05 March 2013

CAUTION IN USE FIELD SAFETY NOTICE
ALL HOSPIRA PLUM A+/A+ 3 FAMILY OF INFUSERS

Product name:	**Plum A+/A+ 3 Family of Infusers**
List Number:	**All**
EMEA FA ID:	**Q.FA.EMEA.2013.008**
Date:	**05 March 2013**

Dear Healthcare Professional and Hospira Customer,

During the past months Hospira completed a comprehensive review of the Plum A+/A+3 infusion platform. This communication provides a summary of the ten (10) FSNs related to the Plum A+/A+3 infusion platform issued since October 2011 (See table below). This latest communication is being issued to assist users in the management of all issues identified and to ensure the safe and effective use of the infusion device.

Hospira has suspended shipping all new Plum A+ pumps into the region for an initial period of ninety days (90) from 28th February 2013. This action was taken due to the number of current FSNs and the recent temporary suspension of our Infusion Pump CE Certification. **Please note that this does not restrict importation of the consumables and other infusion pump accessories that are necessary for the continued use, repair, and service of these devices for our customers.**

For pumps currently in use, the risk information and the actions that we are requesting you take in each of our recent Field Safety Notifications are very important. For your convenience, the table below contains a summary of each issue; the actions we are asking you to perform in the short term, and our plan to address each item. **This summary is not meant to replace the more detailed information contained in the Urgent Device Field Safety notifications you would have received at the time of each event and request that you review each issue below with the relevant Urgent Field Safety Notice.** Please be assured we have plans in place to close out all of the items globally by the middle of 2015 and will work closely with you to implement all necessary corrective actions. Our goal is to correct your devices in one service call to minimize potential disruptions to patient care.

Healthcare professionals are advised to weigh the risk/benefit to patients associated with the use of the device when administering critical therapies. Customers should consider the use of an alternative pump, particularly in patients in which a delay/interruption of therapy could result in serious injury or death.

Although our comprehensive review is complete, Hospira is committed to continuous improvement and patient safety. We will continue to monitor our quality data and will address and resolve issues impacting our products that may arise in the future. This ongoing process demonstrates Hospira's commitment to the Plum infusion pump platform.

Device Field Safety Notification	Correction
Note: this summary is not meant to replace the more detailed information contained in the Device Field Safety Notifications. It is provided here for your convenience.	
Battery Not Fully Recharging (Hospira Ref: EMEA.2013.005) • E321 error code may occur when the infuser is operating on AC power and the software detects that the battery could not be fully recharged within eight (8) hours.	Beginning in Late Q3 2013, Hospira will be proving you with a new battery with improved performance. The new battery is expected to reduce but not completely eliminate instances of E321 and "Warning: Replace Battery" errors. Until you receive the new batteries, if an E321 error code occurs, follow the discharge/charge cycle instructions in the Field Safety Notification letter.
Distal Occlusion pressure sensor calibration drift (Hospira Ref: EMEA.2013.003) • If the distal pressure sensor calibration drift occurs, the pump may not sense the buildup of pressure and will not alarm when occlusion thresholds are exceeded	The corrective action for this issue is to recalibrate the pressure sensor, which has been part of the Piezo remediation activities ongoing since October 2011 and are expected to complete in March 2013.
Fluid Shield - Fluid Ingress (Hospira Ref: EMEA.2013.002) • Potential for the fluid shield to inadequately prevent fluid from entering into the device.	Hospira is inspecting, cleaning, and if necessary, replacing fluid shields as part of the current Piezo remediation activities. Once your devices received the piezo remediation, no further corrective action is required. The piezo remediation activities have been ongoing since October 2011 and are expected to be completed in March 2013. Please clean the device in accordance with the instructions in the System Operations Manual taking caution to not allow cleaning solutions to saturate the air-in-line detectors or enter the device when cleaning the air-inline detectors and not spraying cleaning solutions towards any opening in the instrument that cannot be cleared.
Fluid Shield – Diaphragm (Hospira Ref: EMEA.2013.001) • Diaphragm may be out of specification which may result in the device not recognizing the cassette.	Devices shipped or serviced after September 25, 2012 have diaphragms that are in specification and are not affected by this issue. In Q3 2013, Hospira will begin the process to identify and if necessary replace fluid shields in the field that have diaphragms that are out of specification.

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Broken Distal Occlusion pressure sensor pin (Hospira Ref: EMEA.2013.004) • The potential exists for the distal (occlusion) pressure sensor pin to break.	Hospira is asking you to immediately visually inspect devices to determine if the distal pressure pin is broken or damaged. In order to prevent the occurrence of this issue, it is important to insert a cassette into the pump in accordance with the instructions in the System Operating Manual. Please continue to visually inspect the distal pressure pin as part of your routine servicing of the device.
Door Roller Assembly (Hospira Ref: EMEA.2012.015) • The door roller assembly has the potential to break.	Hospira has redesigned the door roller assembly to improve its strength and reduce the potential for it to break. Devices shipped or serviced after July 1, 2012 have the redesigned assembly and require no further action. For devices that do not have the new assembly, beginning in Q3 2013 Hospira will be contacting you to arrange for replacement of the doors on your devices. Until the doors have been replaced, inspect the door roller assembly for signs of damage prior to use on each new patient, and as part of the routine cleaning process for the infuser.
Volume Knob (Hospira Ref: EMEA.2012.014) • The volume control knob on some single channel devices may not function as described in the System Operating Manual • Triple channel devices are not affected	Beginning in Q3 2013, Hospira will be contacting you to arrange for the application of labels to your devices to indicate the direction of rotation for increased alarm volume. Until you have received the new labels, before beginning therapy confirm that the audible alarm volume is acceptable for the environment where the device will be used.
Recycling/Reboot (Hospira Ref: EMEA.2011.010) • Continuous recycling and/or rebooting of Plum A+ devices when the "Backlight Intensity" and/or "Display Contrast" setting for the LCD display have been adjusted from the original default setting.	Hospira is in the process of upgrading software on all devices to correct the software timing issue. The EU region is not impacted by remediation activities at this time. This is considered as a substantial change within the EU and is currently under review with NSAI. This has been with NSAI since January 2013. Prior to the software upgrade adjust the backlight and contrast setting as described in the Field Safety Notice (FSN).
Regulator Closer (Hospira Ref: EMEA.2011.011) • Incorrect seating of the regulator closer (flow regulator actuator).	Hospira implemented corrective/preventative manufacturing process improvements to ensure the regulator is properly seated. Further, Hospira is inspecting all regulator closers during the Piezo remediation which is expected to be completed March 2013. At all times, close all slide or CAIR™ (roller) clamps prior to opening the cassette door.
No Audible Alarm – Piezo (Hospira Ref: EMEA.2011.002) • The audible alarm has failed.	Hospira is currently replacing all piezo buzzers with ones made with an improved manufacturing process. The piezo remediation activities have been ongoing since October 2011 and are expected to complete in March 2013. Until the piezos have been replaced, perform an audible alarm test prior to use on each new patient as part of the routine cleaning process for the infuser.

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Please refer to the original Field Safety Notifications (FSNs), that were provided, for contact information related to reporting of adverse events or product complaints, and additional information or technical assistance.

***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 Caution in Use Notification 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 Caution in Use Notification.

Yours sincerely,

W.Kennedy 05 MAR 13

Wilson Kennedy
EMEA Devices Quality Manager

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CAUTION IN USE FIELD NOTICE REPLY FORM
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Product name:	**Plum A+/A+3 Family of Infusers**
List Number:	**All**
Hospira ref:	**Q.FA.EMEA.2013.008**

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 Caution in Use Notification, 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 Caution in Use Notification, 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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