MDA/2018/016(Wales)

Medical Device Alert

22st May 2018

Parc Cathays
Caerdydd CF10 3NQ

Llywodraeth Cymru
Welsh Government

Cathays Park
Cardiff CF10 3NQ

Home use and Point of Care blood glucose monitoring system: Accu-Chek Aviva, Accu-Chek Performa and Accu-Chek Inform II test strips – risk of strip error messages and false high and low blood glucose results.

Healthcare personnel who manage patients using these devices:

- Identify patients who use Accu-Chek Aviva, Accu-Chek Aviva Nano, Accu-Chek Aviva Expert, Accu-Chek Aviva Combo, Accu-Chek Aviva Insight, Accu-Chek Performa Nano meters.
- Advise patients to discontinue use of Accu-Chek Aviva and Accu-Chek Performa blood glucose test strips with affected lot numbers, see FSN.
- Return affected test strips to the pharmacy where they were dispensed or purchased from for replacements.
- Ensure that patients are aware of this information and that they have an alternative testing means, if required.
- Ensure the patient can continue to monitor their blood glucose effectively.
- If patients are concerned about their blood glucose readings when using this meter, advise them to contact their healthcare professional.

Sent to:
NHS Wales Shared Services Partnership
Directors of Public Health,
Chief Executives, NHS Trusts
Chief Executives, LHBs
Medical Directors, NHS Trusts
Nurse Directors, LHBs
Executive Nurses, NHS Trusts
NHS Direct
CSSIW
Social Services
HIW

A list of people who need to have early sight of this information is given in the Notice.
This Notice has been endorsed by the Welsh Government as being relevant to NHS Wales.

Points of particular importance in Wales:

Healthcare Quality Division
Welsh Government
Cathays Park
Cardiff CF10 3NQ

Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2018/016 Issued: 18 May 2018 at 11:30 Valid until: May 2019

Home use and Point of Care blood glucose monitoring system: Accu-Chek Aviva, Accu-Chek Performa and Accu-Chek Inform II test strips – risk of strip error messages and false high and low blood glucose results.

Summary

Affected test strips, manufactured by Roche Diabetes Care, may give increased strip error messages prior to dosing with blood and in some cases may give false high or low readings, which may be hard to detect.

Action

Healthcare personnel who manage patients using these devices:

- Identify patients who use Accu-Chek Aviva, Accu-Chek Aviva Nano, Accu-Chek Aviva Expert, Accu-Chek Aviva Combo, Accu-Chek Aviva Insight, Accu-Chek Performa Nano meters.
- Advise patients to discontinue use of Accu-Chek Aviva and Accu-Chek Performa blood glucose test strips with affected lot numbers, see FSN.
- Return affected test strips to the pharmacy where they were dispensed or purchased from for replacements.
- Ensure that patients are aware of this information and that they have an alternative testing means, if required.
- Ensure the patient can continue to monitor their blood glucose effectively.
- If patients are concerned about their blood glucose readings when using this meter, advise them to contact their healthcare professional.

Healthcare personnel who use Accu-Chek Inform II test strips with Accu-Chek Inform II and Accu-Chek Performa meters:

MHRA understands that Accu-Chek Inform II test strips have only been supplied by Roche for professional use in the UK.

- Ensure all relevant members of staff receive the FSN and can continue to monitor patient's blood glucose effectively, using an alternative means if required.
- Dispose of any affected lots.

Action by
Healthcare personnel managing patients who use these devices.
Healthcare personnel who use these devices.

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

NHS National Services Scotland

Llywodraeth Cymru Welsh Government

Deadlines for actions
Actions underway: 04 June 2018
Actions complete: 18 June 2018

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.

Problem / background

The manufacturer issued a Field Safety Notice in May 2018.

Roche has confirmed that only the identified lots are affected by this issue.

Manufacturer contacts

Local Regulatory and Safety Officer
Roche Diabetes Care Ltd
Charles Avenue
Burgess Hill
West Sussex
RH15 9RY

Tel: burgesshill.dcsafety@roche.com
Email: 01444106000

Distribution

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

- A&E consultants
- A&E departments
- A&E nurses
- Adult intensive care units
- All departments
- All wards
- Ambulance services directors
- Ambulance staff
- Anaesthetic medical staff
- Anaesthetic nursing staff
- Anaesthetists
- Cardiology departments
- Cardiology nurses
- Cardiothoracic departments
- Chief pharmacists
- Clinical governance leads
- Clinical perfusionists
- Colposcopy departments
- Community children's nurses
- Community defibrillation officers
- Community diabetes specialist nurses
- Community hospitals
- Community nurses
- Coronary care departments
- Coronary care nurses
- Day surgery units
- Dental departments
- Dental nurses
- Dermatologists

- Diabetes clinics/outpatients
- Diabetes nurse specialists
- Diabetes, directors of
- Dietetics departments
- Dieticians
- District nurses
- Endocrinology units
- Endocrinology, directors of
- ENT departments
- ENT medical staff
- Equipment stores
- Gastroenterology departments
- Gastro-intestinal surgeons
- General surgeons
- General surgery
- Gynaecology departments
- Gynaecology nurses
- Haematologists
- Haemodialysis nurses
- Haemodialysis units
- Health and safety managers
- Health visitors
- Hospital at home units
- Hospital pharmacies
- Hospital pharmacists
- Intensive care medical staff/paediatrics
- Intensive care nursing staff (adult)
- Intensive care nursing staff (paediatric)
- Intensive care units
- IV nurse specialists
- Minor injury units
- Maternity units
- Maxillofacial departments
- Medical directors
- Midwifery departments
- Midwifery staff
- MRI units, directors of
- Neonatal nurse specialists
- Neonatology departments
- Neonatology directors
- NHS walk-in centres
- Nursing executive directors
- Nutrition nurses
- Obstetricians
- Obstetrics and gynaecology departments
- Obstetrics departments
- Obstetrics nurses
- Oncology nurse specialists
- Ophthalmic nurses
- Ophthalmology departments
- Orthopaedic surgeons
- Outpatient clinics
- Outpatient theatre managers

- Outpatient theatre nurses
- Paediatric intensive care units
- Paediatric medicine, directors of
- Paediatric nurse specialists
- Paediatric oncologists
- Paediatric surgeons
- Paediatric surgery, directors of
- Paediatric wards
- Paediatricians
- Paediatrics departments
- Paramedics
- Patient transport managers
- Peritoneal dialysis units
- Pharmaceutical advisors
- Pharmacists
- Phlebotomists
- Point of care testing co-ordinators
- Purchasing managers
- Radiology departments
- Renal medicine departments
- Resuscitation officers and trainers
- Risk managers
- School nurses
- Special care baby units
- Staff supporting patients receiving haemodialysis at home
- Supplies managers
- Theatre managers
- Theatre nurses
- Theatres
- Urological surgeons
- Urological surgery, directors of
- Urology departments
- Walk-in centres

Public Health England

Directors for onward distribution to:

- Collaborating centres
- Consultants in communicable disease control
- Divisional directors
- Heads of department
- Heads of health, safety and quality
- Risk manager
- Safety officers

NHS England area teams

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

- Community pharmacists
- General practitioners

Social services

Liaison officers for onward distribution to all relevant staff including:

- Care at home staff
- Care management team managers
- Children's disability services
- Community care staff
- Day centres (older people, learning disabilities, mental health, physical disabilities, respite care, autistic services)
- In-house residential care homes

Independent distribution

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

- Adult placement
- Care homes providing nursing care (adults)
- Care homes providing personal care (adults)
- Clinics
- Domiciliary care providers
- Further education colleges registered as care homes
- Hospices
- Hospitals in the independent sector
- Independent treatment centres
- Nursing agencies
- Private medical practitioners

Establishments registered with OFSTED

- Children's services
- Educational establishments with beds for children
- Residential special schools

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/2018/016** or **2018/005/004/228/002**.

Technical aspects

Bina Mackenzie, MHRA

Tel: 020 3080 7229

Email: bina.mackenzie@mhra.gov.uk

Clinical aspects

Devices Clinical Team, MHRA

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 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

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).