

24 October 2013

## URGENT FIELD SAFETY NOTICE Gemstar Docking Station

<b>Product name:</b>	<b>Gemstar Docking Station</b>
<b>List Number:</b>	<b>13075-XX-07 &amp; 13075-XX-09</b> <b>in use with Phase 3 GemStar Pumps (List Numbers 13000-XX, 13100-XX and 13150-XX) GemStar Phase 4 Pumps (List Numbers 13086-XX, 13087-XX and 13088-XX) and External Battery Pack (List Number 13073-XX)</b>
<b>EMEA FA ID:</b>	<b>Q.FA.EMEA.2013.034</b>
<b>Date:</b>	<b>24<sup>TH</sup> October 2013</b>

**Dear Healthcare Professional and Hospira Customer,**

Hospira is voluntarily notifying you about two situations that may occur when using the GemStar Docking Station, List Numbers 13075-XX-07 and 13075-XX-09, in conjunction with the GemStar infusion pump. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

**Issue:** When the Docking Station is used in conjunction with a GemStar Phase 3 Infusion pump (List numbers 13000-XX, 13100-XX, or 13150-XX) the potential exists for the pump to fail to power up while connected to the Docking Station.

The second situation arises when a GemStar Phase 4 Infusion pump (List numbers 13086-XX, 13087-XX, or 13088-XX) is used in conjunction with both a Docking Station and an External Battery Pack accessory (List 13073-XX). With this configuration, there exists a possibility that the GemStar pump will display error code 11/003 indicating excessive input voltage from the external sources. The 11/003 error code will stop infusion if the error occurs when an infusion is in process.

**Risk to Health:** If a Gemstar Infusion Pump fails to power up or the 11/003 error code stops an infusion, a delay of therapy may occur which can result in patient injuries that are reversible with medical intervention. It is possible a patient receiving life-sustaining therapy may need medical intervention while a power cycle of the GemStar Infusion Pump occurs or a replacement device is obtained.

**Affected Product Details:**

The products impacted by this issue are identified in the table below:

<b>Impacted/ Affected Product</b>	<b>Issue:</b>	<b>Potential to Occur in Conjunction with Products (Description)</b>	<b>Potential to Occur in Conjunction with List Numbers</b>
<b>13075-XX-07 13075-XX-09</b>	Fail to Power Up	Gemstar Phase 3 Pumps	13000-XX, 13100-XX, 13150-XX
	Error Code 11/003	Gemstar Phase 4 Pumps	13086-XX, 13087-XX, 13088-XX
		External Battery Pack	13073-XX

**Actions to be taken:**

There is no need to return your Gemstar Docking Station at this time and Hospira recommends that users take the actions identified below:

1. Inform potential users in your organization of this notification.
2. If a failure to power up should occur, it can be resolved by removing the pump from the Docking Station and then powering on the GemStar Infusion pump, using two fresh internal AA batteries as specified, before placing it back into the Docking Station.
3. To mitigate the potential for an 11/003 Error Code, remove the battery pack prior to installing the pump into the docking station.
4. Should your facility experience a failure to power up or an 11/003 Error code, report the issue to your local Hospira office.
5. Complete the attached reply form and return it to the fax number or e-mail address on the form, even if you do not have the affected product.
6. If you have distributed the product further to the retail level, notify your accounts that received the product identified above of this notification and ask them to contact your local Hospira office to receive a reply form.

**Product Correction:**

There is no further correction at this time.



**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 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 organization who need to be aware of it or to any organization or persons where the potentially affected devices have been transferred.

**Please maintain awareness of this notice.**

Should you have any further questions please do not hesitate to contact your local Hospira office:

Hospira contact	Contact details	Areas of support
<b>Hospira EMEA Product Safety</b>	T: +44 1926 834 400 Email to: <a href="mailto:devicecomplaintsemea@hospira.com">devicecomplaintsemea@hospira.com</a>	To report adverse events or product complaints
<b>Hospira EMEA Quality</b>	T: +31 36 5274 720 F: +31 36 5274 701 Email to: <a href="mailto:devicesfieldactions@hospira.com">devicesfieldactions@hospira.com</a>	Additional information and technical assistance
<b>Local Contacts</b>		

The Competent Authorities in all countries affected by this action have been informed of this field safety notice.

Yours sincerely,

 24 OCT 13

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## URGENT FIELD NOTICE REPLY FORM Gemstar Docking Station

Product name:	Gemstar Docking Station
List Number:	13075-XX-07 & 13075-XX-09 in use with Phase 3 GemStar Pumps (List Numbers 13000-XX, 13100-XX and 13150-XX) GemStar Phase 4 Pumps (List Numbers 13086-XX, 13087-XX and 13088-XX) and External Battery Pack (List Number 13073-XX)
Hospira ref:	Q.FA.EMEA.2013.034

### 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, and circulated it to all staff/departments that use this product.