

Consumer Letter

(Accu-Chek Insight PFC)



Urgent field safety notice

<Enter address here>

Location, Date

Important information on the Accu-Chek® Insight insulin pump system: Update of the handling instructions for changing an insulin cartridge

Dear Customer [*please personalize*],

We have seen an increase in customer feedback from people with diabetes using the Accu-Chek Insight insulin pump system and experiencing leaking insulin cartridges. We have immediately investigated this feedback and identified the need to update the handling instructions and user manual of the Accu-Chek Insight insulin pump for inserting or changing the pre-filled insulin cartridge. If inserted incorrectly, insulin can leak from the cartridge into the cartridge compartment resulting in an under-delivery of insulin which can lead to complications as e.g. a hyperglycemia. Such a leaking cartridge can be detected by regularly checking the pump a few hours following the cartridge change as the insulin would be visible e.g. through condensation in the pump's cartridge compartment. **To avoid the risk of leaking insulin, please make sure that you always follow the handling steps described below and in the attached training chart when inserting or changing a pre-filled insulin cartridge.**

As patient safety is our key priority, we have started to update and enhance our handling instructions with immediate effect and we will provide an updated user manual at a later stage. In doing so, we aim to ensure that every user of the Accu-Chek Insight insulin pump knows how to insert or change the insulin cartridge correctly. These measures will help reduce the risk of insulin leaking from the cartridge.

As the handling differs from other Accu-Chek insulin pump systems, we would like to draw your particular attention to this and have also started to re-emphasise these specific handling steps with healthcare providers. **It is important that whenever you change the insulin cartridge of your Accu-Chek Insight system you follow the steps as they are described in the attached training chart.**

Please make sure that

1. you always check the cartridge, including the rubber plunger at the bottom of the cartridge. Do not use it if any damage or leakage is seen or if the rubber plunger has been drawn above the white label band at the bottom of the cartridge. This could be a result of leakage of insulin. If you suspect the cartridge is damaged, take it back to your supplier. Do not use the insulin cartridge if the cartridge or the device containing the cartridge is dropped, damaged or crushed.
2. you always hold the pump **in an upright position when inserting the new cartridge** as shown in the attached training chart.
3. every time you change your cartridge, you should also change your adapter and tube.
4. you place a **new adapter** on the bayonet socket of the cartridge compartment. Make sure you insert the **nose of the adapter** into the notches of the pump's housing **at a right angle (90°)**. Otherwise the needle located in the nose of the adapter could bend and lead to leakage of insulin into the cartridge compartment.



5. you turn the adapter clockwise all the way until it stops. The adapter is correctly positioned when it is aligned with the pump's housing.

The enhanced instructions provided with this letter aim to support you in the correct, reliable and satisfactory use of your Accu-Chek Insight insulin pump system. **Please keep these instructions in easy reach until you receive the updated user manual for your Accu-Chek Insight system.** Your national competent authority, healthcare professionals, distributors and retailers have been informed about this field action.

Thank you in advance for your understanding and co-operation. If you need any additional advice on the operation and wearing of the Accu-Chek Insight system or have any further questions, please do not hesitate to contact our Accu-Chek Customer Care line **at xxx-xxx-xxx** at any time.

Kind regards,
Roche Diabetes Care

ATTACHMENT: Accu-Chek® Insight Training Chart