



Urgent field safety notice

<Enter address here>

**YOUR ACTION REQUIRED:
Please complete the enclosed
acknowledgement form and return it
to us**

March 2017

Important information update on the Accu-Chek® Insight insulin pump: New instructions to improve the battery lifetime

Dear Healthcare Professional,

Your patients using the Accu-Chek Insight insulin pump system have been trained on how to change the battery of their insulin pump and the handling steps they need to follow. With this letter, we would like to bring additional important handling aspects to your attention that will help your patients to further improve the battery lifetime of their insulin pump.

Choosing the wrong battery type during a change or use of low-quality batteries can lead to a rapid power drop or a system shut off due to battery issues. In some cases, such a very rapid voltage drop can result in the pump not giving an alarm, which would normally happen and enable a clear and early detection of the low battery status and remind the user to change the battery. Such an undetected sudden shut-off of the insulin pump could potentially be followed by an equally undetected insulin under-delivery, particularly during night-time. Selecting the incorrect battery type (choose between Lithium or Alkaline) on the insulin pump may impact the detection of the remaining voltage, which can also lead to the above described issues, as lithium and alkaline batteries have different type-specific characteristics.

As your patients' safety is our top priority, we are further enhancing the handling instructions for the Accu-Chek Insight system and are informing users of the Accu-Chek Insight system to be aware of this topic. Using Energizer® Ultimate Lithium batteries (1.5V AAA / FR03) and following the steps described in the attached handling instructions will prevent the future occurrence of such battery issues and improve the battery lifetime.

We kindly ask you to support us in bringing this important information to your patients' attention and to contact the Accu-Chek Pump Careline if you become aware of your patients experiencing additional problems. Please rest assured that this issue is only affecting the Accu-Chek Insight insulin pump. All other Accu-Chek pump systems are not affected by this. Your local competent authority as well as users of the Accu-Chek Insight system have been informed about this field action in parallel.

Important Information:

- 1.** If you or your facility supply consumables directly to patients, we may not be able to contact these individuals to advise them of the information contained in this letter. Your local Accu-Chek insulin pump representative will be in touch with you directly in order to discuss the best way to share this information.
- 2.** If you have any Accu-Chek Insight insulin pump systems in stock, please include a copy of the patient FSN in the pump literature pack that is provided to each patient with their insulin pump at initiation - please contact Roche Diabetes Care (by emailing burgesshill.dcsafety@roche.com) to request copies of the patient FSN letter.

Thank you in advance for your understanding and co-operation. If you need any additional support in handling the Accu-Chek Insight system or have any further questions, please do not hesitate to contact our Accu-Chek Pump Careline on 0800 731 2291, burgesshill.insulinpumps@roche.com or your local Accu-Chek insulin pump representative at any time.

Kind regards, Roche Diabetes Care