



URGENT RECALL FOR PRODUCT CORRECTION

23 April 2015

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Accu-Chek® Spirit Combo Insulin Pump and Accu-Chek® Spirit Insulin Pump: Update of the handling instructions to ensure a correct change of the insulin cartridge

Dear Customer

We became aware that some customers using the abovementioned Accu-Chek pump systems are experiencing an increase of mechanical errors with their insulin pump showing E6 and E10 error messages. Having evaluated the customer complaints and the products' instructions for use, we have identified the opportunity to improve the handling instructions for the cartridge change to prevent the future occurrence of this issue. We are certain that the improved handling information provided with this letter will support you in the reliable and satisfactory use of your Accu-Chek insulin pump.

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 dripping into the cartridge compartment. Such small insulin amounts would reside in the compartment and result in 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. Such an 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 initiated an enhancement of its handling instructions for the Accu-Chek Combo system (attached below – note instructions are valid for both abovementioned pump systems). With these new and advanced handling instructions we aim to ensure that every user of the Accu-Chek 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 Customer Care line at **1800 633 457**.

The Therapeutic Goods Administration has been notified of this action.

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 at **1800 633 457** or your local Accu-Chek sales representative at any time.

Kind Regards

Roche Diabetes Care

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The Accu-Chek® Combo System Training Chart

How to change the cartridge of the Accu-Chek Spirit Combo insulin pump



Remove the protective cap from the cartridge. (Do not touch the cartridge tip).



Push the adapter all the way onto the cartridge tip, to the stop.



Carefully prepare a new Accu-Chek infusion set, following the instructions supplied for use.



Hold the adapter and twist the infusion set luer-lock connection by hand, clockwise into the adapter. Do not over-tighten.



Remove the cartridge, if necessary. Unscrew carefully. Do not pull the cartridge out until it is completely unscrewed.



Press the menu button to move to the cartridge change screen. Press the OK button to select.



Make sure your infusion set is disconnected and the cartridge has been removed. Please hold the OK button for 3 seconds, until you hear a melody.



The piston rod begins to return. Do not touch or otherwise disturb the piston rod while it is rewinding, as this could result in damage to your pump.



When the piston rod has returned completely, the cartridge volume screen displays the maximum volume, 315 U.



Hold your pump upright. Hold the new filled cartridge so, that the connected adapter and infusion set points upwards, parallel and close to the cartridge compartment.



Make sure that the top edge of the threaded part of the adapter is level with the top of the cartridge compartment.



Press or to move the piston rod in level with the bottom of the cartridge plunger.

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Position your pump diagonally downwards (with the adapter pointing down). Insert the cartridge into the cartridge compartment.



Twist (do not push) the adapter clockwise until it is correctly seated against the cartridge compartment.



The cartridge is correctly inserted when the end plate of the piston rod is correctly seated against the cartridge plunger.



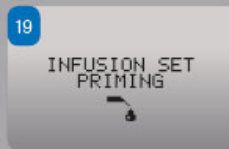
If the end plate of the piston rod is not correctly aligned with the cartridge plunger, remove the cartridge from the compartment and repeat steps 10-14.



Check that the infusion set luer-lock connector is still correctly connected to the adapter. Tighten the infusion set clockwise by hand until it sits tightly in the adapter.



Press OK after correctly inserting the cartridge. Your pump performs a self-test.



When the self-test process is finished, the infusion set priming screen is displayed. Priming the infusion set means filling the tubing with insulin and pushing any air bubbles out. Please continue with this process as described in the manual.



Incorrect use can cause damage to your insulin pump



Do NOT insert the cartridge without the connected infusion set tubing into the insulin pump. This may lead to insulin flowing into the cartridge compartment. If insulin would reside in the compartment this can result in a damage of the piston rod over time and potentially limit or cause a blockage of the insulin pumps motor functions.



Do NOT hold your pump upright when inserting the cartridge. This may lead to insulin flowing into the cartridge compartment and a blockage of the piston rod. Consequently the pump would display an E6 or E10 error message or stop.

Experience what's possible.

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