30 January 2013

URGENT FIELD SAFETY NOTICE
ALL HOSPIRA PLUM™ A+ FAMILY OF INFUSERS
Fluid Shield – Fluid Ingress

Product name:	**Plum A+ Family of Infusers**
List Number:	**11005 - Plum A+ Hyperbaric Infusion System** **11971 + 12391 - Plum A+ single channel infusion system** **12348 + 12618 - Plum A+3 infusion pump system** **20678 - Plum A+3 Infusion Pump with Hospira MedNet™ Software** **20792 – Plum A+ infusion pump with Hospira MedNet™ software**
EMEA FA ID:	**Q.FA.EMEA.2013.002**
Date:	**21 January 2013**

Dear Healthcare Professional and Hospira Customer,

Hospira, Inc. is issuing this Field Safety Notice to inform you about the potential for fluid ingress into the Plum A+ mechanism assembly. This issue may result in the device being unable to recognize installed tubing or installed cassettes, or cause Valve Cassette Test Failures.

Hospira has identified multiple root causes for this issue, including spillage/contamination on the pressure sensing system from IV and cleaning fluids, design robustness of the fluid shield and fluid contamination/build-up leading to misalignment of the pressure sensor pins with the cassette diaphragm. These failures may occur during setup, infusion, or Performance Verification Testing (PVT) and will cause the device set up to be interrupted or infusion to stop.

If these failures are encountered during setup or infusion, audible and visual alarms are provided to the clinician, and could result in a delay/interruption in therapy. The severity in the delay or interruption in therapy is dependent upon the underlying condition of the patient and the treatment being prescribed. **A delay or interruption in therapy has a worst case potential to result in significant injury or death.**

To correct this issue Hospira is inspecting, cleaning, and, if necessary, replacing fluid shields as part of the current Piezo remediation activities. These activities have been ongoing since October 2011 and are expected to be completed in March 2013. In addition, Hospira is continuing to enhance the Plum platform by evaluating the design of the fluid shield to further reduce the opportunity for fluid ingress.

For proper maintenance of the Plum A+ Infuser, it is important to establish a weekly schedule for cleaning the infuser. The recommended method of cleaning is located in the Plum A+ System Operations Manual (430-95597-008, Section 8) including, on a routine basis, to clean all of the elements behind the cassette door using cotton-tipped swabs saturated with cleaning solution. The cassette door may be unlatched from the door handle to facilitate cleaning. This includes taking caution to not allow cleaning solutions to saturate the air-in-line detectors or enter the device when cleaning the air-in-line detectors and not spraying cleaning solutions toward any opening in the instrument.

If the valve/cassette failures continue to occur after cleaning remove the device from service and contact your local Hospira office to report the issue.

***Please complete the attached Reply Form indicating the number of impacted Plum A+ infusers 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,

_____
Wilson Kennedy
EMEA Devices Quality Manager

Hospira UK Limited
Queensway
Royal Leamington Spa
Warwickshire CV31 3RW
United Kingdom
Telephone +44 (0)1926 820 820
Facsimile +44 (0)1926 835 250
www.hospira.com
Registered in England No. 1923357

URGENT FIELD NOTICE REPLY FORM
Fluid Shield – Fluid Ingress

Product name:	**Plum A+ Family of Infusers**
List Number:	**11005, 11971, 12348, 12391, 12618, 20678, 20792.**
Hospira ref:	**Q.FA.EMEA.2013.002**

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.

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

Section E
☐ Please indicate the number of impacted Infusion Devices at your location.

Hospira UK Limited
Queensway
Royal Leamington Spa
Warwickshire CV31 3RW
United Kingdom
Telephone +44 (0)1926 820 820
Facsimile +44 (0)1926 835 250
www.hospira.com
Registered in England No. 1923357