Hospira

04 October 2013

URGENT UPDATED FIELD SAFETY NOTICE
GemStar™ Infusion System
Keypad Lock Codes

Product Name:	**GemStar™ Infusion System**
List Numbers:	**13000, 13100, 13150, 13086, 13087, 13088**
HMSA/EMEA ID:	**Q.FA.EMEA.2013.025**
Date:	**04th October 2013**

Dear Healthcare Professional and Hospira Customer,

Hospira Inc. has become aware of improper usage of the GemStar Infusion System in the clinical setting. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Issue: Through customer reports, Hospira has become aware that some healthcare professionals may not have appropriately secured their GemStar infusion pumps via the keypad lock code. Reports indicate that patients have been able to locate the default keypad lock code for GemStar infusion pumps through internet searches in order to tamper with the programmed infusion parameters. One of the reports resulted in a serious injury.

Risk to Health: When GemStar is used as a PCA pump, the lockout code allows the healthcare professional to prevent the patient from altering the dosage of drug being administered or the time over which it is given, which, in turn, prevents abuse of the narcotic. If a patient accesses the lockout code and alters the drug delivery, they could receive an overdose which could potentially result in death.

Affected Units: All GemStar Infusion Pumps.

Instructions: Hospira recommends that users take the following actions:

1. Follow the Clinical Instructions that are included with each System Operating Manual regarding locking and unlocking the GemStar infusion pump.
2. Remove the set of Clinical Instructions from the manual as directed to prevent unauthorized access to the features discussed in that section.

List Number	Chapter
13000	Ch. 11
13100	Ch. 11
13150	Ch. 5
13086	Ch. 11
13087	Ch. 11
13088	Ch. 11

3. Store the Clinical Instructions in a secure location.

Product Correction:

Hospira will update the System Operating manual informing healthcare professionals that the default code should be changed upon receipt of the device and prior to delivery to patients. There is no product change or correction planned. It is recommended that each GemStar infusion pump in your facility is secured using the Clinical Locking Sequence described in the GemStar Infusion System Operating Manual.

Additionally, Hospira has contacted known Internet Website Sponsors, which were discovered as a result of this issue, and requested the removal of the GemStar System Operating Manual from their sites.

***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 or persons 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	Area 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,

04 OCT 2013

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URGENT UPDATED FIELD NOTICE REPLY FORM

Keypad Lock Codes

Product names:	**GemStar™ Infusion System**
List Numbers:	**13000, 13100, 13150, 13086, 13087, 13088**
Reference:	**Q.FA.EMEA.2013.025**

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.

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