

# Medical Device Alert

Ref: MDA/2013/004 Issued: 06 February 2013 at 15:00

## Device

Infusion pumps: Plum A+ single channel infuser systems.

Manufactured by Hospira.

Product codes: 11005, 11971, 12391, 20792.



## Problem

Risk of interruption in therapy due to clinical staff failing to hear the alarm.

The operation of the alarm volume control is not consistent with the operator's manual. On some pumps, the knob is turned clockwise to increase the volume, on others, it is anticlockwise.

Hospira will be updating the user manual and providing labels for each device to identify the correct operating direction.

## Action by

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

## CAS deadlines

Action underway: 27 February 2013

Action complete: 20 March 2013

**Note: These deadlines are for systems to be in place to take actions and not for the completion of label placement.**

## Action

Ensure members of staff are aware that the alarm volume level control is not the same on all these pumps.

Ensure that relevant members of staff are familiar with the steps to check the alarm as described in the manufacturer's [Field Safety Notice](#) (dated 29 October 2012), in particular the need to confirm the volume level before beginning therapy.

Contact Hospira to arrange for volume direction labels to be fixed to all devices.

If you have more than one device being used in the same location and they do not have the same alarm volume control, you may contact Hospira for adjustment of the direction of the volume control to ensure consistency.

## Contact

**Manufacturer**  
John McIlvaney  
Hospira UK Limited  
Tel: 0800 028 7304  
Fax: 0800 028 7305  
Email: [custserv@hospira.com](mailto:custserv@hospira.com)

## Device

The following single channel infuser systems are affected by this alert:

- Plum A+ hyperbaric infusion system. Affected product code: 11005
- Plum A+ single channel infusion system. Affected product codes: 11971 + 12391
- Plum A+ infusion pump. Affected product code: 20792.

## 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)
- 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
- 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
- Hospital at home
- 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
- 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](mailto:safetyalerts@dh.gsi.gov.uk) and requesting this facility.

## Contacts

### Manufacturer

John McIlvaney  
Customer Services Manager  
Hospira UK  
Queensway  
Royal Leamington Spa  
CV31 3RW  
Tel: 0800 028 7304  
Fax: 0800 028 7305  
Email: [custserv@hospira.com](mailto:custserv@hospira.com)

## England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2013/004** or **2012/010/029/081/030**

### Technical aspects

Roopa Prabhakar or Catriona Blake  
Medicines & Healthcare products Regulatory Agency  
Floor 4, 151 Buckingham Palace Road, London SW1W 9SZ  
Tel: 020 3080 7293/7219  
Fax: 020 8754 3965  
Email: [roopa.prabhakar@mhra.gsi.gov.uk](mailto:roopa.prabhakar@mhra.gsi.gov.uk)  
[catriona.blake@mhra.gsi.gov.uk](mailto: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](mailto: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](mailto: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](mailto: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:

Improving Patient Safety Team  
Medical Directorate  
Welsh Government  
Cathays Park  
Cardiff CF10 3NQ

Tel: 029 2082 3922

Email: [Haz-Aic@wales.gsi.gov.uk](mailto:Haz-Aic@wales.gsi.gov.uk)

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