



Medical Device Alert

MDA/2019/003

Issued: 29 January 2019 at 11:00

FreeStyle Libre flash glucose sensor – Use of barrier methods to reduce skin reactions to the sensor adhesive.

Summary

Manufactured by Abbott – some users who are experiencing an immune response to the adhesive are applying creams, patches or sprays under their sensor to reduce skin reactions, which may affect device performance.

Action

1. Identify patients who have reported or may be experiencing skin reactions, which may include erythema, itching and blistering.
2. Consider if continued use of this device for patients with skin reactions is suitable.
3. Consider use of alternative glucose monitoring systems for these patients.

This is consistent with the guidance already provided in the manufacturer's instructions for use, which state: "Some individuals may be sensitive to the adhesive that keeps the Sensor attached to the skin. If you notice significant skin irritation around or under your Sensor, remove the Sensor and stop using the FreeStyle Libre system. Contact your health care professional before continuing to use the FreeStyle Libre system"

Report adverse events involving these devices through your local incident reporting system and/or your national incident reporting authority as appropriate: [England](#), [Scotland](#), [Northern Ireland](#), [Wales](#). You should also report directly to manufacturers if your local or national systems do not.

Action by

All healthcare professionals who are responsible for patients that use these devices.

Deadlines for actions

Actions underway: 12 February 2019

Actions complete: 26 February 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.

Problem / background

MHRA is aware that some users of the FreeStyle Libre flash glucose monitoring system are applying barrier creams, patches and sprays before attaching the sensor to reduce skin reactions. These barrier methods have not been tested by the manufacturer and may therefore affect the performance of the device.

The severity of the skin reaction can vary from person to person and for certain users this is a skin hypersensitivity reaction rather than an irritation reaction. For this type of reaction, once the person has become sensitised to the adhesive, every time the sensor is reapplied a skin reaction will occur. With each reapplication, the symptoms might appear more quickly and may worsen.

The manufacturer has confirmed that they have revised the formulation of the adhesive, which will be available to UK customers from April 2019.

Please note this problem may not be unique to the Abbott FreeStyle Libre sensor adhesive. The same actions should be taken if patients experience similar symptoms with a different brand of continuous glucose monitoring system.

Manufacturer contacts

Abbott Diabetes Care UK
Customer Services Complaints (82)
Freepost RRBS-BLAA-SEHT
Maidenhead
SL6 4UD, UK

Phone: 0800 170 1177

Opening Times: 08:00 – 20:00, Monday to Friday (excluding bank holidays)

Email: ADChelpuk@abbott.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 NICAS liaison officers for onward distribution to all relevant staff including:

- All departments
- All staff
- All wards
- Ambulance services directors
- Ambulance staff
- Chief pharmacists
- Clinical governance leads
- Community children's nurses
- Community diabetes specialist nurses
- Community hospitals
- Community nurses
- Dermatologists
- Diabetes clinics/outpatients
- Diabetes nurse specialists
- Diabetes, directors of

- Dietetics departments
- Dieticians
- District nurses
- Endocrinology units
- Endocrinology, directors of
- Health visitors
- Hospital at home units
- Hospital pharmacies
- Hospital pharmacists
- Minor injury units
- Medical directors
- NHS walk-in centres
- Nursing executive directors
- Nutrition nurses
- Outpatient clinics
- Paediatric medicine, directors of
- Paediatric nurse specialists
- Paediatric wards
- Paediatricians
- Paediatrics departments
- Paramedics
- Pharmaceutical advisors
- Pharmacists
- Walk-in centres

NHS England area teams

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

- Community pharmacists
- General practitioners
- General practice nurses

Social services

- Care at home staff
- Care management team managers
- Community care staff
- Day centres (older people, learning disabilities, mental health, physical disabilities, respite care, autistic services)
- In-house domiciliary care providers (personal care services in the home)
- 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
- 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/2019/003** or **2018/003/006/433/003**.

Technical aspects

Emma Harris and Bina Mackenzie, MHRA

Tel: 020 3080 6000

Email: DSS-TM@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.irc@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 \(Wales\)](#).

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

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