13 March 2013

URGENT FIELD SAFETY NOTICE
GemStar™ Infusion System
Lithium Battery – Low Voltage

Product name:	**GemStar™ Infusion System**
List Number:	**13000, 13100, 13150, 13086, 13087, 13088**
EMEA FA ID:	**Q.FA.EMEA.2013.010**
Date:	**07th March 2013**

Dear Healthcare Professional and Hospira Customer,

Hospira Inc. is issuing this Field Safety Notice as we have identified a risk caused by the voltage of the lithium battery dropping below 2.4 volts. This letter details the potential risk and recommended steps for users to take if you encounter this issue.

Affected Units: All GemStar Infusion Pumps

Issue: A lithium battery, that is not user accessible, is used to power the memory that stores the current infusion settings and the event history logs when the pump is turned off. If this battery's voltage level drops below 2.4 volts, an 11/004 error will be displayed and the device will not be able to be used, resulting in a possible delay/interruption in therapy. Additionally, the infusion settings and event history logs will be erased.

Hospira has not received reports of serious injury 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: Lithium batteries that are older than five (5) years should be replaced. Contact your local Hospira office to determine if your battery needs to be replaced and, if necessary to arrange for the return of your device to perform battery replacement.

Hospira Actions: Modification will be made to the GemStar Technical Service Manual (TSM) to indicate that the useful life of the Lithium Battery is five (5) years.

***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,

_____
Wilson Kennedy
EMEA Devices Quality Manager

DRAFT

Hospira UK Limited
Queensway
Royal Leamington Spa
Warwickshire CV31 3RW
United Kingdom
Telephone +44 (0)1926 820 820
Facsimile +44 (0)1926 835 250
www.hospira.com
Registered in England No. 1923357

URGENT FIELD NOTICE REPLY FORM
Lithium Battery – Low Voltage

Product name:	**GemStar™ Infusion System**
List Number:	**13000, 13100, 13150, 13086, 13087, 13088**
Hospira ref:	**Q.FA.EMEA.2013.010**

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.

Hospira UK Limited
Queensway
Royal Leamington Spa
Warwickshire CV31 3RW
United Kingdom
Telephone +44 (0)1926 820 820
Facsimile +44 (0)1926 835 250
www.hospira.com
Registered in England No. 1923357

DRAFT