Recall detail

Type of Product[i]	Medical Device
TGA Recall Reference[ii]	RC-2014-RN-00762-1
Product Name/Description[iii]	MobileDiagnost wDR (digital x-ray system) All units affected ARTG Number: 187112
Recall Action Level[iv]	Hospital
Recall Action Classification[v]	Class II
Recall Action Commencement Date[vi]	9/07/2014
Responsible Entity[vii]	Philips Electronics Australia Ltd
Reason / Issue[viii]	Under the following conditions the system may execute an unintended movement and injure the operator or bystander: - Strain gauges fail to reach the specified life time - Operator requests movement by pressing the dead man handle switch and pushing or pulling the handle bar - Operator/bystander standing close to the device
Recall Action[ix]	Recall for Product Correction
Recall Action Instructions[x]	End users are advised to release the drive handle (dead man switch) in the event of unintended movement. Philips will be updating the strain gauges of the MobileDiagnost wDR.
Contact Information[xi]	1800 251 400 - Philips Customer Care 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.
- Hospital - includes nursing homes and institutions, hospital pharmacists, ambulance services, blood and tissue banks and laboratories as well as wholesale as appropriate.