24 January 2013

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

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.2013.001**
Date:	**24 January 2013**

Dear Healthcare Professional and Hospira Customer,

Hospira, Inc. is issuing this Field Safety Notice to inform you about the potential for the Plum A+ fluid shield diaphragm to be out of specification and cause N250 “Door Open while pumping” or N100 “Unrecognisable Cassette” alarms.

These alarms invoke audible and visual warnings to the user, which may occur during setup, infusion or Performance Verification Testing (PVT) and will cause the device set up to be interrupted or the infusion to stop. If these alarms occur whilst the clinician is setting up the pump or an infusion is in progress, a delay or interruption in therapy may result. 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.

In order to prevent the occurrence of N250 and N100 alarms, it is important to take the following steps, as detailed in the Plum System Operating Manual (430-95597-008 B, 2012-11), regarding the insertion of the cassette.

- Prior to loading the primed cassette confirm the flow regulator is closed on the cassette and the slide clamp/roller clamp is closed.
- Open the cassette door by lifting the handle.
- Ensure that the primed cassette is loaded into the door guides.
- Close the cassette door using the door handle.
- Confirm there is no flow after the door is closed.

If the unrecognisable cassette alarm (N100) occurs during the cassette loading process prior to infusion, remove the cassette and attempt to reload the cassette again. If this action does not resolve the alarm issue, it is recommended that an alternative pump be used to minimise delay in patient treatment. If either the N250 or N100 alarm occurs during the infusion, safely remove the set from the pump (clamp the line before removal, as detailed in the System Operating Manual) and continue the infusion with another Plum A+ Pump. In either case, isolate the affected pump so that it can be tested away from the patient environment with a new tubing set. If the problem continues, please remove the pump from active service and contact your local Hospira office to report the issue.

To correct this issue, in September 2012, Hospira implemented a screening process to identify out of specification diaphragms at our manufacturing and service centres. Plum A+ devices shipped since that point successfully went through this screening process and have diaphragms that are within specification. Additionally Hospira is working with the supplier to ensure all future parts are manufactured within specification. Hospira will be contacting you to arrange for screening and if necessary replacement of any out of specification diaphragms.

***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.

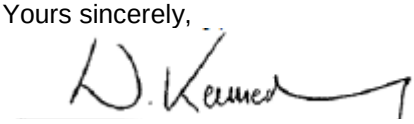
Please maintain awareness of this notice until Hospira notifies you of completion.

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: UK Customer Service	T: +44 800 028 7304 F: +44 1926 835 251 Email to: custserv@hospira.com	Contact point for return of reply forms

The Competent Authorities in all countries affected by this action have been informed of this field safety notice.

Yours sincerely,



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URGENT FIELD NOTICE REPLY FORM
Fluid Shield Diaphragm

Product name:	**Plum A+ Family of Infusers**
List Number:	**11005, 11971, 12348, 12391, 12618, 20678, 20792.**
Hospira ref:	**Q.FA.EMEA.2013.001**

Section A
Hospital / Facility Details
Please fill out the information below and fax the completed form to Hospira at **+44 1926 835 251** or email to **custserv@hospira.com**

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.

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