Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2019/009 Issued: 19 February 2019 at 12:00

Accu-Chek® Insight insulin pumps – some need to be fitted with key frames to reduce the risk of accidentally unlocking keys or pressing the bolus buttons

Summary

Manufactured by Roche Diabetes Care – Important instructions on how to fit 2 separate key frames to prevent accidentally activating the pump.

Action

- Identify affected patients and pumps (serial numbers below 32100000)
- Ensure that all patients and carers:
  - > receive a copy of manufacturer's Field Safety Notice (FSN) and instructions for use dated December 2018
  - > understand the information detailed in the FSN
  - > apply the new key frames as instructed by the manufacturer
- Return the FSN acknowledgment form to Roche as currently they have not received enough responses

This Medical Device Alert is to ensure that all relevant organisations are aware of this FSN and encourage their patients to apply the key frames.

Action by
• All healthcare workers responsible for patients who use these devices.
• Diabetes departments.

Deadlines for actions
Actions underway: 12 March 2019
Actions complete: 02 April 2019

Medical Device Safety Officers (in England): ask the manufacturer to add you to their distribution list for field safety notices (FSNs). This is to help with reconciliation.

Remember: if your organisation receives an FSN from a manufacturer, always act on it. **Do not wait** for a communication from MHRA.

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

NHS National Services Scotland

Llywodraeth Cymru Welsh Government

Problem / background

The key lock function of the pump locks only the buttons on the front of the insulin pump.
It does **not** lock the quick bolus keys on the top of the pump.

The manufacturer has received reports of unintended boluses being delivered. Revised handling instructions were published in 2016 (MHRA issued MDA/2016/016) and now Roche Diabetes Care is providing users with key frames to fit onto all affected Accu-Check Insight pumps (i.e. pumps with serial numbers below 32100000) to further reduce the risk of accidental bolus delivery.

Manufacturer contacts

Roche Diabetes Care
Tel: 0800 731 2291
Email: burgesshill.insulinpumps@roche.com

Manufacturer FSCA Reference: SB_RDC_2015_05_2

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 NICAS 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 diabetic 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:

- General practitioners (for information only)

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
- Hospices
- 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 Central Alerting System (CAS) by sending an email to: safetyalerts@mhra.gov.uk and requesting this facility.

Enquiries

England

Send enquiries about this notice to MHRA, quoting reference number **MDA/2019/009** or **2018/011/028/701/019**.

Technical aspects

Enitan Taiwo or Natasha Mthethwa, MHRA

Tel: 020 3080 7122/ 7086

Email: enitan.taiwo@mhra.gov.uk or natasha.mthethwa@mhra.gov.uk

Clinical aspects

Devices Clinical Team, MHRA

Tel: 020 3080 7274

Email: dct@mhra.gov.uk

To report an adverse incident involving a medical device in England use the Yellow Card reporting page

Northern Ireland

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

Tel: 0208 9052 3868

Email: niaic@health-ni.gov.uk

To report an adverse incident involving a medical device in Northern Ireland use the forms on the website.

Alerts in Northern Ireland are distributed via the NICAS system.

Scotland

Incident Reporting and Investigation Centre (IRIC), Health Facilities Scotland, NHS National Services Scotland

Tel: 0131 275 7575

Email: nss.iric@nhs.net

To report an adverse incident involving a medical device in Scotland, email IRIC to request a webform account.

For more information, or if you can't access the webform, visit the website: how to report an adverse incident

Wales

Population Healthcare Division, Welsh Government

Tel: 03000 250986 / 03000 255510

Email: haz-aic@wales.gov

To report an adverse incident involving a medical device in Wales, use the Yellow Card reporting page and follow specific advice for reporting in Wales in MDA/2004/054 (Wales).