

Recall detail

Type of Productⁱ	Medical Device
TGA Recall Referenceⁱⁱ	RC-2014-RN-01063-1
Product Name/Descriptionⁱⁱⁱ	Accu-Chek Spirit Combo Insulin Pumps ARTG number: 190251
Recall Action Level^{iv}	Consumer
Recall Action Classification^v	Class I
Recall Action Commencement Date^{vi}	1/10/2014
Responsible Entity^{vii}	Roche Diagnostics Australia Pty Limited
Reason / Issue^{viii}	Roche Diabetes Care has become aware that in a limited number of cases, patients using the Accu-Chek Spirit Combo insulin pump may experience a loss of the date and time settings. Investigations undertaken by Roche revealed that this issue may occur if the pump capacitor fails to function properly due to a leakage. The capacitor provides the necessary voltage to save time and date settings during power interruption, typically during a battery change.
Recall Action^{ix}	Recall for Product Correction
Recall Action Instructions^x	Roche is advising end users and healthcare professionals of the potential issue. End users are advised to ensure that the time and date are set correctly after a battery change. Users who experience any failures are requested contact the Accu-Chek Customer Care Line to arrange for a replacement pump. For more details, please see http://www.tga.gov.au/safety/alerts-device-accu-chek-insulin-pump-141003.htm .
Contact Information^{xi}	1800 633 457 - Accu-Chek Contact 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.