

Urgent Field Safety Notice

<<Suffix>> <<Name>>
 <<Main Street 1>>
 <<Main Street 2>>
 <<Main Street 3>>
 <<Main City>>
 <<Postcode>>



Action required

Scan the QR code to acknowledge this letter by 20th October 2023.

Alternatively, visit accu-chek.co.uk/solosystem, call Accu-Chek Customer Care, or return the enclosed form.

Burgess Hill, 11th September 2023
 Manufacturer's reference: SB_RDC_2023_02/03/04
 SRN number: DE-MF-000006276
Your Customer ID: <<Account ID>>

Important information related to the Accu-Chek Solo system

Dear <<Suffix>> <<Name>>,

This Field Safety Notice provides you with important information relating to the Accu-Chek Solo system. Please read this communication and acknowledge that you have read and understood it by 20th October 2023.

1) Replacement of Accu-Chek Solo diabetes manager

In June, we notified you about a software issue related to the bolus data screen of your Accu-Chek Solo diabetes manager. We are happy to let you know that the issue has been resolved and we will contact you over the next few weeks to arrange your replacement Accu-Chek Solo diabetes manager, including a new pump base and the latest user manual.

2) Updated Accu-Chek Solo handling instructions

We strive for the highest quality of our products and services at Roche Diabetes Care and are committed to keeping you informed of any issue associated with our products. We would therefore like to take the opportunity to also notify you today of a voluntary corrective update that we are initiating in relation to our Accu-Chek Solo handling instructions to promote a safe and reliable use of the pump system as intended.

Description of situation and rationale giving rise to this corrective measure

Because patient safety is our top priority, we are informing you today about a potential risk of the reservoir needle being bent or a wet adhesive due to an incorrectly inserted cannula. This can potentially result in insulin occlusion, insulin leakage and an under-delivery of insulin. Such circumstances would be detectable by an occlusion message on the Accu-Chek Solo

diabetes manager or recognised by increasing glucose levels, or smelling the leaked insulin. However, this might not always be detected immediately by the user or also go unnoticed by the user e.g. during nighttime. Possible consequences of this issue could range from no clinical impact to adverse health events including hyperglycaemia, severe hyperglycaemia, or diabetic ketoacidosis (DKA).

Details on affected devices in the UK

Product Description	Reference Number
Accu-Chek Solo Insertion Device	07835540001
Accu-Chek Solo Reservoir	07858850001
Accu-Chek Solo Cannula and Pump Holder (6mm)	08928495001
Accu-Chek Solo Cannula and Pump Holder (9mm)	08928517001

Actions taken by Roche Diabetes Care

We have conducted an in-depth evaluation of the underlying root cause to the above described issue and have updated the handling instructions for the Accu-Chek Solo micropump system. The amended handling instructions for the Accu-Chek Solo system aim to inform and train all users of the system how to correctly place the Accu-Chek Solo micropump on their body to ensure a safe and reliable use of the device as intended.

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

Please acknowledge this letter by 20th October 2023. You can do this by either scanning the QR code, returning the completed acknowledgement form, calling Accu-Chek Customer Care or by visiting: accu-chek.co.uk/solosystem

- › Familiarise yourself with the updated handling instructions (enclosed)
- › Always follow these instructions when placing a new infusion assembly on your body or attaching the micropump
- › Contact Accu-Chek Customer Care on 0800 731 2291* and select option 2 (available 24 hours a day) if you have any additional questions related to this issue or on how to handle the Accu-Chek Solo micropump system

Communication of this Field Safety Notice

Your national competent authority and healthcare professionals have been informed about this field action. We sincerely apologise for any inconvenience this may cause and hope for your understanding and cooperation. Please call Accu-Chek Customer Care, 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.

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