13 March 2013

# URGENT FIELD SAFETY NOTICE
# GemStar™ Infusion System
# Damage from Battery Leakage May Cause the Device to Shut Off Without Warning

| | |
|---|---|
| **Product name:** | **GemStar™ Infusion System** |
| **List Number:** | **13000, 13100, 13150, 13086, 13087, 13088** |
| **EMEA FA ID:** | **Q.FA.EMEA.2013.011** |
| **Date:** | **07th March 2013** |

**Dear Healthcare Professional and Hospira Customer,**

Hospira Inc. is issuing this Field Safety Notice to remind you of the need, as outlined in the GemStar System Operating Manual (SOM), to routinely inspect the internal AA batteries in your GemStar pump for signs of leakage, corrosion, or damage. This letter details the potential risk and recommended actions to mitigate the potential for damage caused by this issue.

**Affected Units:** All GemStar Infusion Pumps

**Issue:** If the internal AA batteries used to power the device leak, their contents will cause damage to the device's internal components which may result in the device shutting off without issuing a warning or an audible or visual alarm. If the device shuts off it may result in a delay/interruption in therapy

Hospira has not received reports of serious injury or death caused by this issue.

**Risk to Health:** The severity in the delay/interruption in therapy is dependent upon the underlying condition of the patient and the treatment being prescribed**. A delay/interruption in therapy or under-infusion has a worst case potential to result in a significant injury or death.**

**Healthcare professionals are advised to weigh the risk/benefit to patients associated with the use of the device when administering critical therapies. Customers should consider the use of an alternative pump, particularly in patients in which a delay/interruption in therapy or an under-infusion could result in significant injury or death.**

**Required Action:** As directed by the Gemstar SOM, the internal AA batteries and battery compartment should be inspected for signs of leakage, corrosion or other damage prior to each use. In addition, each time the batteries are replaced the battery compartment should be inspected for damage.

If a device exhibits damage caused by leaking batteries, immediately remove it from clinical service and contact your local Hospira office, to arrange for return of your device for repair.

***Please complete the attached Reply Form indicating the number of impacted devices at your facility and return it* to the fax number or e-mail address on the form**, *even if you do not have the affected product.*

Hospira is committed to providing you with the highest level of service, product quality and reliability. We appreciate your understanding and we regret any inconvenience that may cause you.

Please forward this Field Safety Notice to all colleagues within your organisation who need to be aware of it or to any organisation where the potentially affected devices have been transferred.

**Please maintain awareness of this notice until Hospira notifies you of completion.**

Should you have any further questions please do not hesitate to contact your local Hospira office:

| Hospira contact | Contact details | Areas of support |
|---|---|---|
| **Hospira EMEA Product Safety** | T: +44 1926 834 400<br>Email to:<br>devicecomplaintsemea@hospira.com | To report adverse events or product complaints |
| **Hospira EMEA Quality** | T: +31 36 5274 720<br>F: +31 36 5274 701<br>Email to: *devicesfieldactions@hospira.com* | Additional information and technical assistance |
| **Local Contacts** | | |

The Competent Authorities in all countries affected by this action have been informed of this field safety notice.

Yours sincerely,

_____
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EMEA Devices Quality Manager

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# URGENT FIELD NOTICE REPLY FORM

## Damage from Battery Leakage May Cause the Device to Shut Off Without Warning

| | |
|---|---|
| **Product name:** | **GemStar™ Infusion System** |
| **List Number:** | **13000, 13100, 13150, 13086, 13087, 13088** |
| **Hospira ref:** | **Q.FA.EMEA.2013.011** |

### Section A

**Hospital / Facility Details**

Please fill out the information below and fax the completed form to Hospira at [local fax number].

| | |
|---|---|
| **Name of Hospital / Facility:** | |
| **Hospital / Facility Address:** | |
| **Telephone Number:** | |
| **Name:** | |
| **Signature:** | |
| **Date:** | |

### Section B

☐ I have read and understood the contents of this Field Action, circulated it to all staff/departments that use this product and confirm that our inventory has been checked and we have no inventory of the listed products.

**OR**

### Section C

☐ I have read and understood the contents of this Field Action, and circulated it to all staff/departments that use this product.

### Section D

☐ Please indicate the total number of Infusion Devices at your location.

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