

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 advise patients to discontinue use of the bolus advisor function**

Dear Healthcare Professional,

As patient 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 patients 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 the event the impacted bolus advice function erroneously recommended a too high insulin dose.

Please immediately notify your patients, to whom the Accu-Chek[®] Connect diabetes management app bolus advisor has been prescribed, about this safety information and advise them to discontinue using versions 2.0.0, 2.0.1, 2.1.0 (iOS & Android) of the Accu-Chek Connect app bolus advisor. 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 users of the Accu-Chek Connect app about this field action in parallel. We apologise for the 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](tel:xxx-xxx-xxx).

Kind regards,
Roche Diabetes Care