

Medical Device Alert

Action

Amendment: lot numbers on page 2

Ref: MDA/2011/012R **Reissued:** 10 February 2011 at 11:00

Device

GemStar pump sets manufactured by Hospira UK Ltd.

Specific part numbers and lot numbers distributed from November 2008 to June 2010 inclusive.

Problem	Action
Hospira has initiated a product recall due to the potential for under-delivery when these sets are used at flow rate settings of less than 10ml/hour.	Identify and do not use or supply any affected devices. Follow Hospira's instructions in the Field Safety Notice to arrange for the return and replacement of the suspect sets.
Action by	
All those who use or supply these sets.	
CAS deadlines	Contact
Action underway: 10 March 2011 Action complete: 12 April 2011	Manufacturer Mr Robert Cookes Customer Services Manager Hospira UK Ltd Tel: 0800 028 7304 Fax: 0800 028 7305 Email: custserv@hospira.com

Device

Gemstar pump set with yellow striped tubing-SL, non-vented used for epidural infusions.
 Part number 132616102 **Lot number 682075H**

Lot number Set description Part/reference number



Gemstar pump set-SL 1.2 micron filter, non-DEHP, non-vented used for feeding (TPN).
 Part number 132753628 **Lot number 761885H**

Set description Part/reference number Lot number



Note: there are two items referred to in the [Hospira notice](#) that the manufacturer tells us are not available in the UK. These are: the Gemstar set non-vented Prox Luer 1.2 micron (part number 132804328 lot number 761915H) and Gemstar PCA custom set (part number 196685301 lot number 761425H).

Distribution

This MDA has been sent to:

- NHS trusts in England (Chief Executives)
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Chief Executives)
- NHS boards and trusts in Wales (Chief Executives)
- 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:

- Accident and emergency departments
- All clinical departments
- All wards
- Ambulance services directors
- Ambulance staff
- Anaesthesia, directors of
- Chief pharmacists
- Clinical governance leads
- Hospital at home units
- Intensive care, directors of
- IV nurse specialists
- Medical directors
- Neonatal nurse specialists
- Nursing executive directors
- Outpatient clinics
- Outpatient theatre managers
- Palliative care teams
- Paramedics
- Pharmacists
- Radiographer superintendents
- Resuscitation officers and trainers
- Risk managers
- Supplies managers
- Theatre managers

Primary care trusts

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

- Community children's nurses
- Community hospitals
- Community midwives
- Community nurses
- District nurses
- Equipment libraries and stores
- Nutritional nurse specialists
- Palliative care teams
- Walk-in centres

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

This alert should be read by:

- Adult placement
- Care homes providing nursing care (adults)
- Hospices
- Hospitals in the independent sector
- Independent treatment centres
- Private medical practitioners

Contacts

Manufacturer

Mr Robert Cookes
Customer Services Manager

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/2011/012R** or **2010/012/020/291/014**

Technical aspects

Mr Jim Lefever or Mrs Mel King
Medicines & Healthcare products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 7262/7286

Fax: 020 8754 3965

Email: jim.lefever@mhra.gsi.gov.uk
mel.king@mhra.gsi.gov.uk

Clinical aspects

Mr Jonathan Plumb
Medicines & Healthcare products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 7128

Fax: 020 8754 3965

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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