

HCP Letter

(Accu-Chek Insight battery)



Urgent field safety notice – SB_RDC_2015_04

<Enter address here>

Location, Date

Important information on the Accu-Chek® Insight insulin pump system: Update of the handling instructions to ensure usage of the appropriate batteries and optimal battery lifetime

Dear Healthcare Professional,

We recently received feedback from a limited number of people with diabetes using the Accu-Chek Insight insulin pump system that they are experiencing rapid power depletion or a system shut down due to battery issues.

We have thoroughly investigated these cases and identified low-quality batteries or an incorrectly selected battery type on the pump to be the root cause of such battery issues. Using the high-quality batteries described below and selecting the correct battery type will prevent the future occurrence of this issue.

We sincerely apologize for any inconvenience this may have caused you and your patients and hope the enhanced handling information provided below supports your patients in the safe, reliable and satisfactory use of the Accu-Chek Insight insulin pump system.

Recommended actions to be taken:

1. Based on our investigation results, we recommend the following high-quality batteries for use with the Accu-Chek Insight insulin pump:

Lithium battery

Use only lithium batteries that comply with IEC 60086-4, e.g. "Energizer® Ultimate Lithium, FR03, 1.5V AAA (FR03)". These have been successfully tested with the Accu-Chek Insight insulin pump. *Please note: Roche Diabetes Care UK only provide Lithium batteries as part of service packs and battery orders.*

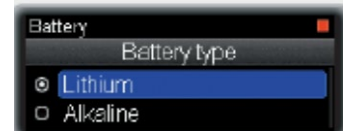
Alkaline battery

Use only high-quality alkaline batteries (1.5V AAA (LR03)) that are suitable for energy-intensive devices, such as those requiring a flash. This is shown by a "Flash" symbol on the packaging (see picture).



Please advise your patients not to use carbon zinc or rechargeable nickel cadmium (NiCd/NiMH) batteries with the Accu-Chek Insight insulin pump.

2. **Please also train your patients to make sure to always confirm the correct battery type** on the insulin pump upon the battery change (see image).



If users follow the battery recommendation and handling instruction provided above the pump will work safely and reliably for up to 30 days with a new high-quality lithium battery, if used as directed.

What are the risks of using low-quality batteries and/or selecting the incorrect battery type?

Using low-quality batteries may lead to a very short battery lifetime of only a few days and sudden power depletion which may cause an unexpected shut down of the insulin pump. In some cases, the pump may not even alarm due to a very rapid decrease in voltage. An unexpected shut down of the insulin pump could potentially result in under-delivery of insulin. Using the recommended batteries will enable early detection of low power and remind the user to change the battery.

Selecting the incorrect battery type on the insulin pump may impact the detection of the remaining voltage in the battery, which can also lead to the above described issues, as lithium and alkaline batteries have different lifetime characteristics

To avoid this risk it is key to follow the battery recommendation, and change the battery as described in the user manual of the Accu-Chek Insight insulin pump. As patient safety is our top priority, Roche Diabetes Care has started to further enhance its handling instructions for the Accu-Chek Insight insulin pump. With this we aim to ensure that every user of the Accu-Chek Insight insulin pump selects the appropriate batteries for the system. This would lessen the risk of a sudden decrease in voltage or an unexpected shut down of the insulin pump.

If your patients experience a rapid decrease in power, please advise them to contact our Accu-Chek Customer Care line on 0800 731 22 91. This issue only affects the Accu-Chek Insight insulin pump system and the competent authority as well as users of the Accu-Chek Insight insulin pump system who have received the product directly from Roche have been informed about this field action. Please forward this information to all those who need to be aware within your organisation.

Actions:

1. Please complete the enclosed Acknowledgement form and return to Roche using your preferred method
2. Ensure that patients using the Accu-Chek Insight insulin pump system where is has 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 Customer Care line on 0800 731 22 91 or yourlocal Accu-Chek sales representative at any time.

Kind regards,
Roche Diabetes Care