

## ***Urgent field safety notice***

December, 2018

**Important information | Accu-Chek Insight insulin pump system (serial numbers. below 32100000): New key frames to prevent unintentional activation of the pump keys and operation of the quick bolus buttons.**

Dear Customer,

At Roche Diabetes Care we hold our products to the highest quality standard and are committed to continuously improving them so they seamlessly integrate into the lives of people with diabetes.

Previously we 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 operation of the quick bolus buttons.

This advancement is the new key frame designed for the Accu-Chek Insight insulin pump system. These key frames are designed to protect the pump keys and quick bolus buttons from accidental activation and unintended operation. The key frame is designed for the Accu-Chek Insight insulin pump with serial numbers below 32100000, all other pumps (Accu-Chek Combo and Accu-Chek Insight with serial numbers 32100000 and above) are not affected by this issue. You can find the serial number on the back of the pump.

Enclosed with this letter, are a key frame kit including cleaning tissues, and detailed instructions on how to apply the frames to your Accu-Chek Insight insulin pump system.

**Important things to keep in mind when preparing your pump for application of the key frames:**

- The key frames need to be kept at room temperature for at least an hour prior to fixing them to the pump, **Please do not attach the frames when they are cold.**
- Remove the protective film (if applicable) from the pump display as otherwise the frames will not adhere properly.
- Follow the advice for the cleaning tissue when cleaning the pump
- Let the pump surface dry completely before attaching the frames to the pump.

**Action:**

- 1. Follow the instructions provided to attach the key frames correctly.**
- 2. Visit [www.accu-chek.co.uk/insightframe](http://www.accu-chek.co.uk/insightframe) to respond to this notice, you may receive a follow up email if we do not receive your acknowledgement.**

The national competent authority and healthcare professionals have been informed about this notice. Thank you in advance for your understanding and co-operation. If you need any additional advice on the operation of the Accu-Chek Insight insulin pump system or have any further questions, please do not hesitate to contact our Accu-Chek Pump Careline at any time:

Tel: 0800 731 2291

Email: [burgesshill.insulinpumps@roche.com](mailto:burgesshill.insulinpumps@roche.com)

Kind regards,



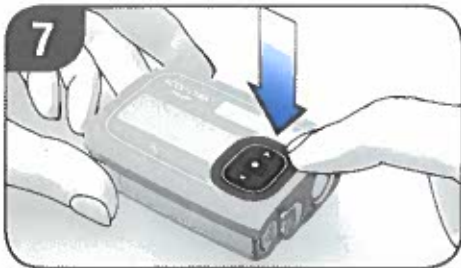
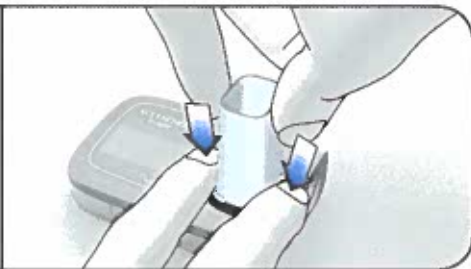
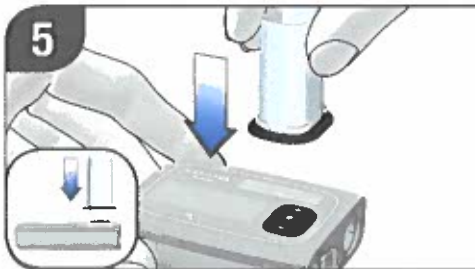
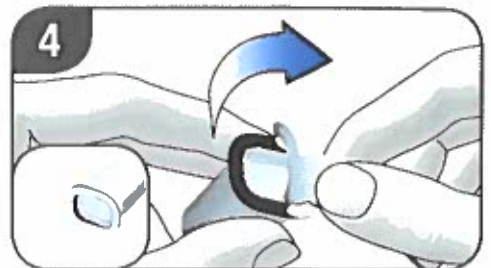
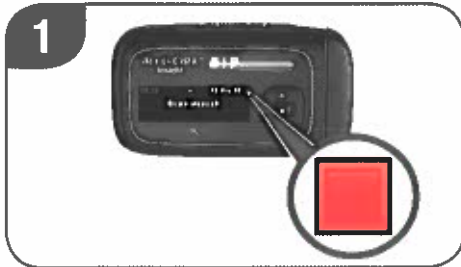
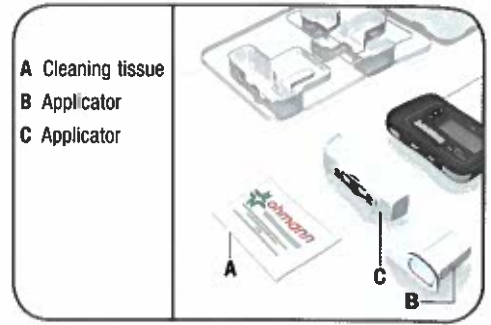
Roche Diabetes Care

Key Frames

Instructions for use

EN

ACCUCHEK<sup>®</sup>



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 **Menu**. The main **Menu** appears.
  - Press **Stop pump**.
  - Press **Stop pump** 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.

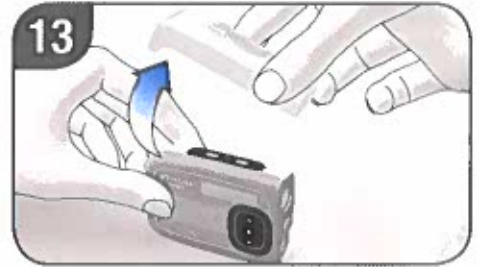
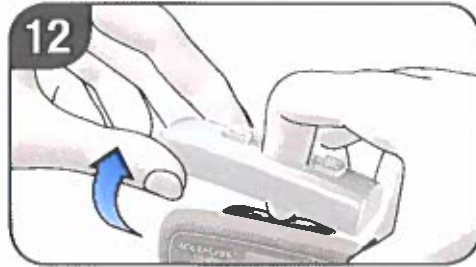
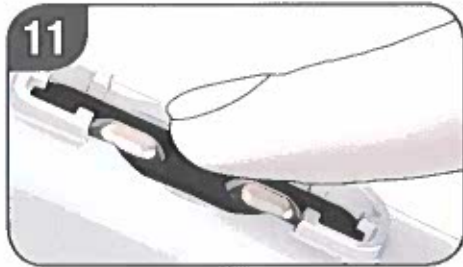
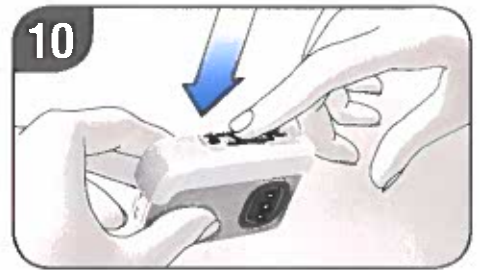
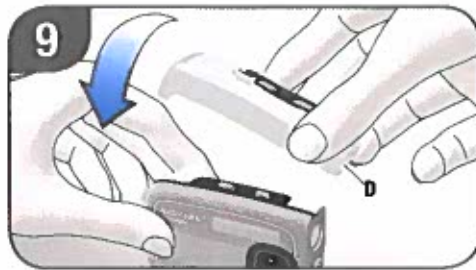
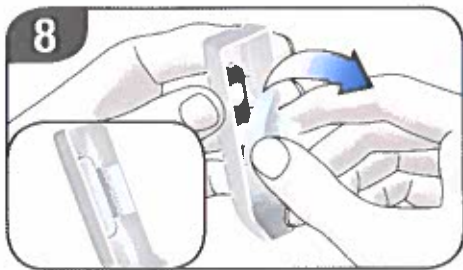
- 3
  - Read the safety instructions on the packaging of the cleaning tissue (A).
  - Wipe the front and the top of the pump thoroughly with the cleaning tissue (A). Make sure to wipe the area around the front and quick bolus keys.
  - Let the keys dry.

- 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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