

Recall detail

Type of Product ⁱ	Medical Device
TGA Recall Reference ⁱⁱ	RC-2015-RN-00122-1
Product Name/Description ⁱⁱⁱ	Allura Xper R7.2.x (Fluoroscopic diagnostic x-ray system) Product codes: 722003, 722005, 722006, 722008, 722014, 722015 with system software release 7.2.x ARTG Number:175708
Recall Action Level ^{iv}	Hospital
Recall Action Classification ^v	Class II
Recall Action Commencement Date ^{vi}	13/02/2015
Responsible Entity ^{vii}	Philips Electronics Australia Ltd
Reason / Issue ^{viii}	In certain circumstances, a software error can lead to a situation where the five minute fluoroscopy audible signal does not sound, as is required. No injuries attributed to the problem are reported.
Recall Action ^{ix}	Recall for Product Correction
Recall Action Instructions ^x	Philips Healthcare is advising the user to always observe realtime dose information and cumulative fluoro time provided by the system. The fault condition is reset when a new patient case is started or when the system is restarted. Philips Healthcare service engineers will install software release R7.2.8 which addresses the buzzer issue.
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