

# **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:

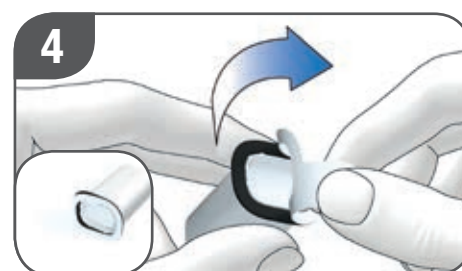
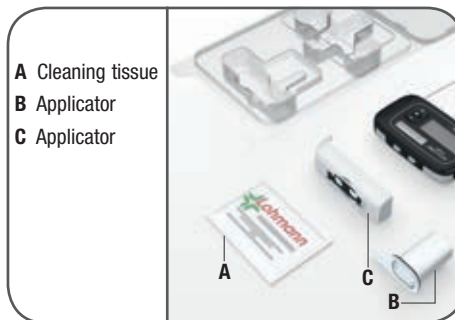
- Safety frame kit including cleaning tissue
- Instructions for use for Accu-Chek Insight safety frames
- Acknowledgement form

## Key Frames

Instructions for use

EN

ACCU-CHEK®



The Accu-Chek Insight key frames consist of a cleaning tissue (A) and two applicators with black frames (B, C). White protective films cover the black frames. The applicators are necessary to place black frames around the keys of the insulin pump. This avoids accidental operation of the pump. Read and follow the instructions in the user's manual that came with your Accu-Chek Insight insulin pump carefully.

- 1**
  - Check if a protective film is stuck on the pump. If a protective film is stuck on, remove it.
  - Stop the pump before mounting the frames. From the status screen, press **OK**. The main **Menu** appears.
  - Press **▼** to move to **Stop pump**.
  - Press **OK** to select. The **Pump stopped** screen appears. You can now disconnect the infusion set from your body and take off your pump.

- 2**
  - Hold the pump in an upright position. Turn the adapter with the tubing anti-clockwise.
  - When you reach an angle of 120°, remove the adapter with the cartridge. The pump starts rewinding the piston rod. The battery remains in the battery compartment.

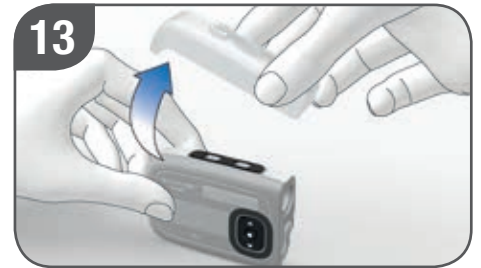
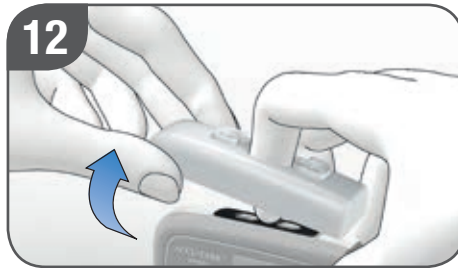
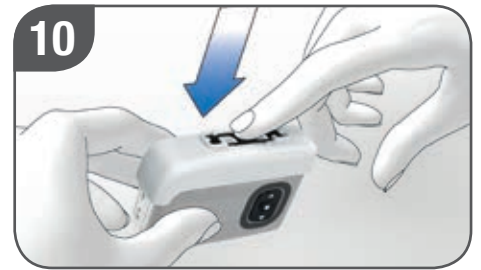
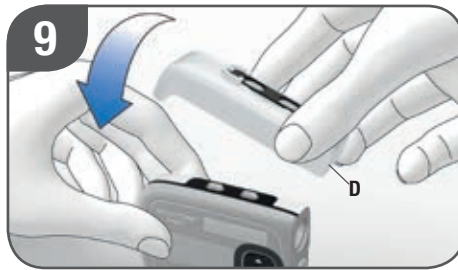
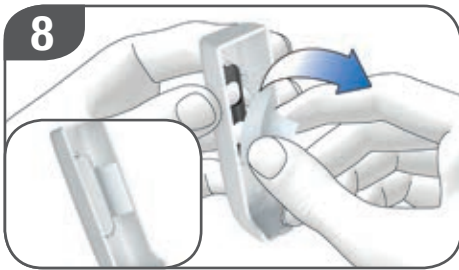
- 3**
  - Read the safety instructions on the packaging of the cleaning tissue (A).
  - Wipe the front and the top of the pump thoroughly with the cleaning tissue (A). Make sure to wipe the area around the front and quick bolus keys.
  - Let the keys dry.

- 4**
  - Remove the white protective film from the applicator (B).

- 5**
  - The applicator (B) has a symmetrical design. Hold the applicator (B) above the front keys of the pump.
  - Place the applicator (B) on the front keys of the pump. If you feel the applicator (B) surrounding the front keys, the applicator (B) is positioned correctly.
  - Use 2 fingers to press the black frame of the applicator (B) firmly onto the pump.

- 6**
  - Remove the applicator (B).

- 7**
  - Swipe with the finger over the black frame and press it firmly all the way around.



- 8**
- Remove the white protective film from the applicator (C).
- 9**
- Place the pump on a flat surface. The quick bolus keys are pointing upwards.
  - Place the applicator (C) on the pump. The flat end (D) of the applicator is aligned with the flat end of the pump.
- 10**
- Use the finger to press the black frame in the middle of the applicator (C) firmly onto the pump.


- 11**
- Press the black frame firmly in the middle.
- 12**
- Keep pressing the black frame firmly while lifting the applicator (C). Your finger will be in the recess of the applicator (C).
- 13**
- Remove the applicator (C).
- 14**
- Swipe your finger over the black frame and press it firmly onto the pump.

- 15**
- You can now insert the cartridge and connect the adapter.
  - Dispose of the cleaning tissue (A), the applicators (B, C) with their protective films, and all packaging material according to the local regulations.

Only for:  
Accu-Chek Insight insulin pump

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ACCU-CHEK®



# URGENT FIELD SAFETY NOTICE

PLEASE COMPLETE AND RETURN BY FAX, E-MAIL OR MAIL

Roche Diabetes Care Reference: Follow-Up SB\_RDC\_2015\_05

Medical Device: Accu-Chek® Insight insulin pump

Manufacturer: Roche Diabetes Care GmbH

Issue: Important information on the Accu-Chek® Insight insulin pump system: New safety frame to prevent unintentional activation of the pump keys and quick bolus buttons

## Acknowledgement Form / Faxback

Please submit this acknowledgement form to Roche Diabetes Care:

via e-mail: \_\_\_\_\_

or via fax: \_\_\_\_\_

or postal address: \_\_\_\_\_

I confirm to have received, read and understood the information in this Field Safety Notice of **dd.mmm.yyyy** for the above mentioned medical devices.

I have applied the Accu-Chek Key Frames to my Accu-Chek Insight insulin pump.

My insulin pump has the following serial number: \_\_\_\_\_.

Form completed and returned by:

Name (CAPITAL LETTERS):	
Phone Number:	
E-mail:	
Address:	
Date (dd-mmm-yyyy):	

\_\_\_\_\_  
Signature