

Safety Notice

Medical Devices

Accu-Chek Spirit and Accu-Chek Spirit Combo Insulin Pumps

Priority 2 – Warning



HPRA Safety Notice: SN2015(08)

Issue Date: 20 May 2015

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Roche Diabetes Care SB_RDC_2015_02	V24017

ISSUE

The Health Products Regulatory Authority (HPRA) has been advised by Roche Diabetes Care of an update to the handling instructions for the Accu-Chek Spirit insulin pump and the Accu-Chek Spirit Combo insulin pump system to ensure a correct change of the insulin cartridge for the above devices.

Roche has become aware that some customers using these devices are experiencing an increase of mechanical errors with their insulin pumps showing E6 and E10 error messages.

ACTION OR RECOMMENDATIONS

The HPRA advise that users:

- 1 Be aware of the potential for the Accu-Chek Spirit and Accu-Chek Spirit Combo insulin pumps to experience mechanical or cartridge errors.
- 2 Refer to the information provided by Roche Diabetes Care in the attached Consumer

	Letter regarding the procedure for changing the cartridge of the Accu-Chek Spirit and Spirit Combo insulin pump.
3	Contact the Accu-Chek Pump Careline (1800 88 23 51) if you experience any failures associated with this issue.
4	Report any concerns regarding these devices to the manufacturer and the HPRA.
The HPRA advise that healthcare professionals;	
1	Inform all patients of the issue outlined in the attached HCP and Consumer Letters.
2	Forward a copy of this Safety Notice and the Field Safety Notices (FSNs) to all relevant personnel.
3	Forward the FSNs and Safety Notice to any other persons/organisations where these devices have been transferred.
4	Report any concerns regarding these devices to the manufacturer and the HPRA.

TARGET GROUPS	
Hospital Managers / CEOs Risk Managers Clinical Directors Clinical Engineers Nursing Managers Nursing staff Purchasing Managers Hospital personnel Palliative Care Units Renal Units Accident & Emergency Departments Nephrology Departments Paediatric wards	Neonatal units General Practitioners Carers General public Dialysis patients / device users Nursing Home staff

BACKGROUND
<p>Roche has become aware that some customers using the Accu-Chek Spirit insulin pump and the Accu-Chek Spirit Combo insulin pump system are experiencing an increase of mechanical errors with their insulin pumps showing E6 and E10 error messages.</p> <p>Roche advised that if users do not follow the step-by-step cartridge change process as described in the attached FSN, there is a potential risk that small amounts of insulin could drip into the cartridge compartment. Such small amounts could remain in the compartment and result in damage to the piston rod over time, so much so that the piston rod will not move correctly. This could potentially limit or block the insulin pump motor function entirely. Eventually, this may result in the insulin not being delivered as intended and an E6 (mechanical error) or E10 (cartridge error).</p> <p>Roche has advised that this issue is easily detectable as the pump will alert the user by acoustic, visual and vibration alerts. However, to avoid this risk users should follow the instructions and assemble the cartridge, adapter and infusion set tubing first, prior to inserting the new cartridge into the insulin pump.</p>

MANUFACTURER / DISTRIBUTOR CONTACT INFORMATION

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

Accu-Chek Pump Care line

Telephone: 1800 88 23 51

Email: burgesshill.insulinpumps@roche.com

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