

## Recall detail

Type of Product <sup>i</sup>	Medical Device
TGA Recall Reference <sup>ii</sup>	RC-2013-RN-01149-1
Product Name/Description <sup>iii</sup>	ADAC ARGUS Gamma Camera Systems (Nuclear medicine system)  Serial numbers: A01100227 and 9807143  ARTG Number: 117642
Recall Action Level <sup>iv</sup>	Hospital
Recall Action Classification <sup>v</sup>	Class I
Recall Action Commencement Date <sup>vi</sup>	8/11/2013
Responsible Entity <sup>vii</sup>	Philips Electronics Australia Ltd
Reason / Issue <sup>viii</sup>	A recent investigation has determined that visual inspections of the fork joints behind the detector that is conducted during six month preventive maintenance (PM) may not detect small cracks or deficiencies in the fork weldment. A failure in the fork weldment has the potential to cause the detector assembly to detach, resulting in serious injury or death to a patient, operator or service personnel member if he or she is in the direct path of the detector assembly and the weldment fails.
Recall Action <sup>ix</sup>	Recall for Product Correction
Recall Action Instructions <sup>x</sup>	Philips Electronics Australia is informing the customers to immediately cease the use of the affected systems. The manufacturer is currently undertaking further analysis regarding the issue and there will be further communication to the customers relating to the corrective action, once the investigation is finalised.
Contact Information <sup>xi</sup>	1800 251 400 - Philips Customer Care

## 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