

Urgent: Medical Device Correction

16-001

September 14, 2016

Dear Valued Customer,

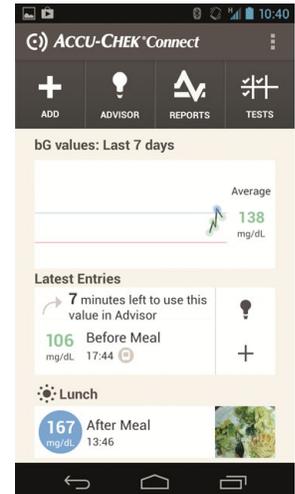
We at Roche Diabetes Care, Inc., strive for quality in our products and services and understand the importance of informing you and your healthcare professional when there are issues you should be aware of.

We recently discovered an issue that can occur in version 1.2.0 of the Accu-Chek Connect app on iOS products (iPhone, iPad). If you have activated the Bolus Advisor, under certain conditions this software issue can lead to bolus insulin advice not being available or the recommended bolus amount being inaccurate. A customer encountering this issue may find:

- The app lightbulb icon does not display and correction bolus advice is not available. A carbohydrate bolus recommendation to cover a meal or snack is still available and is not affected by this issue.
 - A blood glucose value that could not be used initially may then become available for bolus advice calculation at a later time. If the app provides a bolus advice option (lightbulb icon appears) more than 10 minutes after you tested, it could lead to an incorrect bolus insulin recommendation *and should not be used*.
- Incorrect bolus advice could lead to serious health consequences such as hypoglycemia.**
- The amount of active insulin displayed during a carbohydrate bolus recommendation may be incorrect *and should not be used*. When the app is functioning as intended, the displayed active insulin amount serves as information for your convenience only.

As of August 31, 2016, there have been no adverse events reported related to this app issue.

This issue is resolved in the newest version of the app (ver. 1.2.2 or higher). All iOS users should verify that they have installed and are using the latest version of the app. You can verify the version by opening the app and then going to Settings > Version.





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How do you resolve this issue?

- If you use the Accu-Chek Connect app on an iOS product (iPhone, iPad), please verify that you have installed the newest version of the app (ver. 1.2.2 or higher).
 - The following are not affected by this issue
 - § All versions of the Android app
 - § iOS versions other than version 1.2.0
 - You can verify the version by opening the app and then going to Settings > Version
- Contact our Accu-Chek Customer Care at 1-800-628-3346 if you have additional questions.

What actions do you need to take now?

Complete the enclosed Business Reply Card and return it by U.S. mail.

- If you have questions about the information in this notification, please contact Accu-Chek Customer Care at 1-800-628-3346.
- Please keep this notification for future reference.

Thank you for your prompt attention to this issue.

Sincerely,

Roche Diabetes Care, Inc.

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.