

**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

# The Accu-Chek® Combo System Training Chart

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



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



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



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



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



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



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



7 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.



8 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.



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



10 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.



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



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



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.



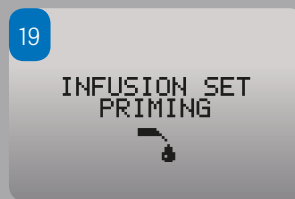
If the end plate of the piston rod is not correctly aligned with the cartridge plunger, remove the cartridge from the compartment and repeat steps 10–14.



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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www.accu-check.com  
Roche Diagnostics GmbH  
D-68298 Mannheim

ACCU-CHEK®

# **HCP 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 Healthcare Professional,

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 your patients experience an E6 or E10 error message being displayed on the pump screen, please advise them to contact our Accu-Chek Pump Care line at 1800 88 23 51.



The competent authority as well as users of the Accu-Chek Spirit insulin pump and the Accu-Chek Combo system who received their devices directly from Roche have been informed about this Field Safety Corrective Action.

**Actions:**

1. Please complete the enclosed Acknowledgement form and return to Roche using your preferred method
2. Ensure that patients using the Accu-Chek Spirit and Accu-Chek Combo insulin pumps which have been supplied directly by yourself and/or your facility receive a copy of the FSN documentation.

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

Kind regards,  
Roche Diabetes Care

# The Accu-Chek® Combo System Training Chart

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



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



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



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



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



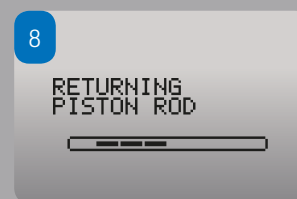
5 Remove the cartridge, if necessary. Unscrew carefully. Do not pull the cartridge out until it is completely unscrewed.



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



7 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.



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



10 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.



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



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



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.



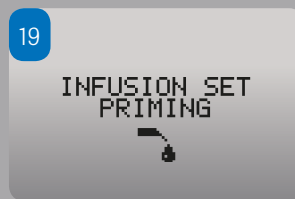
If the end plate of the piston rod is not correctly aligned with the cartridge plunger, remove the cartridge from the compartment and repeat steps 10–14.



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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D-68298 Mannheim

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