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Urgent Field Safety Notice

For attention of: **Accu-Chek Guide users (PwD)**

Manufacturer's reference: SB_RDC_2024_01 SRN number: DE-MF-000006276

Country - India
Date - 08 May 2024

Important information related to the Accu-Chek® Guide system: Voluntary recall of meters showing incorrect measurement unit

Dear Accu-Chek Guide user,

At Roche Diabetes Care we strive for the highest quality of our products and services and are committed to keeping you timely informed on any issue associated with our products. Today, we would like to notify you of a voluntary corrective measure that we are initiating concerning our Accu-Chek Guide blood glucose meter. We recently received a very low number of customer complaints indicating that some Accu-Chek Guide systems out of the below-listed lots were configured incorrectly and thus show the results in a different than labeled measuring unit.

Description of situation and rationale giving rise to this corrective measure

Because patient safety is our top priority, we inform you today about the potential risk resulting from the above-described issue. It becomes visible once a blood glucose measurement is taken and the user could recognise that the result is displayed in a different than the usual measuring unit (mg/dL or mmol/l). If going unnoticed, the incorrectly displayed blood glucose value might trigger inappropriate therapy decisions including the administration of insulin and potentially result in severe consequences. Possible consequences of this issue could range from no clinical impact to adverse health events including hypoglycemia, hyperglycemia, or diabetic ketoacidosis (DKA).

Details on affected devices:

Affected Meter Serial Number	Product Description	Product REF Number	Product Device Identifier (UDI / GTIN)	Product Lot Number
92539453001	Accu-Chek® Guide (SC) Set	07400926027	04015630066742	406124
92539646082	Accu-Chek® Guide (SC) Set	07400926027	04015630066742	406124

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Affected Meter Serial Number	Product Description	Product REF Number	Product Device Identifier (UDI / GTIN)	Product Lot Number
92539453042	Accu-Chek® Guide (SC) Set	07400926027	04015630066742	406124
92539658918	Accu-Chek® Guide (SC) Set	07400926027	04015630066742	406124

Actions taken by Roche Diabetes Care

We have conducted an in-depth evaluation of the underlying root cause of the above-described issue and have adapted our manufacturing and quality control processes to prevent the issue from recurring.

Actions to be performed by Accu-Chek Guide users

We ask all users of the Accu-Chek Guide blood glucose monitoring system to

- please check your meter if the display shows the same measuring unit as the label on the back side of the product or the meter packaging

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- please compare the serial number of your meter with the above list to determine if it belongs to the products impacted by this issue
- please stop using your Accu-Chek Guide meter if you notice that your product shows an incorrect measuring unit or belongs to the listed impacted products
- please contact our Roche Diabetes Care Customer Care Toll Free line at 18001206020 (Monday to Saturday from 07:30 a.m.- 09:30 p.m.) Email - india.accu-chek@roche.com or SMS - type HELP and send to 5757535 (Rs. 3/- per SMS) to receive your replacement meter free of charge.

Please be assured that all other Accu-Chek and Accu-Chek Guide meters not included in this voluntary corrective action are not impacted by this issue and are safe to be used as intended.

Communication of this Field Safety Notice

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

We sincerely apologize for any inconvenience this may cause and hope for your understanding and cooperation. Please contact our Roche Diabetes Care Customer Care Toll Free line at 18001206020 (Monday to Saturday from 07:30 a.m. - 09:30 p.m.) Email - india.accu-chek@roche.com or SMS - type HELP and send to 5757535 (Rs. 3/- per SMS) 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,

For and on behalf of
Roche Diabetes Care India Private Limited

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