



Urgent field safety notice

<Enter address here>

Location, Date

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

Dear Customer [*please personalize*],

As a user of the Accu-Chek Insight insulin pump system, you have been trained on how to change the battery of your insulin pump and the handling steps you need to follow. With this letter, we would like to bring additional important handling instructions to your attention that will help you to further improve the battery lifetime of your insulin pump.

Choosing the wrong battery type during a battery change or the use of low-quality batteries can lead to a rapid power drop or a system shut down. In some cases, a very rapid voltage drop can result in the pump not alarming the user, which would have normally happened and enabled a clear and early detection of the low battery status and remind the user to change the battery. Such an undetected sudden shut-down of the insulin pump could potentially be followed by an equally undetected insulin underdelivery, particularly during use at night. Using an 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 safety is our top priority, we are further enhancing the handling instructions for the Accu-Chek Insight system and are informing users to be aware of this enhancement. 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 contact the Accu-Chek Pump Careline if you experience 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 healthcare professionals have been informed about this field action.

Thank you in advance for your co-operation. If you need any additional support in handling the Accu-Chek Insight system or have any further questions, please do not hesitate in contacting our Accu-Chek Pump Careline.

Tel 0800 731 2291
Email burgesshill.insulinpumps@roche.com

Kind regards,

Roche Diabetes Care

ATTACHMENT: Improving battery lifetime of your Accu-Chek® Insight insulin pump