HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

Accu-Chek Aviva Combo
Accu-Chek Mobile bGM system
Accu-Chek Spirit Combo
Accu-Chek Spirit and Spirit Combo insulin pump

Priority 3 – Advisory

HPRA Safety Notice: SN2016(38) **Issue Date: 10 November 2016**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Roche Diabetes Care Limited	V19092 V20868 V22168 V24017

ISSUE

Over the past number of years Roche conducted field safety corrective actions (FSCAs) for the above listed blood glucose meters and insulin pumps in the Accu-Chek range as follows

- In 2013 Roche advised users of the following in relation to the Accu Chek® Aviva Combo handset's bolus advisor function. 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. The FSN requests that users are aware of the above scenario and to 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.

- In 2014 Roche advised users of enhanced instructions for proper testing with the Accu-Chek® Mobile system to avoid the potential of falsely elevated blood glucose readings. Roche identified that a small number of people with diabetes using the

Accu-Chek® Mobile device experienced falsely elevated blood glucose readings when using the system as a result of not following the described and labelled handling instructions. Such improper handling can include, for example, unclean hands contaminated with glucose-containing substances, pressing the finger too hard and too long on the test field or smearing the blood while performing a test.

- Also in 2014 Roche advised users of important information on Accu-Chek® Spirit Combo insulin pumps regarding the potential for date and time loss due to a capacitor defect, following a battery change. The Accu-Chek Spirit Combo insulin pump may experience a loss of the date and time settings following a battery change. Roche advised users who experience this issue to contact the Accu-Chek Pump Careline for an immediate replacement.

- In 2015 Roche advised users of updated handling instructions for the Accu-Chek® Spirit and Accu-Chek® Spirit Combo insulin pumps to ensure a correct change of the insulin cartridge. Roche had become aware that some customers were experiencing an increase in the number of mechanical errors with their insulin pumps showing E6 and E10 error messages. If users do not follow the step-by-step cartridge change process as described in the training leaflet provided, there is a potential risk that small amounts of insulin could drip into the cartridge compartment, which eventually may result in the insulin not being delivered as intended and an E6 (mechanical error) or E10 (cartridge error).

ACTION OR RECOMMENDATIONS

The HPRA advises that users:

1) Ensure that you have read and followed the instructions that were provided in the various manufacturer's field safety notices (FSNs).

2) Acknowledge receipt of the FSNs if you have not already done so.

3) Report any concerns regarding these devices to the manufacturer and the HPRA.

The HPRA advise that healthcare professionals:

4) Ensure that relevant personnel receive a copy of the attached FSNs.

5) Forward this HPRA Safety Notice to all those who need to be made aware within your organisation or to any organisation/person where these devices have been transferred.

6) Report any concerns regarding these devices to the manufacturer and the HPRA.

TARGET GROUPS

Risk managers	General practitioners
Diabetes clinics	Private medical practitioners
Diabetes nurse specialists	Pharmacists
Supplies managers	General public

BACKGROUND

To date reconciliation in relation to acknowledgement of receipt of these FSNs has been poor so the HPRA is communicating this Safety Notice at this time to ensure that all users of these devices are aware of these issues.

Please note that historically Roche Diabetes Care carried out its business activities through Roche Diagnostics Limited. From late 2014 onwards it moved to a separate legal entity, Roche Diabetes Care Limited. Therefore all FSCAs referenced below and issued before late 2014 are in the name of Roche Diagnostics Limited. For consistency, both Roche companies are referred to interchangeably as "Roche" throughout

MANUFACTURER / AUTHORISED REPRESENTATIVE/ DISTRIBUTOR CONTACT INFORMATION

Enquiries to the **manufacturer** should be addressed to:

Roche Diabetes Care Limited
Charles Avenue
Burgess Hill
West Sussex
RH15 9RY

Telephone: 1800 88 23 51
Fax: +44 (0)1444 256 205
E-mail: burgesshill.dcsafety@roche.com
Website: https://www.accu-chek.co.uk/gb/?diabetescare=IE

HPRA CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:

Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
Fax: +353-1-6344033
E-mail: devicesafety@hpra.ie
Website: www.hpra.ie