

U.S. Food and Drug Administration
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GE Healthcare Nuclear Medicine Systems

Recall Class: Class I

Date Recall Initiated: June 13, 2013

Products: Infinia Nuclear Medicine Systems, VG and VG Hawkeye Nuclear Medicine Systems, Helix Nuclear Medicine Systems, Brivo NM615, Discovery NM630, Optima NM/CT640, Discovery NM/CT670

Models: Infinia 3/8, Infinia-II 3/8, Infinia VC, Infinia II VC, Infinia 3/8 Hawkeye, Infinia VC Hawkeye, Infinia II 3/8 Hawkeye, Infinia II VC Hawkeye, Infinia II 3/8 HE4, Infinia II 5/8 HE4, Infinia II VC HE4, Varicam, Millennium VG 3/8, Millennium VG 5/8, Millennium VG 3/8 Hawkeye, Millennium VG 5/8 Hawkeye, Discovery VH, Helix nuclear medicine systems, Brivo NM615, Discovery NM630, Optima NM/CT640, Discovery NM/CT670

These affected products were distributed from October, 1992 through June, 2013.

Use: These Nuclear Medicine systems are used to perform general Nuclear Medicine imaging procedures for detection of radioisotope tracer uptake in the patient's body, using a variety of scanning modes supported by various acquisition types and optional imaging features designed to enhance image quality in Oncology, Cardiology, Neurology and other clinical diagnostic imaging applications. The scanning modes include planar (Static, Multi-gated, Dynamic, Whole body scanning) and tomographic (SPECT, Gated SPECT, Whole body SPECT, Camera based PET - also known as Coincidence Detection). Acquisition types include single and multi-isotope/multi-peak frame/list mode single-photon and positron imaging. Optional imaging-enhancement features include assortment of collimators, gating by physiological signals, real-time automatic body contouring, and CT-based attenuation correction and functional anatomic mapping.

Recalling Firm:

GE Healthcare, LLC
3000 N Grandview Blvd.
Waukesha WI 53188-1615

Manufacturer:

GE Medical System Israel Ltd
4 Hayozma St.
Tirat Hacarmel, Israel

Reason for Recall: GE Healthcare became aware of an incident at a VA Medical Center facility in the US. A patient died due to injuries sustained while being scanned on an Infinia Hawkeye 4 Nuclear Medicine System. On July 03, 2013 GE notified hospitals that they were recalling several Nuclear Medicine Imaging Systems because serious injuries or deaths could occur due to the failure mode associated with this recall. GE advised hospitals that they cease use of their Nuclear Medicine systems until GE can complete an inspection of the system. In the second notification, GE included all Nuclear Medicine Systems.

Public Contact: For questions about this recall contact GE Healthcare Service Representative at 1-800-437-1171

FDA District: Minneapolis District Office

FDA Comments:

On June 17, 2013 GE sent an Urgent Medical Device Correction letter to all affected customers. The letter identified the affected product, recommended that qualified service personnel maintain the equipment and that Preventative Maintenance procedures were executed according to labeling. In addition, the Safety Chapter Sections should be re-reviewed with personnel to ensure proper operation of the equipment.

On July 03, 2013 GE notified customers again via an **Urgent Medical Device Recall** (http://www3.gehealthcare.com/~media/Downloads/us/Product/Product-Categories/Nuclear-Medicine/GEHC_FMI_40849_July_3_2013_USFDA.pdf) letter (including confirmation of delivery for US customers) and follow-up telephone calls. Healthcare facilities are instructed to cease use of their Nuclear Medicine system until a GE Healthcare Field Engineer is able to do a complete inspection of the system and perform any necessary repairs at no cost. A GE Healthcare representative will contact the hospitals to arrange for the inspection.

Physicians: No action is required beyond the recommendations provided in the Urgent Medical Device Recall letter.

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these products to **MedWatch: The FDA Safety Information and Adverse Event Reporting Program** (<http://www.fda.gov/Safety/MedWatch/default.htm>) either online, by regular mail or by FAX.

Additional Links

- **Urgent Medical Device Recall** (<http://www3.gehealthcare.com/~media/Downloads/us/Product/Product-Categories/Nuclear-Medicine/GEHC%20FMI%2040849%20July%203%202013%20USFDA.pdf>) letter