



# Urgent Field Safety Notice

Burgess Hill, 23<sup>rd</sup> May 2022

For attention of: Accu-Chek Insight Users

Manufacturer's reference: SB\_RDC\_2021\_05

SRN number: DE-MF-000006276

## Important information related to a recall of previous-design versions of Accu-Chek<sup>®</sup> Insight insulin pump adapters and tubings

Dear Accu-Chek Insight customer,

At Roche Diabetes Care, we strive for the highest quality of our products and services and are committed to keeping you informed as soon as there is a potential issue of which you should be made aware.

**This is why we would like to inform you today about a voluntary recall we are conducting related to previous design-versions of the Accu-Chek Insight insulin pump adapter and tubing.**

### Description of situation and rationale giving rise to this corrective measure

As part of our ongoing quality monitoring and market surveillance processes, we have identified that insulin leakage can occur in a low number of cases with the Accu-Chek Insight adapter and tubing consumable which connects the pre-filled insulin cartridge with the insulin pump.

As such, insulin leakage might not be immediately detectable when using the Accu-Chek Insight system, this could lead to an under-delivery of insulin. The potential consequences could range from no clinical impact to adverse health events, including severe hyperglycemia or diabetic ketoacidosis (DKA).

### Details on affected devices

The following products are affected:

| Product Description and Accu-Chek Insight insulin pump adapter and tubing REF numbers: | Product LOT Numbers |
|--|---------------------|
| 06485472001 Accu-Chek Insight Adapter & Tube 40 cm 10 pack                             | lower than 1354241  |
| 06485499001 Accu-Chek Insight Adapter & Tube 70 cm 10 pack                             | lower than 1355360  |
| 06485464001 Accu-Chek Insight Adapter & Tube 100 cm 10 pack                            | lower than 1354242  |

**Please be assured that all other LOTs offered for Accu-Chek Insight adapter and tubings are not affected by this issue. These are fine and safe to use.**

## Actions taken by Roche Diabetes Care

Roche Diabetes Care has conducted an in-depth evaluation of the issue and implemented the appropriate corrective measures by means of technical enhancements to the adapter needle in the Accu-Chek Insight adapter and tubing consumable to reduce the incidence of leakage.

With this voluntary field action, Roche Diabetes Care aims to recall the previous design versions of the Accu-Chek Insight adapter and tubing consumable, and will replace with the new designed version to all users of the pump system.

By doing so we will subsequently replace all affected supplies in home and professional storage with the new designed material.

## Actions to be taken by Accu-Chek Insight Users

**Please acknowledge this communication and check the adapter and tubing supplies you have stored at home by 17<sup>th</sup> June 2022.** If they belong to the LOT numbers listed above, we would like to ask you to:

- › complete our online tool by visiting [www.accu-chek.ie/productrecall](http://www.accu-chek.ie/productrecall) to obtain your free of charge replacements
- › discontinue using adapter and tubing from the affected LOTs immediately
- › in case of any further questions or when in need of additional support please contact the Customer Careline

If you are no longer an Accu-Chek Insight user or do not have access to the internet please call our Roche Diabetes Care Customer Careline on 1 800 882 351\* and select option one (Monday to Friday from 8am-6pm, excluding bank holidays).

Please be assured that all other LOTs offered for Accu-Chek Insight adapter and tubings are not affected by this issue. These are fine and safe to use.

We would also like to use this opportunity to re-emphasise the importance of checking the pre-filled glass insulin cartridge for cracks in case it has been dropped or put under mechanical stress. Please do not use any cartridge that has been dropped regardless of whether a crack has been identified because even micro cracks can cause leakage over time.

Please follow closely the newly updated handling instructions in the pump user manual when changing your pre-filled glass insulin cartridge.

When inserting a new pre-filled glass insulin cartridge please follow these steps for its safe use:

- › As rough handling or misuse may cause inaccurate dosing and may lead to too high or too low blood glucose level, please treat the insulin pump and cartridge with care and carefully follow the instructions.
- › Check the pump and cartridge regularly for damages, for example cracks or leakage. If you smell insulin this could also indicate a leakage. Do not use the cartridge if cracks or leakage are seen. Follow the instructions of your Accu-Chek Insight user manual for replacing a cartridge and for cleaning the cartridge compartment in the insulin pump.
- › During the day and before going to sleep please carefully check that your insulin pump is delivering insulin and there are no leakages. Failure of delivery of your insulin may not result in an alert notification from the



insulin pump and you may be unaware that there is a problem. You may need to check your blood glucose levels. Tell your healthcare professional if you suspect a problem with your insulin delivery.

## **Communication of this Field Safety Notice**

Your national competent authority, distributors, retailers and healthcare professionals have been informed about this field action.

We sincerely apologise for any inconvenience this may have caused and hope for your understanding and cooperation. Please call our Roche Diabetes Care Customer Careline on 1 800 882 351\* and select option one (Monday to Friday from 8am- 6pm, excluding bank holidays), if you need any additional advice or have any further questions or concerns. We appreciate your time and attention to this important notification.

Yours sincerely,  
**Roche Diabetes Care**

\*Some mobile phone operators may charge or restrict access for calls to this number.

© 2022 Roche Diabetes Care Limited. All rights reserved.

ACCU-CHEK and ACCU-CHEK INSIGHT are trademarks of Roche | All other trademarks are the property of their respective owners.

Roche Diabetes Care Limited, Charles Avenue, Burgess Hill, RH159RY, UK | Company registration number: 9055599.

Date of Preparation: May 2022 | For use in Ireland only | [www.accu-chek.ie](http://www.accu-chek.ie)