

PwD Letter



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 1.2.0, 1.2.2, 2.0.0 (iOS & Android)

Dear Customer,

We at Roche Diabetes Care strive for highest quality in our products and services and it is key to us to inform you and your healthcare professional when there is an issue of which you should be aware.

We recently discovered a software bug in the Accu-Chek Connect diabetes management app versions 1.2.0, 1.2.2, 2.0.0 (iOS & Android). Under certain conditions the affected app versions may disregard historical bolus data potentially leading to an invalid bolus insulin recommendation being provided to the user. Additionally, it was discovered that pairing and using multiple meters with the iOS version of the Accu-Chek Connect App can under rare circumstances cause the bolus advisor to fail to offer a blood glucose (BG) correction bolus recommendation within the eligible time window following a bG measurement (10 – 15 minutes).

Depending on the individual metabolic situation a potentially incorrect bolus advice could lead to serious health consequences as e.g. a hypoglycemia in case the impacted bolus advice function erroneously recommended a too high insulin dose. Both software bugs described above may also cause the amount of active insulin displayed during the bolus calculation process to be incorrect. When the app is functioning as intended, the displayed active insulin amount serves as information for your convenience only.

As your safety is our first priority, we have initiated appropriate corrective measures and are informing users of the Accu-Chek Connect diabetes management app to be aware of this issue. **If you are using versions 1.2.0, 1.2.2, 2.0.0 (iOS & Android) of the Accu-Chek Connect app, please immediately discontinue the use of these versions and update your app to the newest version available on the Apple App or Google Play store (greater than 2.0.0 in the U.S. or 1.2.3 OUS).** This update will correct the issue and prevent it from occurring in the future.

Kommentar [VU1]: Needs to be adapted locally

We kindly ask you to contact the Accu-Chek Customer Service Center if you experience additional problems. **Please rest assured that all other versions of the app as well as other Accu-Chek products using the bolus advice feature are not affected by this issue.**

Your local competent authority as well as healthcare professionals have been informed about this field action in parallel. Thank you in advance 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