Healthcare Professional & Distributor Letter

xx October 2013

URGENT FIELD SAFETY NOTICE

Product:	**Accu-Chek® Aviva Combo Meter** **Accu-Chek® Performa Combo Meter**
Serial Numbers:	**- For Accu-Chek® Aviva Combo: All serial numbers XXX 10200001 and higher (only the last 8 digits of the serial number to be considered);** **- For Accu-Chek® Performa Combo: All serial numbers XXX 20200001 and higher (only the last 8 digits of the serial number to be considered).**
Type of action:	**Safety Notice**
Ref:	**SB_RDC_2013_09**

Dear Healthcare Professional or Distributor,

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 or Accu-Chek® Performa Combo blood glucose meter'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 blood glucose meter.

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 meter'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 blood glucose meter, **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 meter for manual delivery, or
- delivers a bolus of any amount manually via the pump more than 10 minutes after the bolus record is

Roche Diagnostics GmbH Diagnostics Division

Roche Diagnostics GmbH

Sandhofer Straße 116; D 68305 Mannheim; Telefon +49 621 759 0; Telefax +49 621 759 2890

entered in the meter.

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 blood glucose meter, manually on the pump **within 10 minutes**, as described in the Accu-Chek® Aviva Combo Advanced Owner's Booklet or Accu-Chek® Performa 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 users take into account and avoid the above described aspects, they are not limited in the safe and reliable manual operation of the pump.

Roche Diabetes Care kindly asks you to inform affected Accu-Chek® Aviva Combo or Accu-Chek® Performa Combo insulin pump system users or any organisation where the devices have been distributed to using the enclosed letter.

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 apologize for any inconvenience the issue may cause. Please do not hesitate to contact the Accu-Chek® customer care line on XX-XXX-XXXX should you have any questions.

Sincerely,

Roche Diagnostics

Signature