

Medical Device Alert

Ref: MDA/2011/066 Issued: 08 June 2011 at 15:00

Device

All Plum A+ infusion pumps:

Pump	List number
Plum A+ Infusion Pump	11971
Plum A+ 3 Infusion Pump System v 10.3	12348
Plum A+ Infusion Pump v 11.3	12391
Plum A+ 3 Infusion Pump v 11.3	12618
Plum A+ 3 with Hospira MedNet Software	20678
Plum A+ Driver	20792



Manufactured by Hospira Inc.

Problem

Risk of delay or interruption to treatment.

The audible alarm on all listed Plum A+ infusion pumps may fail.

The visual alarm is not affected. However, if the user does not notice the visual alarm they may be unaware of an interruption to the infusion e.g. air-in-line or occlusion.

Action by

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

Action

- Identify affected pumps.
- Consider using an alternative device if an undetected interruption to an infusion could compromise patient safety.
- If an alternative is not available, perform the pre-use checks detailed in the manufacturer's [Field Safety Notice](#) (dated 2 March 2011). Be aware that the audible alarm may still fail in some pumps even after the checks have been completed.

CAS deadlines

Action underway: 15 June 2011

Action complete: 06 July 2011

Contact

Manufacturer
Robert Cookes
Hospira UK

Tel: 0800 028 7304

Fax: 0800 028 7305

Email: custserv@hospira.com

Problem

Improper mounting of components, poor soldering, and breakage of internal wiring connections may lead to failure of the audible alarm.

The manufacturer's [FSN](#) advises users to test the audible alarm before each use of the pump as an interim measure. However, these tests will not predict if the audible alarm will fail and will only indicate if it has already failed. It is possible for the audible alarm to fail in use, even after the test has been performed.

Hospira is modifying the design of the audible alarm to resolve this problem. Once this has been completed, Hospira will contact users to arrange for replacement.

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)
- Primary care trusts in England (Chief Executives)
- Social services in England (Directors)

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
- Clinical governance leads
- EBME departments
- Equipment stores
- Health and safety managers
- In-house maintenance staff
- IV nurse specialists
- Medical directors
- Nursing executive directors
- Operating departments
- Paediatric intensive care units
- Pain control teams
- Risk managers
- Supplies managers
- Theatres

Primary care trusts

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

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

Social services

Liaison officers for onward distribution to all relevant staff including:

- Care management team managers
- Equipment supplies managers
- In-house residential care homes
- Loan store managers

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

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

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Customer Services Manager
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Queensway
Royal Leamington Spa
CV31 3RW
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/2011/066** or **2011/003/014/291/003**

Technical aspects

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

Clinical aspects

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Email: jonathan.plumb@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.irc@nhs.net

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

Wales

Enquiries in Wales should be addressed to:

Dr Sara Hayes

Senior Medical Officer

Medical Device Alerts

Welsh Assembly Government

Cathays Park

Cardiff CF10 3NQ

Tel: 029 2082 3922

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

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