MHRA

Regulating Medicines and Medical Devices

Medical Device Alert

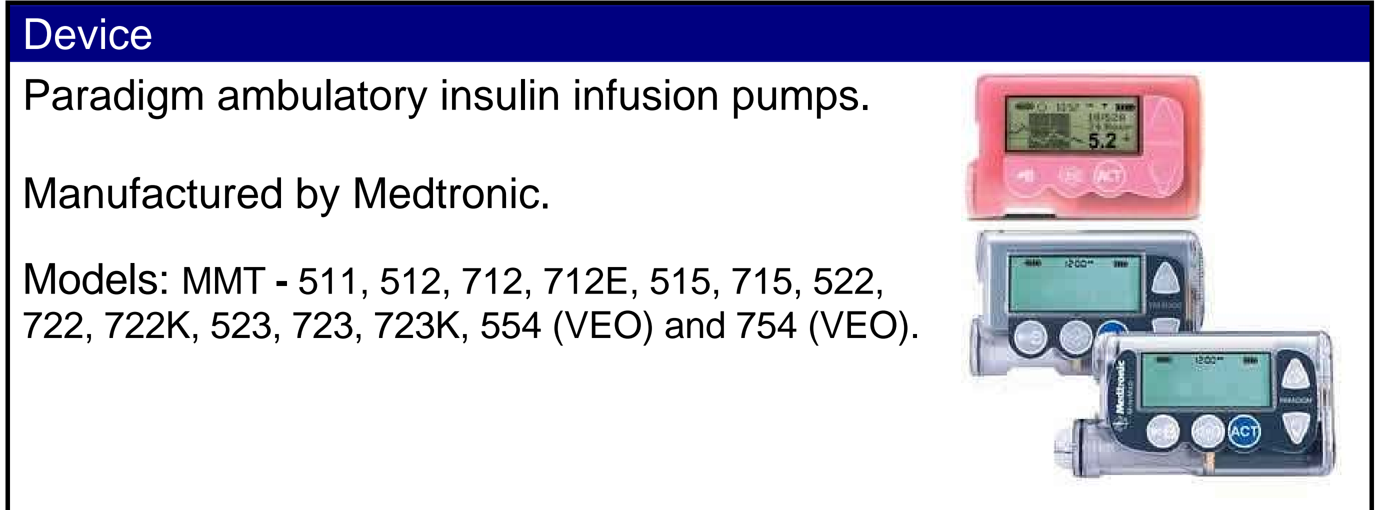
Ref: MDA/2013/035 Issued: 17 May 2013 at 14:00

Device

Paradigm ambulatory insulin infusion pumps.

Manufactured by Medtronic.

Models: MMT - 511, 512, 712, 712E, 515, 715, 522, 722, 722K, 523, 723, 723K, 554 (VEO) and 754 (VEO).



Problem

Risk of compromised insulin therapy, which may lead to severe hypoglycaemia (low blood glucose) or severe hyperglycaemia (high blood glucose). The root causes are:

1. Loose drive support cap (all models)
2. Damage to pump if immersed in water (all models)
3. Programming issue related to the sensor graph timeout (Paradigm VEO MMT-554 and MMT-754 only).

Action by

- Diabetes departments
- Those involved in the supply and use of these devices.

Action

- Identify affected devices.
- Ensure that all staff and patients receive a copy of Medtronic's Field Safety Notice (FSN) dated 28 March 2013 and are aware of the recommendations. In particular:
  - > Discontinue pump use if drive support cap is loose and contact the manufacturer.
  - > Do not immerse the pump in water.
  - > Regularly examine the pump for damage, especially after a shock or drop.
  - > For Paradigm VEO models, check that the default setting for the sensor graph timeout is not 'NONE', if the 'Low Glucose Suspend' feature is used.

CAS deadlines

Action underway: 11 June 2013

Action complete: 02 July 2013

Note: These deadlines are for staff and users to be aware of the problem and the advice as recommended by the manufacturer in the FSN.

Contact

Medtronic Ltd
Lezlie Bridge

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Email: lezlie.j.bridge@medtronic.com

Problem

1. Loose drive support cap:
Medtronic has received a report of a serious injury related to a loose drive support cap. This may become detached from the pump case, due to impact damage. An attempt to press back the drive support cap may result in an unintended delivery of insulin.

2. Water damage:
This may result in a pump alarm or may cause the buttons to stop working.

3. Sensor graph timeout:
This issue only applies to Paradigm VEO (MMT-554 and MMT-754) pump users who are also using both Medtronic ‘Continuous Glucose Monitoring’ and the ‘Low Glucose Suspend’ feature.

Paradigm VEO is equipped with a ’Low Glucose Suspend’ feature, which will automatically suspend insulin delivery when glucose levels are too low, to help reduce the risk of severe hypoglycaemia. Basal insulin delivery may not resume in time if the pump user has the ‘Low Glucose Suspend’ feature enabled and has changed the sensor graph timeout setting to “NONE” from the default setting of two minutes. This could result in hyperglycaemia.

Distribution

This MDA has been sent to:

- Care Quality Commission (CQC) (headquarters) for information
- Clinical commissioning groups (CCGs)
- HSC trusts in Northern Ireland (chief executives)
- Local authorities in Scotland (equipment co-ordinators)
- NHS boards and trusts in Wales (chief executives)
- NHS boards in Scotland (equipment co-ordinators)
- NHS England area teams
- NHS England area teams (chief executives)
- NHS England regional teams
- NHS trusts in England (chief executives)

Onward distribution

Please bring this notice to the attention of relevant employees in your establishment.
Below is a suggested list of recipients.

Trusts

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- Clinical governance leads
- Community children’s nurses
- Community diabetes specialist nurses
- Community hospitals
- Diabetes clinics/outpatients
- Diabetes nurse specialists
- Diabetes, directors of
- Diabetologists
- EBME departments
- Equipment stores
- Hospital pharmacies
- Medical directors
- Medical libraries
- Nursing executive directors
- Paediatric nurse specialists
- Paediatricians
- Risk managers
- Supplies managers

NHS England local area teams

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

- Community pharmacists
- General practitioners

Independent distribution

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

This alert should be read by:

- Clinics
- 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 and requesting this facility.

Contacts

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England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2013/035** or **2013/003/027/291/018**

Technical aspects

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How to report adverse incidents

Please report via our website http://www.mhra.gov.uk

Further information about **CAS** can be found at https://www.cas.dh.gov.uk/Home.aspx

Northern Ireland

Alerts in Northern Ireland will continue to be distributed via the NI SABS system.

Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre
Health Estates Investment Group
Room 17
Annex 6
Castle Buildings
Stormont Estate
Dundonald BT4 3SQ

Tel: 02890 523 704
Fax: 02890 523 900

Email: NIAIC@dhsspsni.gov.uk

http://www.dhsspsni.gov.uk/index/hea/niaic.htm

How to report adverse incidents in Northern Ireland

Please report directly to NIAIC, further information can be found on our website http://www.dhsspsni.gov.uk/niaic

Further information about **SABS** can be found at http://sabs.dhsspsni.gov.uk/

Scotland

Enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre
Health Facilities Scotland
NHS National Services Scotland
Gyle Square
1 South Gyle Crescent
Edinburgh EH12 9EB

Tel: 0131 275 7575
Fax: 0131 314 0722

Email: nss.iric@nhs.net

http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-iric/

Wales

Enquiries in Wales should be addressed to:

Improving Patient Safety Team
Medical Directorate
Welsh Government
Cathays Park
Cardiff CF10 3NQ

Tel: 029 2082 3922

Email: Haz-Aic@wales.gsi.gov.uk

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