Australian Government
Department of Health
Therapeutic Goods Administration

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH

Recall Action Notification

INNOVA 2121IQ (Cardiovascular X-ray imaging system)

Important information on the Recall Portal

Medsafe and TGA (the Regulators) publishes information about therapeutic products (goods) supplied in Australia or New Zealand that have been subject to a recall action in a publicly searchable Recall Portal. Information in the Recall Portal about recall actions in Australia and information about recall actions in New Zealand is also published by Medsafe and the TGA (the Regulators), respectively and separately, on their websites.

Recall action means action taken by the responsible person to resolve a problem with therapeutic goods supplied in Australia or New Zealand that have, or may potentially have, deficiencies relating to safety, quality, efficacy (performance) or presentation.

- **Recall actions include: the permanent removal of therapeutic product(s) from supply in the market, the taking of corrective action in relation to therapeutic product(s) (such as repair, modification, adjustment or relabelling) and, in the case of medical devices that have been implanted into patients, the issuing of a hazard alert containing information for health practitioners on how to manage patients.**
- **More information about Australian recall actions is available at <**http://www.tga.gov.au/safety/recalls-about.htm**>**
- **More information about New Zealand recall actions is available at <** http://www.medsafe.govt.nz/hot/ProductRecallInformation/ProductRecallHome.asp**>**

Note: If you are taking a medicine, are using a medical device or have had a medical device implanted into you that is subject to a recall action and you have any concerns you should seek advice from a health professional. You can also obtain information from the following information lines:

- **Australia - Phone: 1800-022-222 <**http://www.healthdirect.org.au/**>**
- **New Zealand Phone - 0800-611-116 <**http://www.health.govt.nz/healthline**>**

About the release of this information

While reasonable care is taken to ensure that the information is an accurate record of recall actions that responsible entities have agreed with the Regulators, which the Regulators have taken or about which the Regulators have become aware, the Regulators do not guarantee or warrant the accuracy, reliability, completeness or currency of the information or its usefulness in achieving any purpose.

The Australian and New Zealand information contained in the Recall Portal is released under subsection 61(5C) of the Therapeutic Goods Act 1989 (the Act). The New Zealand data is also released in accordance with the purposes of the Official Information Act 1982.

To the fullest extent permitted by law, including but not limited to section 61A of the Act, Medsafe or TGA will not be liable for any loss, damage, cost or expense incurred in or arising by reason of any person relying on this information.

Recall action detail

Type of Product[i]	Medical Device
Recall Reference[ii]	RC-2014-RN-00210-1
Product Name/Description[iii]	INNOVA 2121IQ (Cardiovascular X-ray imaging system) Serial Number 589404BU3 ARTG Number: 93871
Recall Action Level[iv]	Hospital
Recall Action Classification[v]	Class I
Recall Action Commencement Date[vi]	3/03/2014
Responsible Entity[vii]	GE Healthcare Australia Pty Ltd
Reason / Issue[viii]	The Innova system may not boot up properly after a power-on or after a system reset. Additionally it may shut down unexpectedly during an exam which may result in the total loss of real-time interventional imaging. The loss of the fluoro imaging capability may cause substantial harm to a patient, in case it happens during a "sensitive phase" of a coronary intervention.
Recall Action[ix]	Recall for Product Correction
Recall Action Instructions[x]	GE Healthcare is advising users to ensure a quick functional check is performed before use. GE will be correcting all affected systems.
Contact Information[xi]	1800 659 465 - GE Heathcare National Call Centre
Country of Recall Action[xii]	Australia

Footnotes

[i] Type of Product: Medicine / Medical Device / Biological.

[ii] Recall Reference: Unique number given by the regulator (Medsafe/TGA).

[iii] Product Name/Description: Brand name/trade name (including active ingredient for medicines) and may include generic reference for the kind of medical device. Includes all necessary information such as affected catalogue, model and/or batch or serial numbers.

[iv] Recall Action Level: The level (depth of recall action) to which the recall action has to be undertaken is based on the significance of the risk and the channels through which the products have been distributed. The recall action levels are: Wholesale/Hospital/Retail/Consumer/Health Care Professional (Medsafe only).

- Wholesale - Includes wholesalers and state purchasing authorities.
- Hospital - Includes nursing homes and institutions, hospital pharmacists, ambulance services, blood and tissue banks and laboratories as well as wholesale as appropriate.

- Retail - Includes retail pharmacists, medical, dental and other health care professionals as well as wholesale and hospital as appropriate.
- Consumer - Includes patients and consumers, as well as wholesale, hospital and retail levels as appropriate.
- Health Care Professional - It is used where there is an issue that impacts directly on the Health Care Professional (HCP) (i.e. change in technique recommendations, prescribing information, product alert) and where the HCP is the most appropriate conduit for information to the patient. (Medsafe only)

[v] Recall Action Classification: Recall actions of therapeutic products are classified based on the potential risk the deficiency poses to patients/consumers. They are classified as Class I / Class II / Class III.

- Class I recall action occurs when the product deficiency is potentially life-threatening or could cause a serious risk to health.
- Class II recall action occurs when the product deficiency could cause illness, injury or result in mistreatment, but are not Class I.
- Class III recall action occurs when the product deficiency may not pose a significant hazard to health, but action may be initiated for other reasons eg. quality related issues.

[vi] Recall Action Commencement Date: The date the recall action strategy and communication was agreed by the regulator (Medsafe/TGA).

[vii] Responsible Entity: Sponsor / Supplier / Importer responsible for the recall actions.

[viii] Reason / Issue: Reason for the recall action.

[ix] Recall Action: A recall action is an action taken to resolve a problem with a therapeutic product already supplied in the market for which there are issues or deficiencies in relation to safety, quality, efficacy (performance) or presentation. The recall actions are: recall, recall for product correction, hazard alert and product alert (Medsafe only).

- Recall - The permanent removal of an affected therapeutic good from supply or use in the market.
- Recall for product correction - Repair, modification, adjustment or re-labelling of a therapeutic good. The corrective action may take place at the user's premises or any other agreed location.
- Hazard alert - Information issued to health care professionals about issues or deficiencies relating to an implanted medical device or a biological product and advice about the ongoing management of patients.
- Product alert - It is issued in response to a situation where market action is required, but a product recall may put the patient at greater risk; i.e. no alternative product is available and the risk to the patient of having no product is greater than the risk to the patient of using the affected product. Clinicians or patients may use the affected product by implementing additional mitigation strategies. (Medsafe only)

[x] Recall Action Instructions: Information on what the customer should do.

[xi] Contact Information: Who the customer should contact for additional information and clarification regarding the recall action.

[xii] Country of Recall Action: Country where the recall action is implemented.