



URGENT – Recall for Product Correction

Accu-Chek® Connect diabetes management app – Bolus Advisor function

March 2017

**Important information on the Accu-Chek® Connect diabetes management app:
Potential for inaccurate bolus insulin advice in app versions 2.0.0, 2.0.1, 2.1.0 (iOS & Android)
–Discontinue use of the bolus advisor function on the app. All other functions on the app can still be used**

Dear Healthcare Professional,

As patient safety is our first priority, we would like to inform you of a risk of inaccurate bolus advice that may potentially lead to serious health consequences for your patients currently using this functionality in the above app.

We have recently discovered a software issue in the Accu-Chek Connect diabetes management app versions 2.0.0, 2.0.1, and 2.1.0 (iOS & Android). Under certain conditions, the affected app versions may cause the bolus advisor to reset and display an incorrect active insulin amount of 0.0 on the app's home screen, which may lead to an incorrect bolus advice. No warning message is displayed to the user. Depending on the individual patient's metabolic situation, a potentially incorrect bolus advice could result in serious health consequences (e.g. hypoglycaemia). Please note that previous versions of the App are not affected by this software issue. No other Roche product with a Bolus Advisor is affected. Also, all other functions on the Accu-Chek Connect App can still be used.

Please notify your patients, to whom the Accu-Chek® Connect diabetes management app bolus advisor has been prescribed, about this safety information and advise them to discontinue using the bolus advisor function on versions 2.0.0, 2.0.1, 2.1.0 (iOS & Android). We are developing an updated version to ensure that we can prevent this issue in the future. We will inform you once this new version is available shortly.

In addition, we will be placing an alert on our website www.accu-chek.com.au informing patients directly of this safety notification.

This action has been coordinated through the Therapeutic Goods Administration.

Please feel free to contact the Accu-Chek Enquiry Line on 1800 251 816 if you or your patients require additional information.

Yours Sincerely,
Roche Diabetes Care

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