21 September 2012

URGENT FIELD SAFETY NOTICE
ALL HOSPIRA PLUM™ A+ FAMILY OF INFUSERS
CONTINUOUS REBOOT - UPDATE

Product name:	**Plum A+ Family of Infusers**
List Number:	**11005, 11006, 11971, 11973, 12348, 12391, 12618, 20677, 20678, 20679, 20791, 20792**
EMEA FA ID:	**EMEA.2011.010**
Date:	**21 September 2012**

Dear Healthcare Professional and Hospira Customer,

This letter is to provide you with an update on the status of the correction plan for the Plum A+ Reboot/Recycle Urgent Device Field Safety Notice issued by Hospira in October 2011.

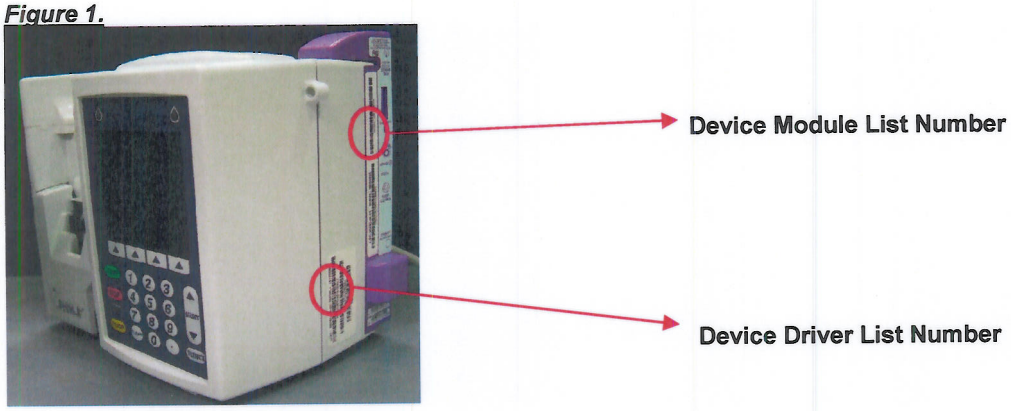
The Field Safety Notice, provided information about a potential software upgrade to correct the continuous reboot/recycling at start-up events and a commitment to contact you when the upgrade was available. Our investigation has determined that there are devices that require the software upgrade and devices that do not.

Devices – Requiring Software Upgrades

a) The Plum A+ single channel pump comprises a device driver and device module. Device modules with **v13.0, v13.1, v13.2, v13.3, v13.40, and v13.5 software** will require the software upgrade.

b) The location of the Device Drive list number and Device Module list number is shown in ***Figure 1. Single channel Plum A+ Pump - Location of Device Module and Device Driver List Numbers.***

Figure 1.



Hospira

Devices – Requiring Software Upgrades:

If you have the following Device Module list numbers, regardless of Device Driver list number, you will be receiving a software upgrade:

Device Module List Number	Requires Software Upgrade	EMEA Impacted
20679	Yes	X
20677	Yes	X
20791 + 20792	Yes	✓ Saudi Arabia Only
11006	Yes	X

If you have the following Plum A+3 triple channel pump list numbers, you will be receiving the software upgrade:

Plum A+3 Device Driver & Module List Number	Requires Software Upgrade	EMEA Impacted
20678	Yes	✓ Saudi Arabia Only

Hospira has a target date for devices requiring a software upgrade, this date is the end of Quarter 1 2013.

Devices – Software Upgrades at a later date:

Hospira continues to monitor the performance of the devices with lower susceptibility (12348, 12618, 11005, 11971, 11973 and 12391). These devices will be remediated at a future date and we will provide a further update on the progress of our remediation activities, by the end of Quarter 1 2013.

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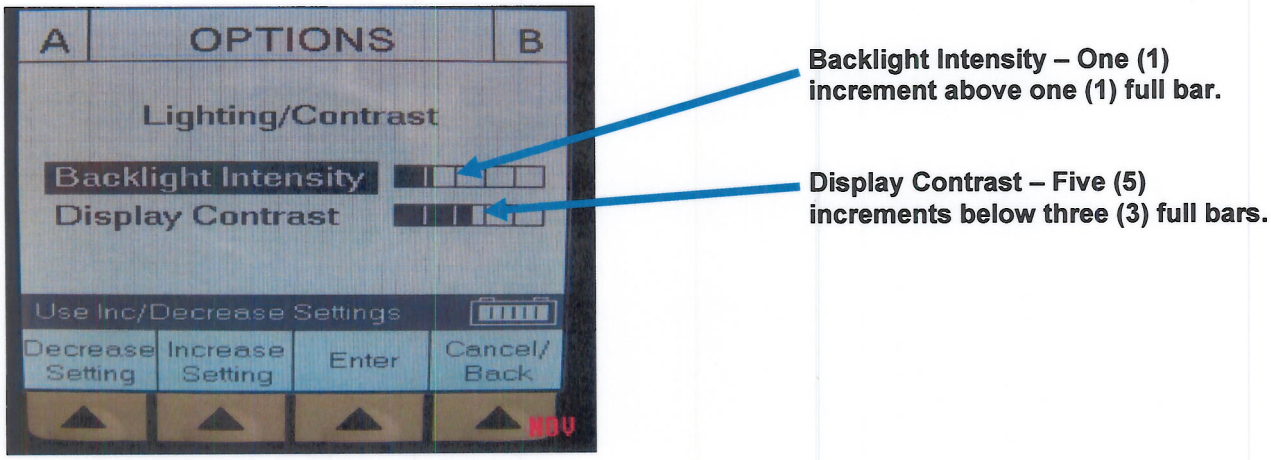
Registered in England No. 1923357

Please continue to keep the display settings at the default condition, as described in the October 2011 letter and re-iterated again below, until the upgraded software is installed at your site.

To prevent an occurrence of continuous recycling/rebooting during start-up, adjust the backlight intensity and contrast settings as described below:

1. Go to the Lighting/Contrast Screen under "Options"
2. Backlight Intensity: Set to one (1) increment past one (1) full bar from the left as shown in the picture below.
3. Display Contrast: Set to five (5) increments below three (3) full bars as shown in the picture below.
4. Press enter to save the settings. Correct LCD settings below:



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

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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,

Wilson Kennedy
EMEA Devices Quality Manager

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URGENT FIELD NOTICE REPLY FORM

Product name:	**Plum A+ Family of Infusers**
List Number:	**11005, 11006, 11971, 11973, 12348, 12391, 12618, 20677, 20678, 20679, 20791, 20792**
Lot Number/s:	

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:	**21 September 2012**

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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