



# Medical Device Alert

MDA/2016/016

Issued: 01 September 2016 at 14:00

## Accu-Chek® Insight insulin pump system – risk of over- or under-infusion of insulin

### Summary

Manufactured by Roche Diabetes Care - inadequately detailed handling instructions of the 'Key Lock' function of the pump may lead to unintentional operation, which could result in rapid and severe deterioration of health e.g. hypoglycaemia or diabetic ketoacidosis.

### Action

Identify users of the Accu-Chek Insight insulin pump system.

Healthcare professionals should ensure that:

- patients/carers understand that the Quick Bolus keys on the top of the Accu-Chek Insight insulin pump are **not locked** by the Key Lock function
- patients/carers receive a copy of manufacturer's [Field Safety Notice \(FSN\)](#), and are made aware of the enhanced handling instructions
- all new patients/carers have a copy of the FSN with their Accu-Chek Insight pump system.

GPs should note that this is for their information only.

### Action by

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

### Deadlines for actions

Actions underway: 08 September 2016

Actions complete: 22 September 2016

## Manufacturer contacts

Roche Diabetes Care Accu-Chek Pump Care Line

Tel: 0800 731 22 91

Email: [burgesshill.insulinpumps@roche.com](mailto:burgesshill.insulinpumps@roche.com)

Manufacturer FSCA Reference: SB\_RDC\_2015\_05

## 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:

Emergency departments

- Community diabetes specialist nurses
- Community hospitals
- Community nurses / district nurses
- Diabetes clinics/outpatients
- Diabetes nurse specialists
- Diabetes, directors of
- Diabetologists
- EBME departments
- Emergency departments
- Equipment stores
- Outpatient clinics
- Paediatric diabetes nurse specialists
- Risk managers
- Supplies managers

### NHS England area teams

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

- General practitioners – for information only

### Independent distribution

Diabetes UK

### 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 Department of Health's Central Alerting System (CAS) by sending an email to: [safetyalerts@dh.gsi.gov.uk](mailto:safetyalerts@dh.gsi.gov.uk) and requesting this facility.

## Enquiries

### England

Send enquiries about this notice to MHRA, quoting reference number **MDA/2016/016** or **2015/008/019/701/009**.

### Technical aspects

Roopa Prabhakar and Helen Stidwill, MHRA

Tel: 020 3080 7293 / 7047

Email: [roopa.prabhakar@mhra.gsi.gov.uk](mailto:roopa.prabhakar@mhra.gsi.gov.uk) and [helen.stidwill@mhra.gsi.gov.uk](mailto:helen.stidwill@mhra.gsi.gov.uk)

### Clinical aspects

Mark Grumbridge, MHRA

Tel: 020 3080 7128

Email: [mark.grumbridge@mhra.gsi.gov.uk](mailto:mark.grumbridge@mhra.gsi.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](mailto: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.irc@nhs.net](mailto:nss.irc@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](mailto: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 \(Wales\)](#).

MHRA is a centre of the Medicines and Healthcare products Regulatory Agency, an executive agency of the Department of Health  
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