

Urgent field safety notice

<Enter address here>

Location, Date

**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)**

Dear Healthcare Professional,

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

We have recently distributed information asking all users of the Accu-Chek Connect diabetes management app versions 2.0.0, 2.0.1, and 2.1.0 (iOS & Android), to please immediately discontinue the use of the bolus advisor. The software bug in these versions has now been fixed. **Before resuming the use of the bolus advisor feature, we ask all users to update their app version the latest version 2.1.1.**

Please immediately notify your patients who have received a prescription to use the Accu-Chek[®] Connect diabetes management app bolus advisor about this safety information. Advise them to follow the directions provided in this letter when pairing a meter with the app for the first time. We are developing and comprehensively testing a corrected version to ensure such issues are prevented in the future.

We recently discovered an issue that can occur in all versions of the Accu-Chek Connect diabetes management app noted above. Under certain rare conditions after pairing a meter with the app for the first time, a customer encountering this issue may find the app countdown timer does not display and 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 a bolus advice option (countdown timer appears) more than 10 minutes after the customer tested, it could lead to an incorrect bolus insulin recommendation and should not be used. **Incorrect bolus advice could result in serious health consequences (e.g. hypoglycaemia).**

This error can only be encountered if the meter is paired with the Accu-Chek Connect diabetes management app for the first time **and** the meter has displayed a single E-10 "Time/Date Error" message **and** the meter has bG records in the Logbook.

To completely avoid the possibility this issue occurs, please inform your patients that using the Accu-Chek Connect app that it is important to follow the directions given below when pairing a meter with the app for the first time.

Important:

Please clear all data from your Accu-Chek blood glucose meter before pairing with the Accu-Chek Connect App. This 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 correct on your blood glucose meter before pairing with the app. Failure to follow these directions might, in rare situations, impact first time use of the App's Bolus Advisor feature.

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

1. Create or login to your Accu-Chek Connect Online account on your PC or Mac.
2. If you have not already, download and install Accu-Chek Connect Device Link.
3. Right-click on Device Link icon in system tray or dock.
4. Select "Settings"
5. Select "Prompt after every successful upload" under the "Delete Patient Results from Device" heading.
6. Connect your meter to your computer via micro-USB cable.
7. Follow the onscreen instructions to upload your data and clear your meter.

If your patients plan to use the App's Bolus Advisor feature, please remind them to carefully review and manage their active insulin and insulin bolus amounts for the first 8 hours after initial installation of the App and pairing their meter.

We are developing and comprehensively testing a corrected version to ensure such issues are prevented in the future.

We have informed your local authority as well as patients about this issue in parallel. We apologise for any inconvenience this may cause and thank you for your understanding and co-operation. If you need any additional support in handling the Accu-Chek Connect system or have any further questions, please do not hesitate to contact our Accu-Chek Customer Service Center at xxx-xxx-xxx.

Kind regards,
Roche Diabetes Care