

Urgent Medical Device Correction

17-004

June 12, 2017

Important information on the Accu-Chek[®] Connect diabetes management app: Potential for inaccurate bolus insulin advice in app versions 1.2.0, 1.2.2, 1.2.3, 2.0.0, 2.0.1, 2.1.0 (iOS & Android).

We at Roche Diabetes Care, Inc., strive for quality in our products and services and understand the importance of informing you when there are issues you should be aware of. Recently, we discovered an issue related to the Bolus Advisor feature that can occur in the Accu-Chek Connect diabetes management app. Please immediately discontinue use of affected versions 1.2.0, 1.2.2, 1.2.3, 2.0.0, 2.0.1, and 2.1.0 of the Accu-Chek Connect app and complete the update to version 2.1.1 of the app.

A software bug has been identified that could potentially result in inaccurate bolus insulin advice. The Accu-Chek Connect app is designed to detect a user's home country by default during the initial set-up of the app. With this, the units of measure for weight, carbs, blood glucose (BG) results, and blood pressure are automatically determined. This software bug only applies to users who switch phone settings to another country and may result in an unexpected change to the units of measure. This may result in values with the incorrect unit of measure (i.e. carbs) being entered for use in the bolus insulin advice calculation. This issue is resolved in version 2.1.1 of the Accu-Chek Connect app.

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Actions you need to take

- Update to version 2.1.1 of the Accu-Chek Connect App.
- Before pairing a meter with the Accu-Chek Connect app for the first time, please clear all data from your Accu-Chek blood glucose meter using the following steps.

Clearing the data in the meter memory can be accomplished on your PC or Mac by using Accu-Chek Connect Device Link. A micro-USB cable and an Accu-Chek Connect Online account are required. Ensure that the date and time are set correctly on your blood glucose meter before pairing with the app. Failure to follow these directions might impact first time use of the app's Bolus Advisor feature.

Steps to clear data from your Accu-Chek meter in Connect Online:

1. Create or login to your Connect Online account on your PC or Mac.
2. Download Accu-Chek Device Link
3. Right-click on Device Link icon in system tray or dock.
4. Select Settings > "Prompt after every successful upload" under the Delete Patient Results from Device heading.
5. Connect your meter via micro-USB cable.
6. Follow the onscreen instructions to upload your data and clear your meter.

If you use the app's Bolus Advisor feature, please carefully review and manage your active insulin and insulin bolus amounts for the first 8 hours after initial installation of the app and pairing your meter. This ensures the software will establish an accurate history for use in future bolus recommendations.

If you have additional concerns, please contact Accu-Chek Customer Care by visiting accu-chek.com or calling 1-800-688-4578.

ACCU-CHEK CONNECT is a trademark of Roche.

This notification is being made with the knowledge of the Food and Drug Administration (FDA).

You may also report adverse events or quality problems experienced with the use of this product to the FDA's MedWatch Adverse Events Reporting Program online at www.fda.gov/Safety/MedWatch/HowToReport/default.htm (form available to fax or mail), or call the FDA 1-800-FDA-1088.