Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2020/005 Issued: 05 February 2020 at 14:00 Valid until February 2021

t: slim X2 insulin pump – discard or destroy defective mains (A/C) power adapters

Summary

Manufactured by Tandem Diabetes Care – an exposed component may cause an electrical shock to the user or patient

Action

- Identify patients supplied with affected insulin pumps.
- Ensure patients have received the manufacturer's Field Safety Notice (FSN) with the replacement adapter. The adapters originally supplied with the pumps MUST be discarded.
- Acknowledge disposal of the adaptors by accessing the link referenced in the FSN, or by contacting the manufacturer directly.
- Report suspected or actual 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
Healthcare professionals managing patients who use these devices.

Deadlines for actions
Actions underway: 04 March 2020
Actions complete: 29 April 2020

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

Device details

Unique Device Identifier(s) (UDI-DI) are:

00853052007806

00850006613021

00853052007820

00850006613052

Manufacturer contacts

Air Liquide Homecare
Tel: 0800 012 1560
Email: diabetes.info@airliquide.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:

- Community nurses
- Diabetes clinics/outpatients
- Diabetes nurse specialists
- Diabetes, directors of
- District nurses
- Endocrinology units
- Endocrinology, directors of
- Hospital pharmacies
- Hospital pharmacists
- Outpatient clinics
- Pharmaceutical advisors
- Pharmacists
- Purchasing managers
- Risk managers

GP Practices registered with CAS

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.

NHS England area teams

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

- Community pharmacists
- Dispensing opticians
- General dental practitioners
- GP practices not yet registered with CAS (for information only)

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Independent distribution

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

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/2020/005** or **2019/010/010/701/037**.

Technical aspects

Roopa Prabhakar or Enitan Taiwo, 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 (Northern Ireland)
Tel: 028 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 255278 or 03000 255510

Email: Haz-Aic@gov.wales

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).