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 2.0.0, 2.0.1, 2.1.0 (iOS & Android) – please discontinue use of the bolus advisor function

Dear Customer,

As your safety is our first priority, we would like to inform you of a risk of an inaccurate bolus advice that may potentially lead to serious health consequences if you are unaware of the situation.

We have recently discovered a software bug in the Accu-Chek Connect diabetes management app versions 2.0.0, 2.0.1, and 2.1.0 (iOS & Android). Under certain conditions, the affected app versions may cause the bolus advisor to reset and display an incorrect active insulin amount of 0.0 on the app's home screen, which may lead to an incorrect bolus advice. No warning message about the unintended value reset is displayed to the user. Depending on the individual metabolic situation, a potentially incorrect bolus advice could result in serious health consequences (e.g. hypoglycaemia), in case the impacted bolus advice function erroneously recommended a too high insulin dose.

If you are using versions 2.0.0, 2.0.1, 2.1.0 (iOS & Android) of the Accu-Chek Connect app, please immediately discontinue the use of the bolus advisor in these versions. We are developing and comprehensively testing a corrected version to ensure that we can prevent such issues in the future. We will inform you once this new version is available shortly.

We have informed your local authority as well as healthcare professionals about this field action in parallel. We apologise for the inconvenience and uncertainty 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