

Urgent Field Safety Notice

For attention of: **Distributor/Retailer**

Manufacturer's reference: SB_RDC_2019_05

<Enter address here>

Location, Date

Important information on the Accu-Chek® Solo micropump system related to a new method to insert the pump into the pump holder in order to avoid insulin leakage

Dear Distributors *[please personalise]*,

At Roche Diabetes Care, we strive for highest quality of our products and services and are committed to keeping you informed as soon as there is a potential issue you should be aware of. This is why we would like to inform you today about a new method to insert the Accu-Chek® Solo micropump into the pump holder in order to avoid insulin leakage at the septum. This new **turn-in method** shall be used by users of the Accu-Chek® Solo micropump and by mediators with immediate effect.

Description of Situation

Roche Diabetes Care received customer feedback related to insulin leakage followed by high blood glucose values while using the Accu-Chek® Solo micropump. Thorough investigation showed that the method to insert the pump into the pump holder currently described in the user's manual in some cases lead to an improper penetration of the septum of the cannula assembly by the connecting needle and, as a consequence, to insulin leakage at the septum. To avoid this situation in the future the handling instructions for the insertion of the pump need to be updated.

Details on affected devices

The following product is affected:

Commercial Name	
Accu-Chek® Solo micropump system	All Accu-Chek® Solo micropump systems available in the market

Rationale giving rise to this corrective measure

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When the customer applies a side load on the Accu-Chek® Solo micropump when inserting the pump into the pump holder, insulin leakage at the septum of the cannula assembly could occur because of an improper penetration of the septum of the cannula assembly by the connecting needle. This may lead to high blood glucose values and potentially to severe hyperglycaemia up to diabetic ketoacidosis (DKA) with a serious outcome.

Actions taken by Roche Diabetes Care

Roche Diabetes Care developed a new method for the insertion of the Accu-Chek® Solo micropump into the pump holder, the so called **turn-in method**, which decreases the risk of leakages significantly. The measures taken by Roche Diabetes Care include

- Insertion of an addendum on the new **turn-in method** to the product manual into the product kit (new customers)
- Dispatch of the addendum on the new **turn-in method** to all current customer users by the countries
- Update of the product manual in due course.

Actions to be taken by the distributors and retailers: Please inform your customers about the below mentioned recommendations for users of the Accu-Chek® Solo micropump system

From now on, patients should only use the new **turn-in method** for inserting the Accu-Chek® Solo micropump into the pump holder following the procedure described below:

1 Place the reservoir needle on the grey cannula head of the pump holder.



2 Place the reservoir needle of the micropump on the grey cannula head of the pump holder.

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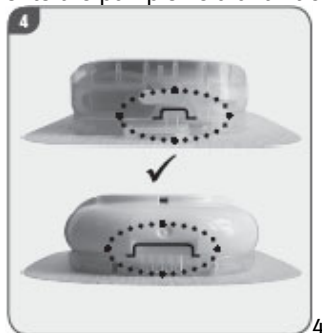
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3 Turn the micropump carefully into place. After a quarter turn, the micropump clicks into the front hooks on the pump holder.



4 Make sure the micropump engages properly with the front and back hooks on the pump holder. If not, press onto the pump shield until it clicks into the pump holder.



If unsure, the patients could check their blood glucose levels at least once within 1 to 3 hours after replacing a component of the micropump system as they may not notice any leakage.

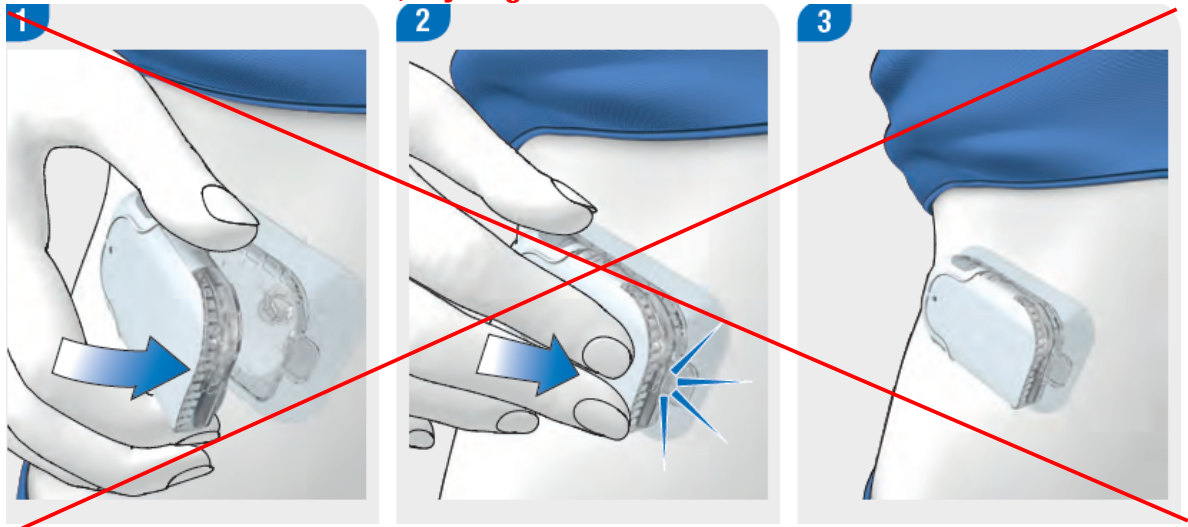
Users should not apply too much force when attaching the micropump, because the septum between the pump and the cannula assembly may become damaged and, as a consequence, insulin leakage can occur. This may lead to an insufficient supply of insulin.

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Patients should not use the insertion method (pictured below), which is currently described in the user's manual, any longer.



Communications of this Field Safety Notice

Your national competent authority, users of the Accu-Chek® Solo micropump system 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 your cooperation.

Please call our Roche Diabetes Care Customer Care line **at xxx-xxx-xxx**, if you need any additional advice on the handling of the Accu-Chek® Solo micropump system or have any further questions or concerns. We appreciate your time and attention to this important notification.

Kind regards,

Roche Diabetes Care

ATTACHMENT: "Correction to the User's Manual"