

Consumer Letter

(Accu-Chek Spirit and Accu-Chek Spirit Combo)



Urgent field safety notice – SB_RDC_2015_02

<Enter address here>

Location, Date

Important information on the Accu-Chek® Spirit and Accu-Chek® Spirit Combo insulin pumps:

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

Dear Customer,

We have recently become aware that some customers using the Accu-Chek Spirit insulin pump and the Accu-Chek Spirit Combo insulin pump system are experiencing an increase in the number 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 an opportunity to offer advanced handling instructions for the cartridge change to prevent the future occurrence of this issue. We sincerely apologise for any inconvenience this may have caused and hope that the enhanced handling information provided with this letter support you and your customers in the safe, reliable and satisfactory use of the Accu-Chek Spirit insulin pump and the Accu-Chek Spirit Combo insulin pump system.

If users do not follow the step-by-step cartridge change process as it is described in the enclosed training leaflet, there is a potential risk that small amounts of insulin could drip into the cartridge compartment. Such small amounts could remain in the compartment and result in damage to the piston rod over time, so much so that the piston rod will not move correctly and this could potentially limit or block the insulin pump motor function entirely. Eventually, this may result in the insulin not being delivered as intended and an E6 (mechanical error) or E10 (cartridge error). 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 insulin pump and the Accu-Chek Spirit Combo system, as well as user training material and the training programme for professionals. With these enhanced handling instructions we aim to ensure that every user of the Accu-Chek Spirit and Accu-Chek Spirit Combo insulin pumps can easily change the insulin cartridge without the risk of insulin



dripping into the cartridge compartment. However, if you experience an E6 or E10 error message being displayed on the pump screen, please advise them to contact our Accu-Chek Pump Care line on 1800 88 23 51.



The Competent Authority has been informed about this field notice.

Actions:

A) If you have received this communication by email – please click through the acknowledgement button provided in the original email message

Or

B) If you have received this notification via post, please complete the enclosed Acknowledgement form and return to Roche

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 Customer Care line on 1800 88 23 51 or your local Accu-Chek sales representative at any time.

Kind regards,
Roche Diabetes Care