

Recall detail

Type of Product ⁱ	Medical Device
TGA Recall Reference ⁱⁱ	RC-2015-RN-00093-1
Product Name/Description ⁱⁱⁱ	AK 200 S and AK 200 ULTRA S nocturnal home hemodialysis machines ARTG Number: 112135
Recall Action Level ^{iv}	Consumer
Recall Action Classification ^v	Class I
Recall Action Commencement Date ^{vi}	4/02/2015
Responsible Entity ^{vii}	Gambro Pty Ltd
Reason / Issue ^{viii}	<p>Gambro has received complaints related to a technical error in the AK 200S nocturnal home haemodialysis machines, which will stop all the pumps and close the venous clamp. This has led to 3 cases of 400mL of blood loss and a 2 day treatment delay. A further 21 reported cases resulted in a technical error and a minor treatment delay.</p> <p>One section in the Operator's Manuals for the AK 200 S and the AK 200 ULTRA S instructs the user to contact technical service and to restart the blood pump to return the extracorporeal blood to the patient. Restarting the blood pump is however not possible, since the venous clamp is closed and the consequence will be a blood loss for the patient.</p> <p>No Deaths or injury have been reported as a result of this issue.</p>
Recall Action ^{ix}	Recall for Product Correction
Recall Action Instructions ^x	An addendum to the Instructions for Use is to be communicated to customers.
Contact Information ^{xi}	02 8852 3700 - Gambro Pty Ltd

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