

Urgent Field Safety Notice

SBN-RDC_2015_02

Version 1
23-Apr-2015

Update of the handling Instructions to ensure a correct change of the insulin cartridge

Product Name	Accu-Chek® Spirit Combo Insulin Pump Accu-Chek® Spirit Pump
GMMI / Part No	05504678001
Device Identifier	05877164001 05344522001 05391750001 04636252001 04636384001
Production Identifier (Lot No./Serial No.)	N.A.
Type of Action	Customer information

Dear Customer,

We became aware that some customers using the Accu-Chek Spirit/ Spirit Combo system are experiencing an increase of mechanical errors with their insulin pumps showing E6 and E10 error messages. Having evaluated the customer reports and the products' instructions for use, we have identified the opportunity to offer advanced handling instructions for the cartridge change to prevent the future occurrence of this issue. We sincerely apologize for any inconvenience this may have caused and hope that the enhanced handling information provided with this letter support you in a safe, reliable and satisfactory use of your Accu-Chek Spirit/ Spirit Combo insulin pump system.

If users do not follow the cartridge change process step-by-step as described in the attached training leaflet, there is a potential risk of small insulin amounts to drip into the cartridge compartment. Such small insulin amounts would reside in the compartment and result in a damage of the piston rod over time, so that the piston rod will not properly move and potentially limit or cause a blockage of the insulin pump motor function. Eventually, this may result in the insulin not being delivered as intended. The issue is easily detectable as the pump will alert the user by acoustic, visual and vibration alerts. However, to avoid this risk it is key, to follow the instructions and assemble the cartridge, adapter and infusion set tubing first, prior to inserting the new cartridge into the insulin pump.

As patient safety is our top priority, Roche Diabetes Care has started to enhance its handling instructions for the Accu-Chek Spirit/ Spirit Combo system, user training material as well as the training program for



professionals. With these new and advanced handling instructions we aim to ensure that every user of the Accu-Chek Spirit /Spirit Combo insulin pump can easily change the insulin cartridge without the risk of insulin dripping into the cartridge compartment. If you however, experience an E6 or E10 error message being displayed on the pump screen, please contact our Accu-Chek ExtraCare line at 6272 9200.

Thank you in advance for your understanding and co-operation. If you have any further questions, please do not hesitate to contact our Accu-Chek ExtraCare line at 6272 9200 or your local Accu-Chek sales representative (Terence Yeo 9831 2517) at any time.

Sincerely,

Roche Diagnostics Asia Pacific Pte Ltd

Email: sg.regulatory@roche.com



ACKNOWLEDGMENT RECEIPT

This is to acknowledge the receipt of Roche Field Safety Notice Reference No. SBN-RDC_2015_02 dated 23 Apr 2015, update of the handling Instructions of Accu-Chek® Spirit Combo Insulin Pump and Accu-Chek® Spirit Pump to ensure a correct change of the insulin cartridge.

Received by:

Name & Signature

Date