Medical Device Alert

Ref: MDA/2013/016 Issued: 26/03/2013 at 12:00

Device

Infusion pumps: GemStar infusion system.

Manufactured by Hospira.

All list numbers are affected.

Problem

The following pump faults may lead to over-infusion, low infusion rates or an interruption of infusion:

- occlusion detection problems, due to pressure sensor calibration drift;
- pump failure without warning, due to leaking batteries;
- voltage of lithium battery dropping below 2.4 volts, causing pump to cease functioning;
- an error with the pump's motor assembly potentially causing the motor to rotate backwards at flow rates of less than 2 ml/hr.

The MHRA continues to investigate this and other recent Field Safety Corrective Actions implemented by Hospira.

Action

Identify affected pumps

Do not use these pumps on neonates and infants aged 2 years and under.

Do not use flow rates of less than 2 ml/hour.

Consider using an alternative device, particularly if an over/under infusion, or an interruption to an infusion could compromise patient safety.

If an alternative is not available, follow the advice in the relevant manufacturer's Field Safety Notices

Action by

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

CAS deadlines

Action underway: 09 April 2013

Action complete: 26 April 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
Fax: 0800 028 7305

Email: custserv@hospira.com

Distribution

This MDA has been sent to:

- NHS trusts in England (Chief Executives)
- Care Quality Commission (CQC) (Headquarters) for information
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Equipment Co-ordinators)
- Local authorities in Scotland (Equipment Co-ordinators)
- NHS boards and trusts in Wales (Chief Executives)
- Health and Safety Executive
- Primary care 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 clinical departments
- All wards
- Biomedical engineering staff
- Biomedical science departments
- Clinical governance leads
- Day surgery units
- EBME departments
- Equipment 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

Primary care trusts

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

- Community hospitals
- Equipment libraries and stores
- Health visitors
- Hospital at home
- Palliative care teams

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/2013/016** or **2013/003/008/081/001**

Technical aspects
Roopa Prabhakar or Sharon Knight
Medicines & Healthcare products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ
Tel: 020 3080 7293/7202
Fax: 020 8754 3965
Email: roopa.rabhakar@mhra.gsi.gov.uk
sharon.knight@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

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