Recall detail

Type of Product[i]	Medical Device
TGA Recall Reference[ii]	RC-2014-RN-00834-1
Product Name/Description[iii]	Discovery XR656 Wall Stand System (X-ray system) Part Numbers: 5374989 and 5397837 Serial numbers: 00000100365HL6, 00000099847HL6, 00000109154HL5, 00000108716HL2, 00000109561HL1, 00000109564HL5 ARTG Number: 167617
Recall Action Level[iv]	Hospital
Recall Action Classification[v]	Class II
Recall Action Commencement Date[vi]	25/07/2014
Responsible Entity[vii]	GE Healthcare Australia Pty Ltd
Reason / Issue[viii]	GE Healthcare has recently become aware of two FlashPad detector falls due to a broken nylon support hook. A detector fall could result in an injury to a patient or operator. There have been reported incidents of detector falls, but no injuries have been reported.
Recall Action[ix]	Recall for Product Correction
Recall Action Instructions[x]	Users are advised that if they observe either one of the nylon support hooks as broken or loose on the Discovery XR656 wall stand system, immediately stop use and contact their local GE Healthcare Service Representative. If the hooks are not broken, users may continue to use the wall stand system. GE Healthcare is correcting all affected systems by replacing the nylon hooks.
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 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.