



## Urgent Medical Device Correction

17-001

March 30, 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, and 2.1.0 (iOS & Android). Please discontinue use of the bolus advisor feature in the Accu-Chek Connect app until an updated version is available and installed.**

Dear Customer,

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.

We recently discovered a software issue in the Accu-Chek Connect app versions 2.0.0, 2.0.1, and 2.1.0 that can result in incorrect bolus recommendations. This software bug may result in errors in the active insulin calculation, creating the potential for a false high insulin bolus recommendation. An insulin bolus delivered based on potentially incorrect bolus advice could lead to serious health consequences such as hypoglycemia.

### What actions do you need to take?

- **Please discontinue use of the bolus advisor feature in Accu-Chek Connect app versions 2.0.0, 2.0.1, and 2.1.0 (iOS & Android) until the updated version is installed.**
  - You can verify the version by opening the Accu-Chek Connect app and then going to Settings > Version.
- Once the updated version of the app is available, install it immediately.
- After the updated version is installed, you may resume use of the bolus advisor feature.
- Complete the enclosed Business Reply Card and return it by U.S. mail.
- If you have additional concerns, please contact Accu-Chek Customer Care by visiting [accu-chek.com](http://accu-chek.com) or calling 1-800-688-4578.
- Please keep this notification for future reference.



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The corrected version of the app is expected to be available on or about April 13, 2017. Please visit [accu-chek.com](http://accu-chek.com) for updates regarding the availability of the corrected version of the app.

Thank you for your prompt attention to this issue.

Sincerely,

Roche Diabetes Care, Inc.

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](http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm) (form available to fax or mail), or call the FDA 1-800-FDA-1088.



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