25 February 2014

UPDATED - URGENT FIELD SAFETY NOTICE

Gemstar™ Infusion system (Versions prior to and including Phase 3)

Product name:	GemStar 7 Therapy Pump – Versions prior to and including Phase 3 GemStar 6 Therapy Pump – Versions prior to and including Phase 3 GemStar Pain Management Pump – Versions prior to and including Phase 3
List Number:	13000, 13100, 13150
EMEA FA ID:	Q.FA.EMEA.2013.038
Date:	25th February 2014

Dear Healthcare Professional and Hospira Customer,

Hospira, Inc. (Hospira) is issuing this field safety notice to inform you about a situation that may occur during start up on GemStar (Versions prior to and including Phase 3) infusion pumps. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.** This is an **update** to the FSN that was issued in January 2014 which listed the incorrect service error code associated with this issue. Please disregard the January 2014 FSN. As outlined in this updated FSN, the correct service error code which will display on the device as a result of this Beeper Error will be 10/001/000.

Issue: In GemStar (Versions prior to and including Phase 3) infusion pumps, list numbers 13000, 13100, and 13150, the connection between the beeper subassembly and the pump may fail. The GemStar infusion pump will identify this failure only during the "self-test" while powering up which will result in a Beeper Error. This Beeper Error will display on the device with a service error "code 10/001/000". This Beeper Error (service code 10/001/000) is a service alarm that places the pump in an inoperable mode and requires service before it can be returned to service. All previous versions prior to Phase 3 carry the list numbers detailed within this FSN.

Risk to Health: If a GemStar fails the "self-test" upon power up, a delay of therapy may occur. The likelihood of harm will depend on the patient's circumstances, such as the severity of their illness, the healthcare setting and the criticality of the infusion. When the GemStar is used in the home healthcare setting, there is no healthcare provider present, but it is extremely rare that a critical medication would be given in that setting. GemStar may also be used in the inpatient setting, where it is possible that a more critical infusion might be administered with this infusion pump; however, the healthcare professional to patient ratio is much higher for inpatients. The visual alarms on the pump make it likely that the delay in therapy will be noticed and of brief duration.

Affected Product Details:

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

Product Description	List Number
GemStar 7 Therapy Pump	13000
GemStar 6 Therapy Pump	13100
GemStar Pain Management Pump	13150

Actions to be taken:

There is no need to return your Gemstar devices at this time. Hospira recommends that users take the following actions:

1. Inform potential users in your organisation of this notification. Please also forward this notification to any organisation or persons (including home users) where the potentially affected devices have been transferred.
2. If a Beeper Error occurs during power up, remove the device from service immediately.
3. 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.
4. 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 product correction at this time. As part of establishing a streamlined and modernised device portfolio that addresses customer needs, Hospira is in the process of retiring the GemStar family of infusion devices as communicated in the details of the global device strategy announced 1st May 2013. As of 31st July 2015, Hospira will consider the products within the GemStar Infusion System family retired and will no longer support them.

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

Please maintain awareness of this notice.

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www.hospira.com
Registered in England No. 1923357

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,

W Kennedy 25 Feb 14

Wilson Kennedy
EMEA Devices Quality Manager

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UPDATED - URGENT FIELD NOTICE REPLY FORM

GemStar™ Infusion System (Versions prior to and including Phase 3)

Product name:	GemStar 7 Therapy Pump GemStar 6 Therapy Pump GemStar Pain Management Pump
List Number:	13000, 13100, 13150
Hospira ref:	Q.FA.EMEA.2013.038

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.

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