

Recall detail

Type of Product ⁱ	Medical Device
TGA Recall Reference ⁱⁱ	RC-2014-RN-00405-1
Product Name/Description ⁱⁱⁱ	ADAC Vertex Classic, Vertex Plus, Vertex V60 and Solus Systems ARTG Number: 117642
Recall Action Level ^{iv}	Hospital
Recall Action Classification ^v	Class I
Recall Action Commencement Date ^{vi}	1/04/2014
Responsible Entity ^{vii}	Philips Electronics Australia Ltd
Reason / Issue ^{viii}	Philips Healthcare received a report from the field about an ADAC Vertex Plus system. During clinical use in the relative 180 degree configuration of the detector heads, the radius drive belt in the superior positioned head slipped off the idler pulley, allowing the detector head to drift down slowly (approximately 1 cm per minute) towards the patient. This resulted in the operator having to perform an emergency removal of the patient from the system. There have been no reports of serious injury or death as a result of this situation.
Recall Action ^{ix}	Recall for Product Correction
Recall Action Instructions ^x	Hospitals are requested to cease use of "Relative 180 degree SPECT" and "pinhole collimator" procedures until the implementation of the correction. Philips will replace the two radius drive belts and idler pulleys to correct the problem.
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.
- Retail - includes retail pharmacists, medical, dental and other health care professionals as well as wholesale