Medical Device Alert

Ref: MDA/2014/010 Issued: 13 March 2014 at 15:30

Device

Infusion pumps: GemStar infusion system.

Manufactured by Hospira.

List numbers: 13000, 13100, 13150.

Problem

Risk of delay to patient therapy due to loss of audio alarms.

The connection between the beeper subassembly and pump may fail so that only visual alarms will be available.

The pump will only identify the beeper failure during 'self-test' whilst powering up, which will prevent it from being programmed or used.

Pumps that were previously fixed for this beeper failure may fail again.

Action

Use an alternative pump, where available.

If an alternative is not available, assess the risks and benefits of using the pump for each patient.

Be aware of the MHRA's advice on GemStar infusers in MDA/2013/078.

Report any adverse incidents involving these pumps to the MHRA.

Action by:
All medical, nursing and technical staff involved in the use of these pumps.

CAS deadlines

Action underway: 20 March 2014

Action complete: 03 April 2014

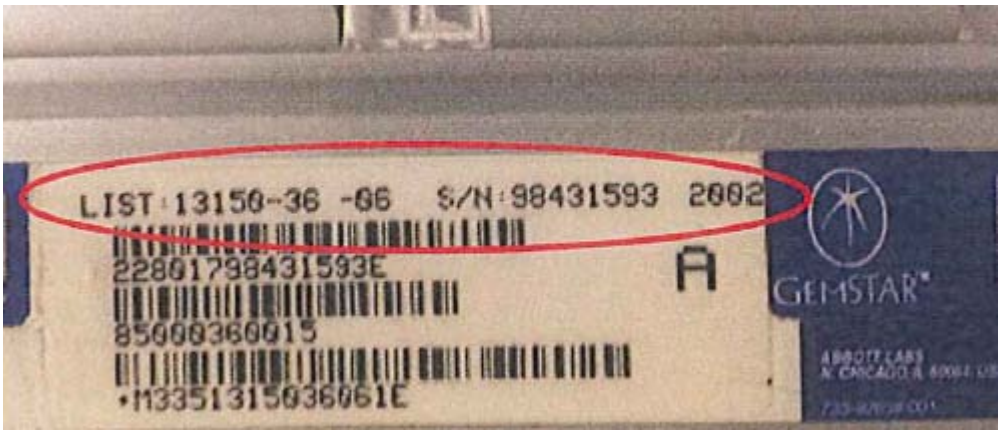
Note: These deadlines are for systems to be in place to identify pumps and ensure users are aware of the problems.

Contact

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

Device

The list numbers can be found on the rear of the device.



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
- Health and safety managers
- In-house maintenance staff
- IV nurse specialists
- Maintenance staff
- Medical directors
- Nursing executive directors
- Oncology units
- Paediatric intensive care units
- Pain control teams
- 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/2014/010** or **2014/001/016/081/019**

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

Tel: 020 3080 6898 / 7202
Fax: 020 8754 3965

Email: patrick.sweeney@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

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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

Tel: 029 2082 5801

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