the pivot bush was installed backwards and the cap screws were not fully tightened so that the screw heads were flush against the bush. Vigorously rocking the table side to side can cause the bush to lift off of the post such that the inner wall of the bush becomes canted on the upper bevel of the post. In this orientation, the bush will more likely slip back onto the post, but it can also slip off of the post causing the table to tip over. Based on our assessment, the table cannot be dislodged from its pivot if the cap screws are fully engaged and their heads facing outward.

ECRI Institute Recommendations:
ECRI Institute recommends the following:
(1) For all Infinia imaging tables manufactured after November 2003, inspect the pivot bush/pivot plate assembly and verify that that table is correctly installed:

- the heads of the pivot bush cap screws should be facing out (i.e., easily seen and accessed when the head lower end cover is removed)
- the cap screws should be fully tightened

(2) If the pivot bush has not been installed correctly, do not use the table until it is properly/securely installed by GE or other qualified service personnel.

(3) Upon inspection, if a different design pivot bush/pivot plate assembly is identified that has a smaller diameter upper tube inserted down into a larger diameter lower tube, no further action is needed. The table can remain in service.
(4) Whenever possible, employ a patient lift to transfer heavier patients to prevent the significant lateral forces applied to the table during a sliding manual transfer.
(5) Before adjusting the position of the imaging table, ensure that there are no obstacles around the table area (i.e., inside the yellow taped lines on the floor). When transferring the patient on or off a stretcher, ensure that the stretcher is not touching the table before adjusting the stretcher's height.

Comment:

- This alert is a living document and may be updated when ECRI Institute receives additional information. In circumstances in which we determine that it is appropriate for customers to repeat their review of an issue (e.g., when additional affected product has been identified), we will post a separate update alert. In other cases, we may add information, such as additional commentary, recommendations, and/or source documents, to the original alert. For additional information regarding the format of this alert, refer to our HDA Format Guide.

Source(s):

- 2014 Sep 4. ECRI Institute researched member report.