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1 November 2013

## URGENT FIELD SAFETY NOTICE

**Product: Accu-Chek® Aviva Combo Handset**  
**Serial Numbers: All serial numbers 68110200001 and higher**  
**Type of Action: Safety Notice**  
**Ref: SB\_RDC\_2013\_09**

Dear Customer,

The purpose of this letter is to notify you that Roche Diabetes Care has become aware that in rare cases the Accu-Chek® Aviva Combo handset's bolus advisor function can potentially recommend a correction bolus amount less than the amount that should have been recommended. The issue **can only occur** in the case that the user confirms delivery of a "Manual Pump" bolus on the handset. This letter provides you with information that will allow you to prevent this from occurring.

For normal use of the product where a bolus is recommended by the handset's bolus advisor and administered wirelessly via the pump, the Accu-Chek® Combo System can be used safely and reliably as normal. The issue has no impact on the basal rate and the meal boluses of the system. They are delivered as intended. The issue only impacts the correction boluses calculated by the bolus advisor to lower elevated blood glucose levels.

The occurrence of this issue is only possible if the user confirms delivery of a "Manual Pump" bolus on the handset, **and**

- does not complete the task of delivering the bolus manually via the pump, or
- delivers a bolus amount manually via the pump which differs from the amount the user entered on the handset for manual delivery, or

- delivers a bolus of any amount manually via the pump more than 10 minutes after the bolus record is entered in the handset.

In subsequent bolus calculations during the insulin acting time, the system could recommend less insulin than is actually needed to lower blood glucose levels, leading to temporary mild hyperglycemia (elevated blood glucose levels).

We ask users to be aware of the above scenario. Always deliver the exact bolus amount, as entered in the handset, manually on the pump **within 10 minutes**, as described in the Accu-Chek® Aviva Combo Advanced Owner's Booklet.

Users are advised to always closely monitor their blood glucose for indications of high blood glucose (hyperglycemia) and to administer insulin appropriately to correct it.

Again, the Accu-Chek® Combo System can be used safely and reliably if used as directed. If you take into account and avoid the above described aspects, you are not limited in the safe and reliable manual operation of the pump.

The competent authority in your country has been notified about this safety notice.

Patient safety is our first priority. As we aim to ensure the safe and proper use of our products at all times, we have chosen to inform our customers about this rare case and how to prevent it from occurring.

We thank you for your understanding and co-operation and apologise for any inconvenience the issue may cause. Please do not hesitate to contact the Accu-Chek Pump Careline on 0800 731 22 91 (UK) / 1 800 88 23 51 (ROI) should you have any questions.

Sincerely,

Roche Diagnostics

Insulin Delivery Systems