

Urgent Medical Device Correction

17-003

June 12, 2017

Important information on the Accu-Chek® Connect diabetes management app: Potential for inaccurate bolus insulin advice in app versions 1.0.5, 1.0.15, 1.2.0, 1.2.2, 1.2.3, 2.0.0, 2.0.1, 2.1.0, 2.1.1 (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 all versions of the Accu-Chek Connect diabetes management app (as noted above) and will require you to take the actions set forth below.

This issue can only be encountered if the blood glucose meter has displayed a single E-10 Time/Date error message ***and*** the meter had blood glucose records in My Diary ***and*** then the meter is paired for the first time with the Accu-Chek Connect App. A customer encountering this issue may find the app does not display the bolus advice option and, consequently, correction bolus advice is not available on the most recent, valid glucose reading. This blood glucose value that could not be used initially may become available for bolus advice calculation at a later time. If the app provides the bolus advice option more than 15 minutes after you tested, it could lead to an incorrect bolus insulin recommendation that should not be used. **Taking actions based on incorrect bolus advice could result in serious health consequences (e.g. hypoglycemia).**

To completely avoid the possibility of this issue occurring, it is important for Accu-Chek Connect app users to follow the directions given below when pairing a meter with the app for the first time.

Actions you need to take

- Please clear all data from your Accu-Chek blood glucose meter following the steps below, before pairing with the Accu-Chek Connect app for the first time. This clearing of the records in the 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. Also 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.



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- 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.

We are developing and comprehensively testing a corrected version of the Accu-Chek Connect app to address this issue.

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.