

Urgent Field Safety Notice

Burgess Hill, 29th May 2024

Manufacturer's reference: SB_RDC_2024_02

SRN number: DE-MF-000006276

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

Dear Healthcare Professionals,

At Roche Diabetes Care, our utmost priority is ensuring the highest quality of our products and services. We are committed to keeping you well-informed about any potential issues that may arise. Therefore, we would like to notify you today about a bug fix that addresses a potential patient data mismatch on the RocheDiabetes Care Platform. This issue occurred with the release v2.10.1, which was deployed on 27 April 2024. Please be assured that we have fully resolved this issue by releasing the cloud-based software update v2.10.3 on 14 May 2024.

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 relevant therapy 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 found the potential patient data mismatch to happen when using the browser's back-and-forth buttons to navigate between patients in the platform. This could have resulted in data from one patient being displayed in the profile of another patient as the need to refresh the page was not prompted 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 adverse health events including severe hypoglycaemia.

Details on affected devices

The following product was affected:

Product Description	Device identifier	Version
RocheDiabetes Care Platform	07835540001	Versions 2.10.1 and 2.10.2

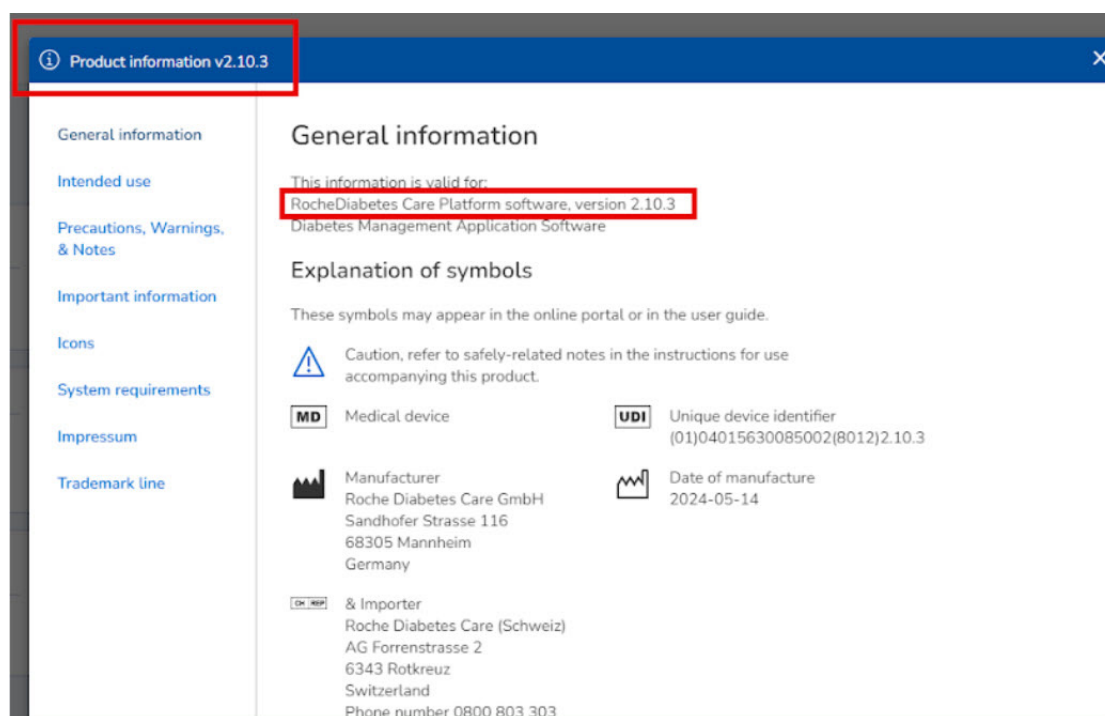
Actions taken by Roche Diabetes Care

Roche Diabetes Care has already conducted an in-depth evaluation of the issue and implemented the bug fix on 14 May 2024, with the roll-out of RocheDiabetes Care Platform version 2.10.3.

Actions to be taken by Healthcare Professionals

Since the issue has been fully resolved with the cloud-based software update rolled out on 14 May 2024, there is no action required from you. You will have access to the latest version (2.10.3) whenever you log into the RocheDiabetes Care Platform. In case you would like to verify the version number you are working with, please refer to the following click path: "Help center" > "Product information" > "General information".

Please do not hesitate to reach out to Accu-Chek Customer Care (details below) for more information about the RocheDiabetes Care Platform or in case you have any questions or concerns about this topic.



Communication of this Field Safety Notice

Your national competent authority and users have been informed about this field action. We sincerely apologise for any inconvenience this may have caused and hope for your understanding and cooperation. If you need any additional advice or have any further questions or concern, please call Accu-Chek Customer Care on 0800 701 000 in the UK or 1 800 709 600 in Ireland* (Monday to Friday 8am–6pm excluding bank holidays). 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.