Recall detail

Type of Product[i]	Medical Device
TGA Recall Reference[ii]	RC-2014-RN-00632-1
Product Name/Description[iii]	Proteus XR/a X-ray imaging systems and Revolution XR/d X-ray imaging systems Proteus XR/a X-ray imaging systems installed with collimator part numbers 2261763 and 2261765 ARTG 98099 All Revolution XR/d X-ray imaging systems ARTG 114083
Recall Action Level[iv]	Hospital
Recall Action Classification[v]	Class II
Recall Action Commencement Date[vi]	12/06/2014
Responsible Entity[vii]	GE Healthcare Australia Pty Ltd
Reason / Issue[viii]	GE Healthcare has become aware of a potential safety issue due to a collimator installation error during a service maintenance activity. If a device is improperly re-installed, the collimator may not be properly seated and may loosen and fall. Such an event may occur immediately following re-installation during a service maintenance activity, but may also occur a few months after a service activity and continued use. A fall of a collimator while the system is in use could result in an injury to a patient or operator. There was a reported incident of a collimator fall which caused a serious patient injury.
Recall Action[ix]	Recall for Product Correction
Recall Action Instructions[x]	GE is advising customers that if they observe any abnormal collimator movement, immediately stop using the system and contact their local GE Healthcare Service Representative. During planned maintenance, customers are also advised not to perform the demounting and re-mounting of collimator for Proteus XR/a and Revolution XR/d X-ray imaging systems as stated in the manuals. A GE Healthcare service representative will contact customers to verify that all affected systems are properly installed and to implement correction if necessary.
Contact Information[xi]	1800 659 465 - GE Healthcare National Call Centre

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