URGENT RECALL FOR PRODUCT CORRECTION

1st October, 2014

Important information on Accu-Chek® Spirit Combo insulin pumps:
Potential date and time loss due to a capacitor defect

Dear Customer

We would like to inform you about an issue potentially occurring with the Accu-Chek Spirit Combo insulin pump. 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. Our thorough investigation of the situation 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.

Given the rare case that the above mentioned issue occurs, this will result in the pump resetting to the default date and time and requiring the user to set or re-program the correct date and time on the pump. In such cases the user might accidentally overlook the change to the default date and time and confirm the default date and time settings provided by the pump. As a result, a shift of the basal rate time block would occur, which could potentially contribute to hyper- or hypoglycaemic events. In users with impaired vision, it may be particularly difficult to detect the date and time loss. We have compiled important information on the following pages on how to change the battery as well as the pump screens that are displayed in case the defect occurs.

As patient safety is our first priority, Roche Diabetes Care informs users of the Accu-Chek Spirit Combo insulin pump to be aware of this issue and to ensure time and date are set correctly on their pump after a battery change. Users who experience any failures associated with this issue are asked to contact the Accu-Chek Customer Service Centre on 1800 633 457. The affected Accu-Chek Spirit Combo insulin pumps will be replaced immediately. Roche Diabetes Care has addressed the issue and is taking measures to resolve it.

The Therapeutic Goods Administration has been notified of this action

We would like to thank you for your co-operation with this issue and apologise for any inconvenience that this may cause you. Should you have any additional queries or need further clarification, please do not hesitate to contact our Accu-Chek Contact Centre on 1800 633 457 or your local Accu-Chek representative at any time.

Kind regards,
Roche Diabetes Care
Procedure for inserting and changing the battery of the Accu-Chek Spirit Combo insulin pump system:

1. Press \( \text{STOP} \) to move to the STOP YOUR PUMP screen.
2. Press \( \text{STOP} \) to select. Your pump is now in STOP mode and insulin delivery stops.
3. Remove the battery cover.
4. Insert the battery, negative (−) end first, positive (+) end up, into the compartment.
5. Place the cover on the positive end and gently push the battery in, while turning the cover clockwise to partially tighten it.
6. Use the battery key to fully tighten the battery cover. You can verify that the battery cover is correctly tightened by checking that it is in line with the pump casing. Do not overtighten.

Data memory
When you remove the battery, the pump keeps track of the time and date for about one hour. The insulin pump settings (such as the hourly basal rates, bolus increment and active user menu) as well as the event memory (e.g. bolus and alarm history, history of daily insulin totals and temporary basal rates) are saved, regardless of battery condition or the amount of time your pump has been without a battery when the capacitor is working correctly. Please refer also to the instruction for use of your Accu-Chek Combo system.

After you have inserted the new battery, the pump begins its start-up process. In case the pump does not begin the start-up process after inserting the battery, please make sure that the battery is inserted correctly (negative end first). Please keep in mind to change the battery together with the new battery cover to have an optimal power supply for your insulin pump system.
**What does the Accu-Chek Combo system show in case of the capacitor defect:**

*Screens shown on the pump in case the battery is running low*

*Screens shown on the pump in case the capacitor issue is occurring*

*Warning screens shown on the pump and the meter in case the pump detects inappropriate time and date settings*
Setting the time and the date:

1. Press \( \downarrow \) to move to the TIME AND DATE SETTINGS screen.
   Press \( \uparrow \) to select.

2. The HOUR screen is displayed.
   Press \( \downarrow \) or \( \uparrow \) to set the hour.

3. Press \( \downarrow \) to move to the MINUTE screen.
   Press \( \downarrow \) or \( \uparrow \) to set the minute.

4. Press \( \downarrow \) to move to the YEAR screen.
   Press \( \downarrow \) or \( \uparrow \) to set the year.

5. Press \( \downarrow \) to move to the MONTH screen.
   Press \( \downarrow \) or \( \uparrow \) to set the month.

6. Press \( \downarrow \) to move to the DAY screen.
   Press \( \downarrow \) or \( \uparrow \) to set the day.

7. Press \( \downarrow \) to move to the TIME FORMAT screen.
   Press \( \downarrow \) or \( \uparrow \) to set the time format.

8. Press \( \downarrow \) to move to the DATE FORMAT screen.
   Press \( \downarrow \) or \( \uparrow \) to set the date format.
   Press \( \downarrow \) to save and exit.