Medical Device Alert

Ref: MDA/2013/078 Issued: 04 November 2013 at 11:30

Device

Infusion pumps.
Plum A+ and A+3 family of infusers, Gemstar infuser and Lifecare PCA infuser. Manufactured by Hospira.
All models and list numbers.

Problem

The CE marking for these pumps has been withdrawn.

Hospira will not be able to supply any new pumps. However, they can continue to supply consumables for pumps already in use.

There are a number of current Field Safety Notices detailing faults that may lead to over-infusion, low infusion rates or an interruption to therapy. The manufacturer's proposed corrective actions for the Plum pumps (which include design changes) will not be carried out in the UK at this time, as their safety and performance have not been subjected to independent assessment by a notified body.

Action by

All medical, nursing and technical staff involved in the use of these devices.

Action

Gemstar and Plum pumps

- Use an alternative pump, where available.
- If an alternative is not available:
  - assess the risks/benefits associated with the use of these pumps for each individual patient when administering therapies
  - ensure that staff are aware of all the issues highlighted in the manufacturer's Field Safety Notices, and MDA/2013/006 and MDA/2013/016
  - exercise caution in use
  - report any adverse incidents involving these devices to the MHRA.

Gemstar pump only

Hospira are offering the Sapphire pump, manufactured by Q Care, on a part exchange basis.
Contact Hospira to discuss options for your hospital.

CAS deadlines

Action underway: 18 November 2013

Action complete: 16 December 2013

Note: These deadlines are for systems to be in place to identify pumps and ensure users are aware of the problems.

Contact

Manufacturer
John McIlvaney
Hospira UK Limited
Tel: 0800 028 7304
Email: custserv@hospira.com

Problem

In March 2013 the MHRA issued Medical Device Alert MDA/2013/016 in relation to the Gemstar infusers. The relevant Field Safety Notices are:

- Pressure sensor calibration drift (dated 21 March 2013)
- Battery leakage may lead to shut down (dated 20 June 2013), an update to FSN 21 March 2013
- Lithium battery low voltage (dated 21 March 2013)
  Backward motor movement (dated 31 July 2013), an update to FSN 21 March 2013

In February 2013 we issued MDA/2013/006 in relation to the Plum A+ and A+3 family of infusers. The relevant Field Safety Notices are:

- Battery not fully charging (dated 19 February 2013)
- Volume control knob (dated 29 October 2012)
- Door roller assembly (dated 12 December 2012)
- Distal pressure sensor calibration (dated 14 February 2013)
- Fluid ingress (dated 25 January 2013)
- Fluid shield diaphragm (dated 24 January 2013)
- Distal pressure sensor pin fracture (dated 24 January 2013)
- Recycling / rebooting (dated 21 September 2013).
  Please note that although MDA/2011/110 and the related Field Safety Notices indicated that a software update would be provided, Hospira have now stated that, on review, the UK market is not affected by this issue.

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 for information
- 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:

- A&E departments
- Adult intensive care units
- All wards
- Biomedical engineering staff
- Biomedical science departments
- Clinical governance leads
- Day surgery units
- EBME departments
- Equipment libraries and stores
- In-house maintenance staff

- IV nurse specialists
- Maintenance staff
- Medical directors
- Nursing executive directors
- Oncology units
- Paediatric intensive care units
- Risk managers
- Supplies managers
- Theatres

Independent distribution

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

This alert should be read by:

- Care homes providing nursing care (adults)
- Clinics
- Hospices
- Hospitals in the independent sector
- Independent treatment centres

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
John McIlvaney
Customer Services Manager
Hospira UK
Queensway
Royal Leamington Spa
Tel: 0800 028 7304 Fax: 0800 028 7305 Email: custserv@hospira.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2013/078** or **2013/002/004/291/031**

Technical aspects
Sharon Knight or Catriona Blake
Medicines & Healthcare Products Regulatory Agency
Floor 4, 151 Buckingham Palace Road, London SW1W 9SZ

Tel: 020 3080 7202/7219 Fax: 020 8754 3965

Email: sharon.knight@mhra.gsi.gov.uk
catriona.blake@mhra.gsi.gov.uk

Clinical aspects
Mark Grumbridge
Medicines & Healthcare Products Regulatory Agency
Floor 4, 151 Buckingham Palace Road, London SW1W 9SZ

Tel: 020 3080 7128 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

Tel: 029 2082 3922 Email: Haz-Aic@wales.gsi.gov.uk