13 March 2013

URGENT FIELD SAFETY NOTICE
GemStar™ Infusion System
Backward Motor Movement

Product name:	**GemStar™ Infusion System**
List Number:	**13000, 13100, 13150, 13086, 13087, 13088**
EMEA FA ID:	**Q.FA.EMEA.2013.009**
Date:	**07th March 2013**

Dear Healthcare Professional and Hospira Customer,

Hospira Inc. is issuing this Field Safety Notice to inform you of the potential for the motor assembly to rotate backwards in the GemStar Infusion Pump. This letter details the potential risk and recommended steps for users to take if they encounter this issue.

Affected Units: All GemStar Infusion Pumps

Issue: During infusions at flow rates of 1mL/hr or less, the motor assembly may rotate backwards (roll-back), capturing additional medication that will be delivered resulting in over-infusion.

Additionally, users may receive X09/001 backward motor movement alarms during the device's Power On Self Test (POST) or during an infusion. This alarm will invoke visual and audible warnings to the user and the infusion will not begin or stop, resulting in a possible delay or interruption in therapy.

Hospira has received a report of one death related to these issues.

Risk to Health: **Depending on the drug and the dosage delivered, over-infusion has the worst case potential to result in significant injury or death.**

The severity in the delay or interruption of 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/over-infusion could result in significant injury or death.

Required Action: If your GemStar device displays an X09/001 error, immediately remove it from clinical service and contact your local Hospira office to arrange for return of your device for repair.

Hospira Actions: Hospira will be adding a warning to the GemStar System Operating Manual (SOM) informing users of the potential for over-infusion at rates of 1mL/hr or less. In addition, Hospira will be implementing a redesigned clutch assembly into new manufacturing and service operations in late 2013.

***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 Email to: devicecomplaintsemea@hospira.com	To report adverse events or product complaints
Hospira EMEA Quality	T: +31 36 5274 720 F: +31 36 5274 701 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
Backward Motor Movement

Product name:	**GemStar™ Infusion System**
List Number:	**13000, 13100, 13150, 13086, 13087, 13088**
Hospira ref:	**Q.FA.EMEA.2013.009**

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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