

Recall detail

Type of Product ⁱ	Medical Device
TGA Recall Reference ⁱⁱ	RC-2014-RN-01180-1
Product Name/Description ⁱⁱⁱ	MammoDiagnost DR ARTG number: 117662
Recall Action Level ^{iv}	Hospital
Recall Action Classification ^v	Class II
Recall Action Commencement Date ^{vi}	4/11/2014
Responsible Entity ^{vii}	Philips Electronics Australia Ltd
Reason / Issue ^{viii}	Philips has identified that the pin implemented in the safety switch may not put enough pressure on the safety circuit to prohibit movement. The needle positioning device may move even with the safety switch engaged. If this occurs while the needle is inserted, it could lead to an unintended patient injury.
Recall Action ^{ix}	Recall for Product Correction
Recall Action Instructions ^x	A Philips Service representative will contact affected customers to schedule a service visit where the safety switch will be modified. In the interim Philips is reminding end users of the safety instructions in the user manual and recommending that the switch be inspected before every biopsy.
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 and hospital as appropriate.
- Consumer - includes patients and consumers, as well as wholesale, hospital and retail levels as appropriate.