Ö	**Immediate Action Required**
	Action Required
	Information Only

URGENT FIELD SAFETY NOTICE

IMMEDIATE ACTION REQUIRED

Field Safety Notice Ref No: SB_RDC_2013_09
Document Date: 28/10/2013
Type of Action: Safety Notice

Product Affected:	Accu-Chek® Aviva Combo Handset
System Affected:	All serial numbers 68110200001 and higher.
Summary of Issue:	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.

Material No:	0517259400X Accu-Chek® Aviva Combo Handset
Lot: No:	Model Number 681

Reason for Notice:	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

Roche Diagnostics
Charles Avenue
Burgess Hill
West Sussex
RH15 9RY

Registered No 571546

Ö	**Immediate Action Required**
	Action Required
	Information Only

- 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).

Action Required:

We ask users to be aware of the above scenario. Always deliver the exact bolus amount, as entered in 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 users take into account and avoid the above described aspects, they 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. A copy of the patients' communication is also included for your convenience. 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) or 1800 88 23 51 (ROI) should you have any questions.

To assist with compliance to the IVD Directive 98/79/EC, please complete the enclosed faxback form and return within 7 days.

Attachments: Faxback Form

This action is being conducted with the knowledge of the Medicines and Healthcare products Regulatory Agency (MHRA), the Irish Medicines Board (IMB), and other

Roche Diagnostics
Charles Avenue
Burgess Hill
West Sussex
RH15 9RY

Registered No 571546

Ö	**Immediate Action Required**
	Action Required
	Information Only

International Regulatory Agencies.

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

To enable Roche Diagnostics to fulfil its vigilance duties in entirety with respect to the IVD Directive 98/79 EC, please complete and return the fax-back form which accompanies this Field Safety Notice.

Roche Diagnostics
Charles Avenue
Burgess Hill
West Sussex
RH15 9RY

Registered No 571546