



Urgent Field Safety Notice

For attention of: **Healthcare Professionals**

Manufacturer's reference: SB_RDC_2022_02

SRN number: DE-MF-000006276

Location, Date

Important information about an implemented bug fix related to patient data mismatch on the RocheDiabetes Care Platform

Dear Healthcare Professionals [please personalise],

At Roche Diabetes Care, we strive for the highest quality of our products and services and are committed to keeping you timely 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 bug fix related to the potential issue of patient data mismatch and which we solved by implementing a cloud-based software update of the RocheDiabetes Care Platform on February 24, 2022.

Description of Situation and Rationale giving rise to this corrective measure

The RocheDiabetes Care Platform is a browser-based solution designed for use in professional settings, like hospitals, Point of Care, etc., by healthcare professionals to document, visualise and analyse important therapy-related information such as e.g. glucose values, insulin, nutrition, and activity data to derive informed treatment decisions for their patients with diabetes. Roche Diabetes Care became aware of a potential patient data mismatch when using the browser's "back" button to navigate between patients in the RocheDiabetes Care Platform resulting in data from one patient being displayed in the profile of another patient as the need to reload the page was not detected properly and previously rendered patient data were displayed. This issue might not have been immediately detectable by the physician and potentially could have led to an inappropriate therapy recommendation while eventual health consequences, in particular for patients on insulin therapy, were not to be excluded. The potential consequences could have ranged from no clinical impact to health events including severe hypoglycemia.

Details on affected devices

The following product was affected:

Product Description	Product Material Numbers
RocheDiabetes Care Platform HCP/M (version 2.5.2 (in the U.S.), and version 2.5.3 (Outside of U.S.))	08888353001

Actions taken by Roche Diabetes Care

Roche Diabetes Care has already conducted an in-depth evaluation of the issue and implemented the bug fix on February 24, 2022, with the roll-out of RocheDiabetes Care Platform version 2.5.5.



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Actions to be taken by the healthcare professional

Since the issue has been fully resolved with the cloud-based software update rolled out on February 24, 2022, there is no action required from you. You will have access to the latest version (2.5.5) whenever you log into the RocheDiabetes Care Platform next time. Please do not hesitate to reach out to your Roche Diabetes Care sales representative at any time for more information about the RocheDiabetes Care Platform or in case you have any questions or concerns about this addressed issue.

Actions to be taken by patients

As the issue identified only impacted the RocheDiabetes Care Platform portal for healthcare professionals there is no action required from your patients.

Communication of this Field Safety Notice

Your national competent authority and healthcare professionals using the RocheDiabetes Care Platform 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 Care line at **xx-xxxxx-xxxxx** (workdays from xx a.m.- xx p.m.), 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