

Medical Device Alert

MHRA

Immediate action

This alert replaces MDA/2009/024. Action points have been changed.

Ref: MDA/2009/027 Issued: 20 April 2009 at 11:30

Device

Ambulatory insulin infusion pump. Accu-Chek Spirit manufactured by Roche Diagnostics. Only serial numbers up to and including 10006093 are affected (number is located on the back of the pump).



Problem

Due to a design fault, the 'up' and 'down' arrow buttons can fail. If both the buttons fail at the same time, the activation of the bolus function and the adjustment of the preset basal function will be inhibited.

This means that there is a risk that insulin therapy is compromised.

Action by

- Diabetes departments.
- Pharmacists.
- Those involved in supplying and using these devices.

CAS deadlines

Action underway: 27 April 2009
Action complete: 12 May 2009

Action

- Ensure that patients using the pump are aware of the potential for the 'up' and 'down' buttons to fail.
- Patients who are concerned should contact the manufacturer for further advice.
- Patients who experience problems with their pump should immediately contact the manufacturer's 24 hour care line to arrange a replacement device.
- A back-up delivery method should be available at all times.
- Report any problems with the pump to the MHRA.

Contact

Manufacturer/supplier
Accu-Chek Pump Careline
Roche Diagnostics Ltd

Tel: 0800 731 2291
Fax: 0808 100 8060
E-mail: burgesshill.insulinpumps@roche.com

[Link to full Medical Device Alert](#)