

20 Jun 2013

UPDATED - 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:

20 Jun 2013

Dear Healthcare Professional and Hospira Customer,

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

Affected Units: All GemStar Infusion Pumps

Issue:

UPDATED INFORMATION - Power can be lost when the pump loses contact with the batteries, or when components on the Middle Printed Wire Assembly (PWA) fail, or when the Middle PWA does not receive appropriate signals from elsewhere in the pump. Loss of contact can be due to a mechanical disconnect at either the positive or negative battery terminal. Inappropriate or missing input signals can be due to contamination, corrosion damage, electronic defects or keypad problems disrupting turn on/turn off signals.

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 will result in a delay or 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. Always replace both batteries at the same time with disposable alkaline type batteries. Batteries that have exceeded their expiration date should not be used in the pump, including when being used as the back-up power source along with the Power Adaptor, Docking Station, or the Battery Pack.

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

In the event that your facility's ability to administer proper care is severely impacted by this issue, Hospira will provide loaner devices

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.

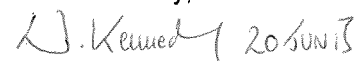
Please maintain awareness of this notice until Hospira notifies you of completion.

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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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.