



رقم المحفوظات: ٥٨٢٥
رقم الصادر: ١٣/٧٢٦.٢٩
بيروت، في: ٥ - آب - ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي

Nuclear medicine systems, Infinia nuclear medicine systems, VG and VG Hawkeye nuclear medicine systems and Helix nuclear medicine systems

الجهاز المعنى بالمتابعة:

- Nuclear medicine systems, Infinia nuclear medicine systems, VG and VG Hawkeye nuclear medicine systems and Helix nuclear medicine systems
- Trade Mark: GE healthcare
- Local Representative:

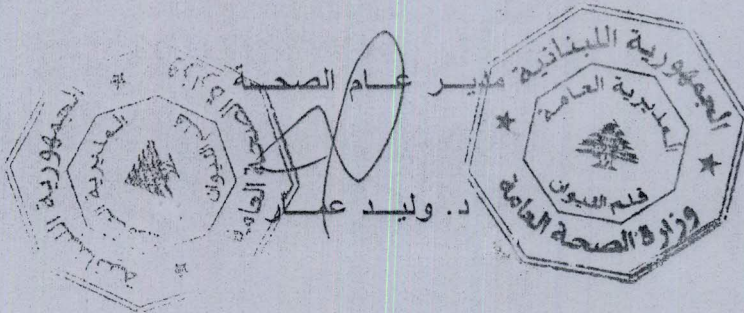
بناء على التقرير الصادر عن الوكالة الأسترالية TGA والذي يشير الى وجود خلل في عمل الصنف الوارد أعلاه مما قد يؤثر على سلامة المريض، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطا:

- التقرير الصادر عن الوكالة الأسترالية TGA

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات





Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

GE Healthcare nuclear medicine imaging systems

Recall for product correction

9 July 2013

Health professionals and consumers are advised that GE Healthcare, in consultation with the TGA, has initiated a recall for product correction for a number of its nuclear medicine imaging systems.

Nuclear medicine imaging systems are used to take images of parts of the body to diagnose a variety of diseases.

GE Healthcare has advised hospitals and radiology clinics that have the affected nuclear medicine imaging system to stop using the machine until it can be inspected by a GE technician.

This action has been taken in response to an incident in the United States, in which a patient died due to injuries sustained when a portion of an Infinia Hawkeye 4 nuclear medicine imaging system fell onto them during a scan. It has been identified that the bolts securing the camera to the gantry were loose, resulting in stresses on the imaging system support mechanism.

Please note that there have been no deaths or injuries relating to this issue reported in Australia.

All types and manufacturing dates of the following GE Healthcare nuclear medicine imaging systems are affected:

- Infinia and Infinia Hawkeye nuclear medicine systems
- VG and VG Hawkeye nuclear medicine systems
- Helix nuclear medicine systems (manufactured by Elscint Ltd).

Additionally, the following specific models are also affected:

- Brivo NM615
- Discovery NM630
- Discovery NM/CT670
- Optima NM/CT640.

Information for consumers

GE Healthcare has contacted all hospitals and clinics that have one of the affected nuclear medicine imaging systems and has advised them to stop using the system until it can be inspected.

Due to the prevalence of affected nuclear medicine imaging systems in Australia and the need to have such systems inspected regarding this issue before use, there may be delays in accessing some diagnostic scan services.

If you have any questions or concerns about the above issue, please talk to your health professional.

Information for health professionals, nuclear medicine technologists, hospitals and imaging clinics

GE Healthcare has contacted all hospitals and clinics that have one of the affected nuclear medicine imaging systems and advised them to stop using the system until it can be inspected.

GE Healthcare will inspect all affected systems to verify that the support mechanism fasteners are secured properly. If an issue with the support mechanism fasteners is found on your system, this will be corrected by GE Healthcare.

Nuclear medicine technologists and other health professionals are asked to report any problems, near misses, or adverse events associated with the use of nuclear medicine imaging systems.

Reporting problems

Consumers and health professionals are encouraged to report problems with medical devices. For more information see the TGA Incident Reporting and Investigation Scheme (IRIS).

The TGA cannot give advice about an individual's medical condition. You are strongly encouraged to talk with a health professional if you are concerned about a possible adverse event associated with a medical device.

Content last updated: Wednesday, 10 July 2013

Web page last updated: Thursday, 11 July 2013

URL: <http://www.tga.gov.au/safety/alerts-device-nuclear-medicine-imaging-system-130709.htm>