14 March 2013

CAUTION IN USE FIELD SAFETY NOTICE
ALL HOSPIRA GEMSTAR FAMILY OF INFUSERS

Product name:	**Gemstar Family of Infusers**
List Number:	**All**
EMEA FA ID:	**Q.FA.EMEA.2013.013**
Date:	**14 March 2013**

Dear Healthcare Professional and Hospira Customer,

During the past months Hospira completed a comprehensive review of the Gemstar infusion platform. This communication provides a summary of the six (6) FSNs related to the Gemstar infusion platform issued since October 2011 (See table below). This latest communication is being issued to assist users in the management of all issues identified and to ensure the safe and effective use of the infusion device.

Hospira has suspended shipping all new Gemstar pumps into the region for an initial period of ninety days (90) from 28th February 2013. This action was taken due to the number of current FSNs and the recent temporary suspension of our Infusion Pump CE Certification. **Please note that this does not restrict importation of the consumables and other infusion pump accessories that are necessary for the continued use, repair, and service of these devices for our customers.**

For pumps currently in use, the risk information and the actions that we are requesting you take in each of our recent Field Safety Notifications are very important. For your convenience, the table below contains a summary of each issue; the actions we are asking you to perform in the short term, and our plan to address each item. **This summary is not meant to replace the more detailed information contained in the Urgent Device Field Safety notifications you would have received at the time of each event and request that you review each issue below with the relevant Urgent Field Safety Notice.** Please be assured we have plans in place to close out all of the items globally by the second quarter of 2015 and will work closely with you to implement all necessary corrective actions.

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 of therapy could result in serious injury or death.

Although our comprehensive review is complete, Hospira is committed to continuous improvement and patient safety. We will continue to monitor our quality data and will address and resolve issues impacting our products that may arise in the future.

Device Field Safety Notification	Correction
Note: this summary is not meant to replace the more detailed information contained in the Device Field Safety Notifications. It is provided here for your convenience.	
Backward Motor Movement **Q.FA.EMEA.2013.009** • Motor assembly may rotate backwards resulting in X09/001 alarms	• If your device displays an X09/001 error, immediately remove the device from clinical service and contact Hospira. • Hospira will be adding a warning to the System Operating Manual informing users of the potential for over infusion at rates 1 ml/hr or less
Lithium Battery – Low Voltage **Q.FA.EMEA.2013.010** • A lithium battery is used to power the memory that stores the infusion settings and event history logs when the pump is turned off. • The voltage on this lithium battery may drop below 2.4 Volts resulting in an 11/004 error. If this error occurs, the device will not be able to be used and the infusion settings and event history logs will be erased.	• Lithium batteries that are older than three (3) years should be replaced. • Please contact Hospira to determine if your battery needs to be replaced and to arrange for the return of your device to perform battery replacement • Hospira will be updating the Technical Service Manual to indicate the useful life of the lithium battery is three (3) years.
Battery Leakage **Q.FA.EMEA.2013.011** • If the internal AA batteries used to power the device leak, the leakage may 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.	• The AA batteries and battery compartment should be inspected for signs of leakage, corrosion or damage prior to each use. • Each time the batteries are replaced the battery compartment should be inspected for damage. • 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.

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Pressure Sensor Calibration Drift **Q.FA.EMEA.2013.012** • The pressure sensor calibration may drift • Only pumps that were either manufactured or had a pressure sensor replaced during servicing of the pump since 1 January 2009 are affected.	• Immediately perform the proximal and distal occlusion tests, as defined in the Technical Service Manual and add these tests to your annual GemStar maintenance schedule. • If the device fails either of the tests, remove it from clinical service and contact Hospira to arrange for the return of your device for recalibration.
Docking Stations – Fluid Ingress **Q.FA.EMEA.2011.006** • Fluid ingress into the docking station may result in sparking, smoking, charring or electrical shock	• Design improvements have been implemented. Hospira began contacting customers in October, 2012 to arrange for replacement of their docking stations. Replacements are expected to be complete by the end of Q2 2013 • Until you receive the new docking station, please take care to avoid any fluid ingress into the docking station: o Do not hang fluid containers over the docking station o Do not spray fluid directly on the docking station o Clean the docking station using a damp cloth
Bolus Cords **Q.FA.EMEA.2012.004** • Bolus cords may become cracked or damaged which may result in an open or short circuit	• Design improvements are being developed to make the bolus cord less vulnerable to damage • Beginning in Q1 2014, Hospira will be contacting you to arrange for replacement of your bolus cords. • Until your bolus cords are replaced, please take care when removing the bolus cord from the base of the pump. Please do not twist or bend the cord or connector.

Please refer to the original Field Safety Notifications (FSNs), that were provided, for contact information related to reporting of adverse events or product complaints, and additional information or technical assistance.

***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 Caution in Use Notification to all colleagues within your organization who need to be aware of it or to any organization where the potentially affected devices have been transferred.

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

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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 Caution in Use Notification.

Yours sincerely,

W. Kennedy 14 MAR 13

Wilson Kennedy
EMEA Devices Quality Manager

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CAUTION IN USE FIELD NOTICE REPLY FORM
ALL HOSPIRA GEMSTAR FAMILY OF INFUSERS

Product name:	**GemStar Family of Infusers**
List Number:	**All**
Hospira ref:	**Q.FA.EMEA.2013.013**

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 Caution in Use Notification, 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 Caution in Use Notification, 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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