



رقم المحفوظات: ١٣/١٢/٢٠١٢
رقم الصادر: ١٣/١٢/٢٠١٢
بيروت، في: ١٢ حزيران ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي

Infusion systems – electrically powered infusion pump

الجهاز المعنى بالمتابعة:

- Infusion systems – electrically powered infusion pump
- Trade Mark: Hospira Inc
- Local Representative:

بناء على التقارير الصادرة عن الوكالة البريطانية

Medicine and Health Care Products Regulatory Agency (UK) MHRA

والتوصية الصادرة عن الشركة المصنعة والتي تشير الى وجود خلل في عمل الصنف الوارد أعلاه مما قد يؤثر على سلامة المريض، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطا:

- التوصية الصادرة عن الشركة المصنعة

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

مدير عام الصحة
د. وليد عمار



28 February 2013

URGENT FIELD SAFETY NOTICE LifeCare PCA™ Infusion System Worn Half Nut

Product name:	LifeCare PCA™ Infusion System
List Number:	0F782
EMEA PA ID:	Q.FA.EMEA.2013.007
Date:	28 th February 2013

Dear Healthcare Professional and Hospira Customer,

Hospira, Inc. is issuing this field safety notice as we have received reports of PCA pumps not detecting distal occlusions, one of which resulted in a serious injury. This issue is caused by normal wear and tear on the Half Nut which prevents it from properly detecting the pressure build-up associated with a distal occlusion.

Undetected distal occlusions could result in delay or interruption of therapy. **A delay or interruption in therapy has a worst case potential to result in a serious injury (i.e., a significant increase in pain) that requires medical intervention (e.g., administering additional or other medications to relieve the patient's pain).**

Hospira recommends that facilities immediately inspect their PCA devices to determine if the half-nut is worn and unable to effectively detect a distal occlusion by performing the following steps:

- Perform the Performance Verification Test (PVT) Occlusion Test as defined in your device's Technical Service Manual (TSM).
- If the device does not pass this test, you may have a device with a worn half nut; remove it from clinical service and contact your local Hospira office at to report the issue.
- Perform the appropriate troubleshooting and repair activities defined by your facility, which may include returning the device to Hospira for further diagnosis and servicing.

This issue is caused by normal wear and tear and is not the result of a defect within the device, thus no corrective actions will be required to address this issue. Hospira is in the process of establishing a useful life for the half-nut, which will determine when it will require replacement. Additionally a requirement for an annual PVT Occlusion Test, which will verify the proper operation of the half-nut, is being developed. Both of these changes will be integrated into the System Operating Manual (SOM) in late 2013.

There is no need to return your PCA pump at this time; however If you suspect that your device may be impacted by this issue contact your local Hospira office to report the issue.



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

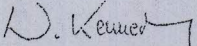
Please maintain awareness of this notice until Hospira notifies you of completion.

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,

 28 Feb 13
Wilson Kennedy
EMEA Devices Quality Manager

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URGENT FIELD NOTICE REPLY FORM Worn Half Nut

Product name:	LifeCare PCA™ Infusion System
List Number:	0F782
Hospira ref:	Q.FA.EMEA.2013.007

Section A

Hospital / Facility Details

Please fill out the information below and fax the completed form to Hospira at

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.

Section D

Please indicate the total number of Infusion Devices at your location.

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