Australian Government
Department of Health
Therapeutic Goods Administration

Recall Action Notification

Product names: SIGNA Premier, SIGNA Pioneer, SIGNA Architect, Discovery MR750w 3.0T, Discovery MR750 3.0T, SIGNA Voyager, Optima MR450w 1.5T, SIGNA Artist, SIGNA Creator, SIGNA Explorer, 1.5T Signa HDxt (HD29)

Important information on the System for Australian Recall Actions

The TGA publishes information about therapeutic goods supplied in the Australian market that have been subject to a recall action in a publicly searchable database.

Recall action means action taken by the responsible entity (being the person who is responsible for taking the recall action) to resolve a problem with therapeutic goods supplied in the Australian market that have, or may potentially have, deficiencies relating to safety, quality, efficacy (performance) or presentation.

- **Recall actions include: the permanent removal of therapeutic goods from supply in the market, the taking of corrective action in relation to therapeutic goods (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://tga.gov.au/safety/recalls-about.htm**>**
- **If you are taking a medicine, using a medical device or have had a medical device implanted into you, that is the subject to a recall action, and you have any concerns you should seek advice from a health professional. <**http://www.healthdirect.org.au/**>**

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 reported to the TGA or of which the TGA has become aware, the TGA does not guarantee or warrant the accuracy, reliability, completeness or currency of the information or its usefulness in achieving any purpose.

To the fullest extent permitted by law, including but not limited to section 61A of the Therapeutic Goods Act 1989, the 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.

The information contained in the SARA database is released under s 61(5C) of the Therapeutic Goods Act 1989. Copyright restrictions apply to the System of Australian Recall actions (SARA) <http://tga.gov.au/about/website-copyright.htm>.

Recall detail

Type of Product[i]	Medical Device
TGA Recall Reference[ii]	RC-2021-RN-01945-1
Product Name/Description[iii]	Product names: SIGNA Premier, SIGNA Pioneer, SIGNA Architect, Discovery MR750w 3.0T, Discovery MR750 3.0T, SIGNA Voyager, Optima MR450w 1.5T, SIGNA Artist, SIGNA Creator, SIGNA Explorer, 1.5T Signa HDxt (HD29) Multiple GTINs ARTG 231238 (GE Healthcare Australia Pty Ltd - MRI system, full-body, superconducting magnet)
Recall Action Level[iv]	Hospital
Recall Action Classification[v]	Class II
Recall Action Commencement Date[vi]	28/09/2021
Responsible Entity[vii]	GE Healthcare Australia Pty Ltd
Reason / Issue[viii]	GE Healthcare has recently become aware about the issue with running the Sagittal VIBRANT application with ASSET. The issue arises when the NoSlabWrap factor is set to a value larger than the default value of 1.0. This issue impacts breast imaging and it was observed that some slices are missing from the reconstructed images which can lead to a gap of anatomy in the 3D Volume images. This issue may lead to a permanent or irreversible impairment or life-threatening changes in clinical status. There have been no injuries reported to GE Healthcare as a result of this issue to date.
Recall Action[ix]	Product Defect Correction
Recall Action Instructions[x]	GE Healthcare are advising customers to continue to use the device while ensuring for the users prescribing Sagittal VIBRANT application with ASSET, the NoSlabWrap factor is set to 1.0. Customers are also advised to re-review any exams previously conducted with Sagittal VIBRANT series with ASSET where the NoSlabWrap factor was set to greater than 1.0. The sponsor is also advising that the customers will be contacted by a representative to arrange the correction for all the affected products.
Contact Information[xi]	1800 659 465 - Customer service center - GE Healthcare

Footnotes

[i] Type of Product: Medicine, Medical Device, or Biological

[ii] TGA Recall Reference: Unique number given by the TGA

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

[iv] Recall Action Level: The level to which the recall action is to be undertaken. This is based on the significance of the risk and the channels through which the goods have been distributed. The recall action levels are / Wholesale / Hospital / Retail / Consumer.

- **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.

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

- **Class I** - A situation in which there is a reasonable probability that the use of, or exposure to, the deficient therapeutic good(s) will cause serious adverse health consequences or death.
- **Class II** - A situation in which use of, or exposure to, the deficient therapeutic good(s) may cause temporary or medically reversible adverse health consequences, or where the probability of serious adverse health consequences is remote.
- **Class III**- A situation in which use of, or exposure to, the deficient therapeutic good(s) is not likely to cause adverse health consequences.

[vi] Recall Action Commencement Date: The date the recall strategy and communication was agreed by the TGA.

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

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

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

- **Recall** - The permanent removal of an affected therapeutic good from supply or use in the market.
- **Product defect 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 healthcare professionals about issues or deficiencies relating to an implanted medical device or biological product and advice about the ongoing management of patients.
- **Product defect alert** - Information issued to raise awareness about issues or deficiencies for a therapeutic good where a recall action will result in interruption of patient treatment or a medicine shortage, including advice to reduce potential risks of using affected goods.

[x] Recall Action Instructions: What customers with affected goods should do.

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

** These definitions are applicable to the 2017 URPTG (Implemented from Jan 15 2018). Recall Action types and Recall Action Classifications prior to 15 Jan 2018 can be found at:
https://www.tga.gov.au/sites/default/files/recalls-urptg-170412.pdf