Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2017/030 Issued: 20 September 2017 at 14:00

All Accu-Chek® Insight insulin pumps – risk of alarm failure

Summary

Manufactured by Roche Diabetes Care – the audible and/or vibration alarms might not function, which may lead to **hyperglycaemia** if the user doesn't see the notification message on the pump.

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 information detailed in the FSN and follow the advice given by the manufacturer
  - > check the display of the insulin pump regularly
  - > seek clinical advice if they are concerned and have an alternative insulin therapy available if necessary
  - > contact Roche Careline to get a replacement if the pump continues to display the 'E7' error message
- Return the FSN acknowledgment form to Roche as currently the manufacturer has not received sufficient responses

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

Deadlines for actions
Actions underway: 04 October 2017
Actions complete: 18 October 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

Due to an electrical issue there is a risk of a vibrator alarm failure and an intermittent audible alarm failure.

The alarm failures will be detected during a pump's self-test, which is prompted by changing the battery or insulin cartridge. If the failures are detected, the E7 error shows on the pump's display.

Users should contact the customer careline as instructed in the user manual if they cannot resolve an E7 error message.

Manufacturer contacts

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

Manufacturer FSCA Reference: SB_RDC_2017_04

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
- Medical libraries
- 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
- Hospices
- 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/2017/030** or 2017/007/025/291/019.

Technical aspects
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Clinical aspects
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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 NICAS 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).