13 March 2013

URGENT FIELD SAFETY NOTICE
GemStar™ Infusion System
Pressure Sensor Calibration Drift

Product name:	**GemStar™ Infusion System**
List Number:	**13000, 13100, 13150, 13086, 13087, 13088**
EMEA FA ID:	**Q.FA.EMEA.2013.012**
Date:	**07th March 2013**

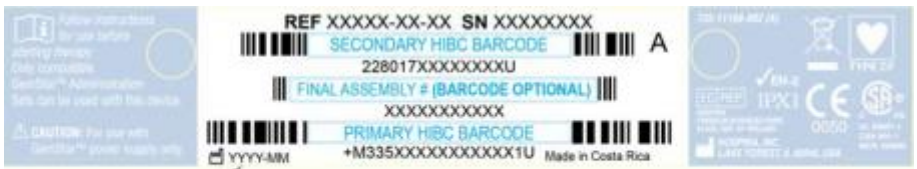
Dear Healthcare Professional and Hospira Customer,

Hospira, Inc. is issuing this Field Safety Notice to inform you of the potential for pressure sensor calibration drift 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 that were either manufactured, or had a pressure sensor replaced during servicing of the pump since January 1, 2009, could be affected.

The pump's date of manufacture can be found on the Product Identity label located on the back of the pump.



If you are unsure if the pressure sensor in your device has been replaced since January 1, 2009, please contact your local Hospira office to find out if your device is affected.

Issue:

The proximal and distal pressure sensor calibration can drift resulting in the pump failing the Proximal or Distal Occlusion Operational Test, as described in the GemStar Technical Service Manual (TSM), or reporting one of the following errors during device setup or infusion:

Cassette Check – D
Cassette Check – P
Proximal Occlusion
Distal Occlusion
Pressure Calibration Error
Bad Pressure Sensor Event
Bad Pressure Sensor State
Distal Pressure is Out of Range
Proximal Sensor is Out of Range

A pump with this issue may, instead of reporting an error, not detect occlusions or issue false occlusion alarms, which will stop the infusion and invoke visual and audible warnings to the user.

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

Potential Risk:

If these errors are observed, the infusion is stopped, resulting in delay/interruption in therapy.

A full or partial occlusion may prevent fluid from reaching the patient, resulting in delay/interruption of therapy and under-infusion.

An undetected distal occlusion may cause excessive pressure and fluid build-up within the distal line undetected by the pressure sensor**.** When the distal occlusion is resolved, the built up fluid will be administered into the patient possibly causing an over-infusion.

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.**

Depending on the drug and the dosage delivered, over-infusion has the worst-case potential to result in 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.

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Required Action: Hospira recommends immediately performing proximal and distal occlusion tests, as defined in the GemStar Technical Service Manual (TSM). If the device fails either of the tests remove it from clinical service. Contact your local Hospira to report the issue and arrange for the return of your device for recalibration.

Additionally, Hospira recommends that you add the performance of a proximal and distal occlusion test to your yearly GemStar maintenance schedule.

Hospira Actions: Hospira is modifying the GemStar TSM to add proximal and distal occlusion operational tests annually to confirm that devices do not require recalibration.

***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
Pressure Sensor Calibration Drift

Product name:	**GemStar™ Infusion System**
List Number:	**13000, 13100, 13150, 13086, 13087, 13088**
Hospira ref:	**Q.FA.EMEA.2013.012**

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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