Medical Device Alert

Ref: MDA/2014/008 Issued: 11 March 2014 at 12:00

Device

Insulin infusion pump:
Accu-Chek Spirit Combo insulin pump
Manufactured by Roche Diagnostics Ltd.

All pumps with serial numbers in the range 10171897 to 10281629 (inclusive).

Problem

Risk of delay to treatment.

There is an increased risk that the vibration alarm will not work, as a result of a changed component. This fault will only be detected at pump start up, when it will display an 'E-7' error message and give an audible signal, but will fail to start.

Roche will replace pumps that display this 'E-7' error message, but does not intend to replace all potentially affected pumps.

Action by

All those responsible for the use and maintenance of these devices, particularly diabetes departments.

Action

- Identify affected pumps.
- If a delay to insulin therapy could compromise patient safety, consider using an alternative device.
- When using these pumps:
  - > ensure that users are aware of the problem
  - > ensure that users have a syringe or insulin pen available in case the pump stops.
  - > if the pump displays an 'E-7' error, contact Roche for a replacement
- Report any adverse incidents involving these devices to the MHRA.

CAS deadlines

Action underway: 01 April 2014

Action complete: 06 May 2014

Note: These deadlines are for systems to be in place to identify pumps and ensure users are aware of the problem.

Contact

Manufacturer

Accu-Chek Pump Careline

Tel: 0800 731 2291

Distribution

This MDA has been sent to

- Care Quality Commission (CQC) (headquarters) for information
- Clinical commissioning groups (CCGs)
- HSC trusts in Northern Ireland (chief executives)
- Local authorities in Scotland (equipment co-ordinators)
- NHS boards and trusts in Wales (chief executives)
- NHS boards in Scotland (equipment co-ordinators)
- NHS England area teams
- NHS trusts in England (chief executives)

Onward distribution

Please bring this notice to the attention of relevant employees in your establishment.
Below is a suggested list of recipients.

Trusts

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- Clinical governance leads
- Community diabetes specialist nurses
- Community hospitals
- Diabetes clinics/outpatients
- Diabetes nurse specialists
- Diabetes, directors of
- Diabetologists
- EBME departments
- Equipment stores
- Medical directors
- Medical libraries
- Nursing executive directors
- Outpatient clinics
- Paediatric diabetes nurse specialists
- Paediatric nurse specialists
- Paediatricians
- Pharmacists
- Risk managers
- Supplies managers

NHS England area teams

CAS liaison officers for onward distribution to all relevant staff including:

- Community pharmacists
- General practitioners

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)

This alert should be read by:

- Clinics
- Hospitals in the independent sector
- Independent treatment centres
- Private medical practitioners

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive MDAs directly from the Department of Health's Central Alerting System (CAS) by sending an email to: safetyalerts@dh.gsi.gov.uk and requesting this facility.

Contacts

Manufacturer
Accu-Chek Pump Careline
Tel: 0800 731 2291

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2013/008** or **2013/009/006/081/012**

Technical aspects
Sharon Knight or Patrick Sweeney
Medicines & Healthcare Products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ
Tel: 020 3080 7202 / 6898
Fax: 020 8754 3965
Email: sharon.knight@mhra.gsi.gov.uk
patrick.sweeney@mhra.gsi.gov.uk

Clinical aspects
Mark Grumbridge
Medicines & Healthcare Products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ
Tel: 020 3080 7128
Fax: 020 8754 3965
Email: mark.grumbridge@mhra.gsi.gov.uk

How to report adverse incidents

Please report via our website http://www.mhra.gov.uk
Further information about **CAS** can be found at https://www.cas.dh.gov.uk/Home.aspx

Northern Ireland

Alerts in Northern Ireland will continue to be distributed via the NI SABS system.

Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre
Health Estates Investment Group
Room 17, Annex 6, Castle Buildings, Stormont Estate
Dundonald BT4 3SQ
Tel: 02890 523 704
Fax: 02890 523 900
Email: NIAIC@dhsspsni.gov.uk
http://www.dhsspsni.gov.uk/index/hea/niaic.htm

How to report adverse incidents in Northern Ireland

Please report directly to NIAIC, further information can be found on our website http://www.dhsspsni.gov.uk/niaic
Further information about **SABS** can be found at http://sabs.dhsspsni.gov.uk/

Scotland

All requests regarding return, replacement or modification of the devices mentioned in this alert should be directed to the relevant supplier or manufacturer.

Other enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre
NHS National Services Scotland
Gyle Square
1 South Gyle Crescent
Edinburgh EH12 9EB

Tel: 0131 275 7575
Fax: 0131 314 0722

Email: nss.iric@nhs.net

http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-iric/

Wales

Enquiries in Wales should be addressed to:

Improving Patient Safety Team
Medical Directorate
Welsh Government
Cathays Park
Cardiff CF10 3NQ

Tel: 029 2082 5801

Email: Haz-Aic@wales.gsi.gov.uk