URGENT DEVICE FIELD CORRECTION

AFFECTED DEVICES: GemStar™ Infusion System (Models 13000, 13100, 13150, 13086, 13087, 13088)
Pressure Sensor Calibration Drift

March 15, 2013

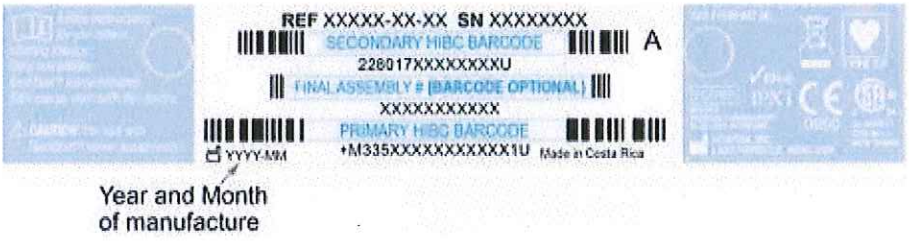
Dear Valued Hospira GemStar Customer:

Hospira, Inc. (Hospira) is issuing this letter to inform you of the potential pressure sensor calibration drift in the GemStar Infusion Pumps. 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, contact the Hospira Advanced Knowledge Center at 1-800-241-4002, option 4.

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.

Hospira, Inc.
275 North Field Drive
Lake Forest, IL 60045
(224) 212-2000
www.hospira.com

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.

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 a maximal over-infusion of < 1.0 mL.

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 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 over-infusion could result in significant injury or death.

Required Action: Hospira recommends immediately performing proximal and distal occlusion tests, as defined in the GemStar TSM. If the device fails either of the tests remove it from clinical service. Contact Hospira at 1-800-441-4100 (M-F 8am-5pm CST) to report the issue and arrange for the return of your device for recalibration.

Additionally, you must 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.

The US Food and Drug Administration (FDA) has been notified of this issue.

Please complete the attached reply form and return it to the fax number or e-mail address on the form, *even if you do not currently have the impacted devices.* Please contact Stericycle at 1-866-606-8264 (M-F, 8am - 5pm EST) to obtain additional copies of the reply form.

If you have further distributed these devices, please notify your accounts who may have received these infusers from you and ask them to contact Stericycle at 1-866-606-8264 (M-F, 8am- 5pm EST) to receive a reply form.

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For further inquiries, please contact Hospira using the information provided below.

Hospira Contact	Contact Information	Areas of Support
Hospira Global Complaint Management	1-800-441-4100 (8am-5pm CST, M-F) (ProductComplaintsPP@hospira.com)	To report adverse events or product complaints
Hospira Advanced Knowledge Center	1-800-241-4002, option 4 (Available 24 hours a day/7 days per week)	Additional information or technical assistance

Adverse events or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting Program either online, by regular mail or by fax.

- **Online**: www.fda.gov/medwatch/report.htm
- **Regular Mail**: use postage-paid, pre-addressed form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm. Mail to address on the pre-addressed form
- **Fax**: 1-800-FDA-0178

Hospira is committed to providing our customers with the highest level of service and product quality. We appreciate your cooperation and we regret any inconvenience this action may cause.

Sincerely,

Chris Eustace
Vice President, Quality Device Operations

Urgent Device Field Correction Reply Form - RESPONSE REQUIRED

GemStar™ Infusion System (Models 13000, 13100, 13150, 13086, 13087, 13088)
Pressure Sensor Calibration Drift

March 15, 2013

Fax the completed form to 1-888-714-5077 or email it to Hospira7906@stericycle.com.
If you have questions about this form please call Stericycle at 1-866-606-8264 (M-F, 8am - 5pm EST).

Customer Information

_____ _____
Business Name Hospira Customer # (if applicable)

_____
Address/City/State/Zip

_____
Contact Name/Phone/E-mail Address

_____
Completed by: Printed Name/Signature/Date

- I have received the letter and have notified users in my facility: YES__ NO__ (if NO state reason below)

  ____ Devices transferred/no longer owned** ____ Other (explain)
  ***If the devices have been transferred, indicate new owner contact information below:*

- Number of Infusers at facility: _____
- Have you distributed the product further to the retail level? YES___ NO___
  - If yes, have you notified your retail customers? YES___ NO___ (if NO, explain)

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