

## Urgent field safety notice

<Enter address here>

Location, Date

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

Dear Healthcare Professional / Distributor

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 hypoglycemic 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 healthcare professionals, distributors and users of the Accu-Chek Spirit Combo insulin pump to be aware of this issue and to ensure time and date is 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 Center. 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.

Your local competent authority has been informed about this issue. We would kindly like to ask you to inform your patients / customers to whom the Accu-Chek® Spirit Combo insulin pumps have



been distributed to about this safety information.

We would like to thank you for your co-operation and apologise for any inconvenience this may cause. If you may have any further questions, please do not hesitate to contact our Accu-Chek Customer Service Center on xxx-xxx-xxx or your local Accu-Chek insulin delivery specialist at any time.

Kind regards,

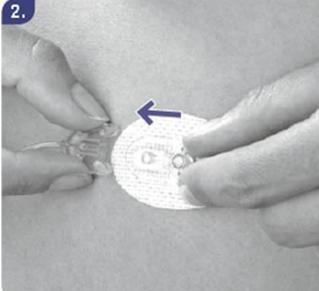
Roche Diabetes Care

## Procedure for inserting and changing the battery of the Accu-Chek Spirit Combo insulin pump system:

**1.** 

Press  to move to the STOP YOUR PUMP screen.

Press  to select. Your pump is now in STOP mode and insulin delivery stops.

**2.** 

Remove or disconnect your infusion set from the infusion site, to ensure that there is no risk of accidental insulin delivery.

**3.** 

Remove the battery cover.

Use the battery key to turn the battery cover anti-clockwise. Make sure that the opening of the battery compartment and the seal are clean and undamaged. Where appropriate, remove the old battery.

**4.** 

Insert the battery, negative (-) end first, positive (+) end up, into the compartment.

**5.** 

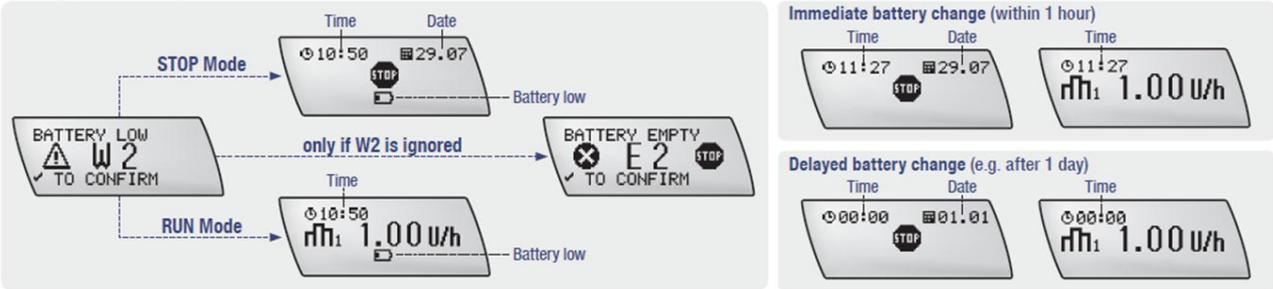
Place the cover on the positive end and gently push the battery in, while turning the cover clockwise to partially tighten it.

**6.** 

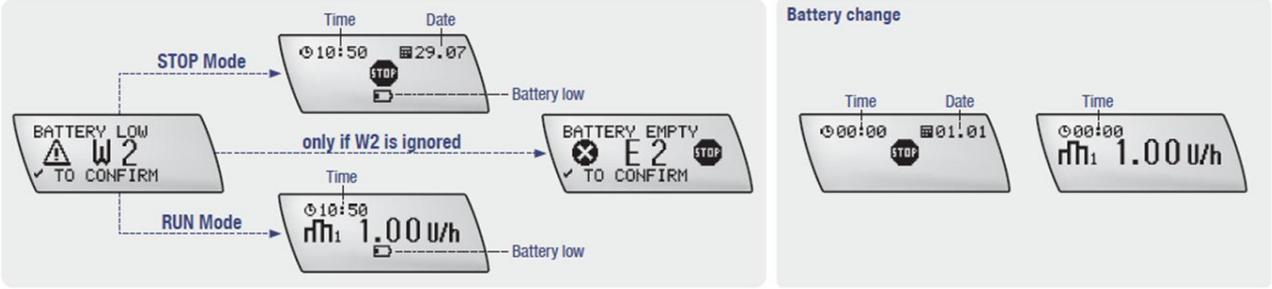
Use the battery key to fully tighten the battery cover. You can verify that the battery cover is correctly tightened by checking that it is in line with the pump casing. Do not over-tighten.

# What does the Accu-Chek Combo system show in case of the capacitor defect?

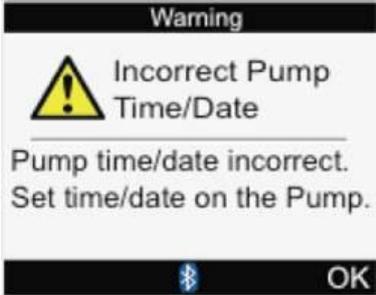
## Screens shown on the pump in case the battery is running low



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



## Warning screens shown on the meter in case date and time settings of the pump and the meter are not synchronized



## Setting the date and time

**1.**  Press  to move to the TIME AND DATE SETTINGS screen.  
Press  to select.

**2.**  The HOUR screen is displayed.  
Press  or  to set the hour.

**3.**  Press  to move to the MINUTE screen.  
Press  or  to set the minute.

**4.**  Press  to move to the YEAR screen.  
Press  or  to set the year.

**5.**  Press  to move to the MONTH screen.  
Press  or  to set the month.

**6.**  Press  to move to the DAY screen.  
Press  or  to set the day.

**7.**  Press  to move to the TIME FORMAT screen.  
Press  or  to set the time format.

**8.**  Press  to move to the DATE FORMAT screen.  
Press  or  to set the date format.  
Press  to save and exit.