Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2017/010 Issued: 02 May 2017 at 14:30

All Accu-Chek® Insight insulin pumps – updated information for battery management

Summary

Manufactured by Roche Diabetes Care – Replacement and update to MDA/2015/029 with new instructions to improve battery lifetime and prevent unexpected pump shut down or rapid battery depletion.

Action

- Identify all users of Accu-Chek Insight insulin pumps.
- Ensure that all patients and carers:
  - receive the manufacturer's Field Safety Notice (FSN)
  - understand the instructions detailed in the FSN and follow the advice given by the manufacturer
  - use Energizer® Ultimate lithium batteries (1.5V AAA / FR03) provided by the manufacturer and follow the steps described in the handling instructions in the FSN
- Contact Roche if you experience unexpected pump shut down or rapid battery depletion.
- Return the FSN acknowledgment form to Roche as currently the manufacturer hasn't received enough responses.

Action by
Everyone responsible for the use and maintenance of these devices, particularly diabetes care specialists.

Deadlines for actions
Actions underway: 23/05/2017
Actions complete: 06/06/2017

Department of Health
An Roinn Sláinte
Männystrie O Poustie
www.health-ni.gov.uk

NHS National Services Scotland

Llywodraeth Cymru
Welsh Government

Problem / background

Note that this alert replaces and updates MDA/2015/029, which we published in August 2015.

Roche has provided updated handling instructions and frequency for battery change to every 14 days from the 30 days previously recommended.

Manufacturer contacts

Roche Diabetes Care

Accu-Chek Pump Care UK telephone line: 0800 731 22 91

Email: burgesshill.dcsafety@roche.com

Distribution

If you are responsible for cascading these alerts in your organisation, these are our suggested distribution lists.

Trusts (NHS boards in Scotland)
CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- Community diabetes specialist nurses
- Community hospitals
- Diabetes clinics/outpatients
- Diabetes nurse specialists
- Diabetes, directors of
- EBME departments
- Outpatient clinics
- Paediatric diabetes nurse specialists
- Paediatric wards
- Paediatricians
- Paediatrics departments
- Pharmacists
- Risk managers
- Supplies managers

NHS England area teams
CAS liaison officers for onward distribution to all relevant staff including:

- Community pharmacists
- General practice managers
- General practice nurses
- General practitioners

This Medical Device Alert is being sent to GPs for information only, in circumstances where patients may seek advice about the contents of this notice. GPs need take no further action on receipt of this alert.

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

- 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.

Enquiries

England
Send enquiries about this notice to MHRA, quoting reference number **MDA/2017/010** or **2017/003/001/291/005**.

Technical aspects
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Clinical aspects

MHRA Devices Clinical Team

Tel: 020 3080 7274

Email: dct@mhra.gov.uk

Reporting adverse incidents in England
Through Yellow Card https://yellowcard.mhra.gov.uk/

Northern Ireland
Alerts in Northern Ireland are distributed via the NI SABS system.

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

Northern Ireland Adverse Incident Centre
CMO Group
Department of Health, Social Services and Public Safety

Tel: 028 9052 3868

Email: niaic@health-ni.gov.uk
https://www.health-ni.gov.uk/niaic

Reporting adverse incidents in Northern Ireland
Please report directly to NIAIC using the forms on our website.

Scotland
Enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre
Health Facilities Scotland
NHS National Services Scotland

Tel: 0131 275 7575
Fax: 0131 314 0722

Email: nss.iric@nhs.net

Reporting adverse incidents in Scotland
NHS Boards and Local Authorities in Scotland – report to Health Facilities Scotland.

Contractors such as private hospitals carrying out NHS work and private care homes that accept social work funded clients – report to Health Facilities Scotland.

Private facilities providing care to private clients report to the Care Inspectorate and MHRA.

Wales

Enquiries in Wales should be addressed to:
Healthcare Quality Division, Welsh Government

Tel: 02920 823 624 / 02920 825 510

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

Reporting adverse incidents in Wales

Report to MHRA through Yellow Card https://yellowcard.mhra.gov.uk/ and follow specific advice for reporting in Wales in MDA/2004/054 (Wales).