Medical Device Alert

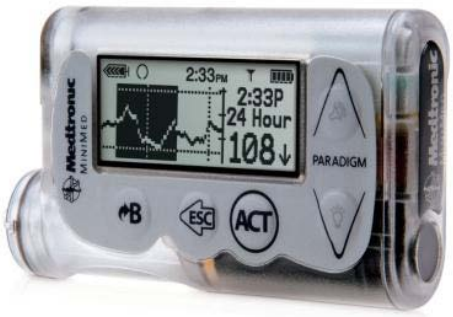
Ref: MDA/2014/019 Issued: 29 May 2014 at 15:00

Device

Paradigm ambulatory insulin infusion pumps.

Manufactured by Medtronic.

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



Problem

Risk of hypoglycaemia due to incorrect selection and delivery of bolus amount.

Medtronic has received reports of users accidentally programming the pump to deliver the maximum bolus amount.

Action by

- All those responsible for the use, service and maintenance of these devices.
- Diabetes departments.

Action

Identify affected pumps.

Ensure that all staff and patients receive the relevant copy of Medtronic's Field Safety Notice (FSN) dated March 2014 and follow the recommendations.
In particular:

1. When programming insulin doses through the 'Main Menu', be aware that scrolling down allows the dose displayed on the screen to go from 0.0 units to the maximum programmed insulin dose.
2. Always confirm that the insulin dose flashing on the display screen is correct before starting delivery.
3. Make sure the 'Max Bolus' and 'Max Basal' settings are programmed according to individual insulin needs as determined by the healthcare professional.

CAS deadlines

Action underway: 12 June 2014

Action complete: 26 June 2014

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

Contact

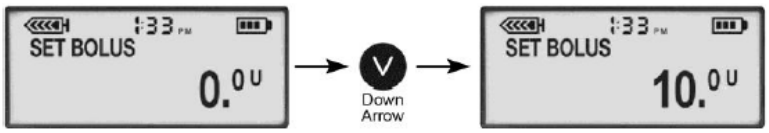
Manufacturer
Medtronic Limited
Lezlie Bridge
Tel: 01923 212 213
Email: lezlie.j.bridge@medtronic.com

Problem

Bolus Example through the Main Menu

A single press of the down arrow button will move the bolus from 0.0 units to the programmed Max Bolus (The default Max Bolus is 10.0 units).

Main Menu > Bolus Menu



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 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 diabetes specialist nurses
- Community hospitals
- Diabetes clinics/outpatients
- Diabetes nurse specialists
- Diabetes, directors of
- Diabetologists
- EBME departments
- Equipment stores
- Medical directors
- Medical libraries
- Nursing executive directors
- Outpatient clinics
- Paediatric diabetes nurse specialists
- Paediatric nurse specialists
- Paediatricians
- Pharmacists
- Risk managers
- Supplies managers

NHS England 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

Manufacturer
Lezlie Bridge
Regulatory Affairs Manager, UK & Ireland
Medtronic Limited
Building 9
Croxley Green Business Park
Watford
WD18 8WW

Tel: 01923 212 213
Fax: 01923 225 273

Email: lezlie.j.bridge@medtronic.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2014/019** or **2014/003/018/081/002.**

Technical aspects
Enitan Taiwo or Elke Kerwick
Medicines & Healthcare Products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 7122 / 6826
Fax: 020 8754 3965

Email: enitan.taiwo@mhra.gsi.gov.uk
elke.kerwick@mhra.gsi.gov.uk

Clinical aspects
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London SW1W 9SZ

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Fax: 020 8754 3965

Email: mark.grumbridge@mhra.gsi.gov.uk

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

All requests regarding return, replacement or modification of the devices mentioned in this alert should be directed to the relevant supplier or manufacturer.

Other enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre
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

Email: improvingpatientsafety@wales.gsi.gov.uk