

Urgent Field Safety Notice

Burgess Hill, 6th December 2022

For attention of: Accu-Chek Solo Users

Manufacturer's reference: SB_RDC_2022_09

SRN number: DE-MF-000006276

Important information related to Accu-Chek® Solo cannula assembly and pump holder - your action required by January 31st 2023

Dear Accu-Chek Solo User,

At Roche Diabetes Care, we strive for the highest quality of our products and services and are committed to keeping you informed on any update to our offering.

This is why we would like to notify you today of a voluntary recall that we are initiating to promote access to the improved version of the Accu-Chek Solo cannula assembly and pump holder for people with diabetes using the Accu-Chek Solo micropump system.

Description of situation and rationale giving rise to this corrective measure

As part of our ongoing quality monitoring, we have identified that insulin leakage has occurred in a low number of cases with the Accu-Chek Solo cannula assembly and pump holder. As such insulin leakage might not be noticed immediately when using the Accu-Chek Solo system, this could potentially lead to an under-delivery of insulin. The possible consequences could range from no clinical impact to adverse health events including severe hyperglycemia or diabetic ketoacidosis (DKA).

Details on affected devices

| Product Description | Ref Number | Device Identifier | LOT Number |
|--|-------------|-------------------|---|
| Accu-Chek Solo cannula assembly and pump holder (9 mm; 10+3) | 07858833001 | 04015630881659 | Cannula lot numbers 847468303 and lower |
| Accu-Chek Solo cannula assembly and pump holder (6 mm; 10+3) | 07858841001 | 04015630881642 | |
| Accu-Chek Solo supply kit (9 mm) | 07858817001 | 04015630881666 | |
| Accu-Chek Solo supply kit (6 mm) | 07858825001 | 04015630881673 | |

Actions taken by Roche Diabetes Care

Roche Diabetes Care has conducted an in-depth evaluation of the issue and implemented the appropriate product improvement measures. We have enforced a number of changes to the Accu-Chek Solo cannula production which is leading to a more seamless user experience and shows a more robust product performance compared to previous versions. To expedite access for users to this improved version of the Accu-Chek Solo cannula assembly and pump holder, we are now initiating a voluntary recall for the prompt replacement of the remaining product quantities in the market.

Actions to be taken by users of the Accu-Chek Solo system

Please acknowledge this communication and your inventory for Accu-Chek Solo cannulas or Accu-Chek Solo supply kits with Lot Number 847468303 and lower by 31st January 2023.



The relevant Lot Number is shown on the single cannula assembly and pump holder blister (see picture).

Please note, this is especially important for the supply kits, where the Lot Number of the individual blister will be different to the Lot Number on the outside of the box. Please also check the expiry date of the products.

In case you have affected material at home, please discontinue use immediately and:

- › complete our online tool at www.accu-chek.co.uk/recall to inform us of any affected stock that you have that is within the expiry date to receive instructions on how to send back affected materials and obtain replacements free of charge.
- › dispose of any affected material that has already passed its expiry date, according to your local regulations.

Please be assured that all other Accu-Chek Solo cannula assembly and pump holder Lots are not affected by this issue. These are safe to use.

Communication of this Field Safety Notice

Your national competent authority (the Medicines and Healthcare Products Regulatory Agency) and healthcare professionals have been informed about this field action.

We understand that this may be concerning for you and sincerely apologise for any inconvenience this may cause. Please call our Roche Diabetes Care insulin pump Careline on 0800 731 2291* 8:30am - 5:00pm Monday to Friday (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.