

Consumer Letter

(Accu-Chek Insight – Safety Frames)



Urgent field safety notice

<Enter address here>

Location, Date

Important information | Accu-Chek Insight insulin pump system (serial no. below 32100000): New key frames to prevent unintentional operation of pump keys and quick bolus buttons

Dear Customer,

At Roche Diabetes Care we hold our products to the highest quality standards and are committed to continuously improve them so they seamlessly integrate with the everyday therapy needs of people with diabetes. This is why we had previously informed you about the enhanced handling instructions regarding the key lock functionality of the Accu-Chek Insight insulin pump. Today, we would like to introduce you to an additional advancement to reduce the risk of an unintentional activation of the pump keys and quick bolus buttons. The new key frames designed for the Accu-Chek Insight insulin pump system with a serial number below 32100000 will protect the quick bolus buttons and pump keys from accidental activation and unintended operation. All other pumps are not affected by this issue. You can find the serial number of your Accu-Chek Insight insulin pump on the back side of the system.

Enclosed to this letter you will find your safety frame kit including a cleaning tissue, a detailed instruction how to apply the frames to your Accu-Chek Insight insulin pump system.

Important to keep in mind when preparing your pump for the safety frame application:

- Please do not affix the frames when these are cold. Frames need to be stored at room temperature at least for 1 hour prior to application
- Please remove the protective foil from the pump display as the frames otherwise would not properly stick
- Please follow the advice for the cleaning tissue when cleaning the pump
- Please let the surface of your pump dry for approx. 1 minute after cleaning before affixing the frames

After application please return the acknowledgement form back to us via e-mail, fax or mail. For general information on the functionality of the pump keys and quick bolus buttons, please refer to your Accu-Chek Insight pump manual. Your time and cooperation is very much appreciated. In parallel, we have informed the national competent authority, about this field action.

Please call our Accu-Chek Customer Care line **at xxx-xxx-xxx**, if you need any additional assistance regarding the operation of your Accu-Chek Insight insulin pump system or have any further questions or concerns. It is through the careful monitoring of customer reports that we are able to identify issues and implement solutions.

Kind regards,



Roche Diabetes Care

Appendices:

- Safety frame kit including cleaning tissue
- Instructions for use for Accu-Chek Insight safety frames
- Acknowledgement form