

## Recall detail

Type of Product <sup>i</sup>	Medical Device
TGA Recall Reference <sup>ii</sup>	RC-2015-RN-01058-1
Product Name/Description <sup>iii</sup>	Revolution CT Scanners, software version 15MW03.12 ARTG Number: 156650
Recall Action Level <sup>iv</sup>	Hospital
Recall Action Classification <sup>v</sup>	Class II
Recall Action Commencement Date <sup>vi</sup>	28/10/2015
Responsible Entity <sup>vii</sup>	GE Healthcare Australia Pty Ltd
Reason / Issue <sup>viii</sup>	A potential hazardous situation can occur during a routine head scan with possible artefacts that may emulate pathology between the brain tissue and bone in the head images. No injuries have been reported to date related to this issue.
Recall Action <sup>ix</sup>	Recall for Product Correction
Recall Action Instructions <sup>x</sup>	To minimise the effects of beam hardening artefacts during routine head scans, GE Healthcare recommends that in addition to the information in the existing CT User Manual, the site also follow the additional recommendations identified in the customer letter. GE Healthcare will be delivering an addendum to the User Manual that reiterates these mitigations. Additional improvements to image quality are currently in development. This software will be distributed and installed on affected systems.
Contact Information <sup>xi</sup>	1800 659 465 - GE National Call Centre

## Footnotes

<sup>i</sup> Type of Product: Medicine, Medical Device, or Biological

<sup>ii</sup> TGA Recall Reference: Unique number given by the TGA

<sup>iii</sup> 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.

<sup>iv</sup> 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.