

Camera Crushes Patient; Sparks Recall

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This week, the U.S. Food and Drug Administration (FDA) [announced](#) [1] the recall of GE Healthcare's Nuclear Medicine Systems following an incident at a VA Medical Center in which a patient died due to injuries sustained while being scanned. A 66-year-old patient was being scanned by an Infinia Hawkeye 4 Nuclear Medicine System when the bolts securing the machine came loose, dropping the attached camera, and crushing the patient.

According to [GE's official statement](#) [2], "Bolts securing the camera to the gantry were loose, thereby stressing the support mechanism and resulting in the incident. The safety concern is related to a potential patient entrapment or crush hazard if the camera falls during a patient exam."

The 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 Class I recall was initiated on June 13, 2013 and because of the similarities in the support mechanism's design, it affected seven products and more than 20 different models (listed below). Class I recalls are reserved for dangerous or defective products that predictably could cause serious health problems or death.

On July 3, 2013, GE notified hospitals that it was recalling several nuclear medicine imaging systems, because serious injuries or deaths could occur due to the aforementioned failure mode. In a subsequent notification, GE included all nuclear

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medicine systems. The company has advised hospitals to cease use until the company can complete an inspection

According to the company's release to hospitals, "GE Healthcare will inspect all affected systems to verify that the support mechanism fasteners are secured properly. A GE Healthcare service representative will contact you to arrange for this inspection as soon as possible. If an issue with the support mechanism fasteners is found on your system, your GEHC Field Engineer will coordinate the replacement of impacted parts in your Gantry and ensure that your system is operating safely and meets all specifications. These activities will be performed at no cost to you."

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](#) [3] either online, by mail, or by FAX.

Recalled Products:

- Infinia Nuclear Medicine Systems (pictured)
- VG and VG Hawkeye Nuclear Medicine Systems
- Helix Nuclear Medicine Systems
- Brivo NM615
- Discovery NM630
- Optima NM/CT640
- Discovery NM/CT670

Recalled 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

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- Discovery NM630
- Optima NM/CT640
- Discovery NM/CT670

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Links:

[1] <http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm362946.htm>

[2] <http://www3.gehealthcare.com/~media/Downloads/us/Product/Product-Categories/Nuclear-Medicine/GEHC%20FMI%2040849%20July%203%202013%20USFDA.pdf>

[3] <http://www.fda.gov/Safety/MedWatch/default.htm>