

Consumer Letter (Accu-Chek® Insight PFC)



Urgent field safety notice

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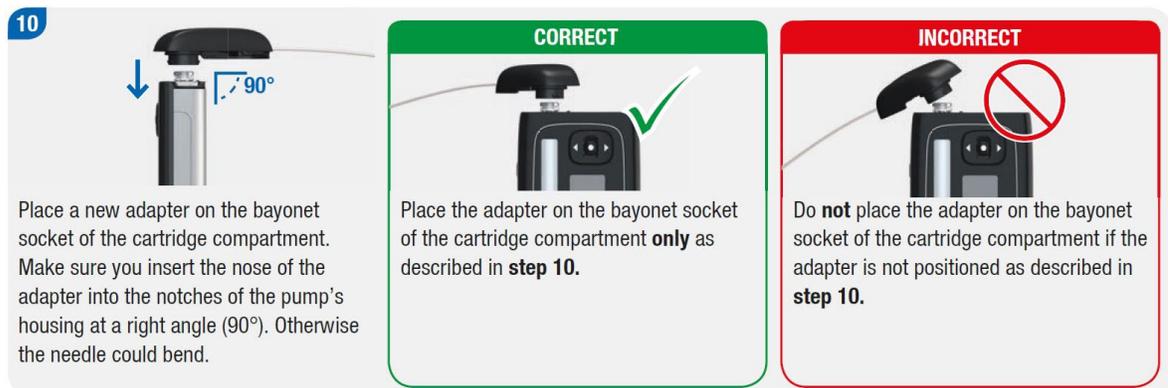
Location, Date

Important information on the Accu-Chek® Insight insulin pump system: Minimizing the risk of leakage, when changing a pre-filled insulin cartridge

Dear Customer [*please personalize*],

Today, we would like to reemphasize some key handling aspects to support you as a user of the Accu-Chek® Insight insulin pump system, in minimizing the risk of leakage, when changing your pre-filled insulin cartridge. We are still seeing some cases of leaking cartridges occur, which in some cases have led to serious adverse events such as ketoacidosis.

As patient safety is our first priority, we would like to ensure that the risk for leakage is minimized by reemphasizing important handling aspects. It is of utmost importance to follow the instructions for use when inserting or changing the pre-filled insulin cartridge, especially to hold the pump in an upright position and to connect the cartridge and the adapter in an 90° angle as illustrated below. Otherwise the membrane may be damaged by the adapter needle, which could result in a leakage of insulin.



In addition, please make sure to:

- Always change the adapter and tubing with every cartridge change
- Check that there is insulin in the tube after changing an insulin cartridge
- When changing the cartridge, please do this at least 3 hours before bedtime
- Monitor blood glucose values for up to 3 hours after changing an insulin cartridge
- Always check the pump for leakage if you have unusual fluctuating blood glucose levels
- Always have an alternative therapy, e.g. an insulin pen available.



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