Urgent Field Safety Notice
ALL HOSPIRA PLUM A+ FAMILY OF INFUSERS UPDATE TO SYSTEM OPERATING MANUAL AND TECHNICAL SERVICE MANUAL

Product name:	**Plum A+ Single Channel Infusion System** **Plum A+3 Infusion Pump System** **Plum A+3 Infusion Pump with Hospira MedNet software** **Plum A+ Infusion Pump with Hospira MedNet software** **Plum A+ Infusion Pump**
List Number:	**11971, 12348, 12391, 12618, 20678, 20792, 20677**
EMEA FA ID:	**Q.FA.EMEA.2015.007**
Date:	**29 July, 2015**

Dear Healthcare Professional and Hospira Customer,

Hospira, Inc. (Hospira) is issuing this letter to inform you the System Operating Manual (SOM) and the Technical Service Manual (TSM) for the Plum A+/A+3 infusers have been updated as part of the corrective actions for the following Field Corrections that were previously communicated by Hospira during the period of 2011-2013:

Issue	FSN Number
Regulator Closer	Q.FA.EMEA.2011.011
Pump Volume Knob	Q.FA.EMEA.2012.014
Door Roller	Q.FA.EMEA.2012.015
Fluid Shield Ingress	Q.FA.EMEA.2013.002
Distal Occlusion Pressure Sensor Drift	Q.FA.EMEA.2013.003
Broken Distal Occlusion Pressure Sensor Pin	Q.FA.EMEA.2013.004
E321 Error Code - Battery	Q.FA.EMEA.2013.005

Issue: As corrective actions for previously communicated Field Safety Notices, Hospira updated the System Operating Manual (SOM) and Technical Service Manual (TSM) for the Plum A+/A+3 infusion pumps. The original Field Safety Notices did not explicitly reference all changes that would be made as part of the corrective actions. As such, Hospira is notifying customers of the updates made to the SOM and TSM through this Field Safety Notice and would like to ensure the appropriate action is taken to circulate the revised information to all staff within your facility that use the devices.

Risk to Health: The risks to health that were communicated in the previous Field Safety Notifications have not changed.

Affected Product Details: A summary of the updates made to the manuals is provided below:

Device Field Safety Notification	Field Action	Location in SOM	Location in TSM
Regulator Closer • Incorrect seating of the regulator closer (flow regulator actuator).	Q.FA.EMEA.2011.011	Discontinuing Electronic Flow control and Setting Gravity Flow Section 3	Unrestricted Flow Section 6.4.1
Volume Knob • 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 • The system operating manual will be updated to clarify the instructions for setting the volume. Hospira will issue updated manuals as soon as they are available.	Q.FA.EMEA.2012.014	Rear Case Controls Section 3	N/A
Door Roller Assembly • The door roller assembly has the potential to break.	Q.FA.EMEA.2012.015	N/A	Door Roller Annual Inspection and Test Section 5.2.4
Fluid Shield - Fluid Ingress • Potential for the fluid shield to inadequately prevent fluid from entering into the device.	Q.FA.EMEA.2013.002	N/A	Fluid Shield Annual Inspection Section 5.2.5

Affected Product Details: (continued)

Device Field Safety Notification	Field Action	Location in SOM	Location in TSM
Distal Occlusion Pressure Sensor Calibration Drift • 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.	Q.FA.EMEA.2013.003	N/A	Distal Occlusion Annual Test Section 5.3.13
Broken Distal Occlusion Pressure Sensor Pin • The potential exists for the distal (occlusion) pressure sensor pin to break.	Q.FA.EMEA.2013.004	N/A	Distal Pressure Pin Annual Inspection Section 5.2.6
Battery Not Fully Recharging • 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.	Q.FA.EMEA.2013.005	N/A	Battery Section Section 4.2.2.9 Battery Inspection and Replacement Section 5.2.10 Troubleshooting Section 6 Battery Specification Section 8

Hospira has also included a "Preventive Maintenance" plan under Section 5.2 in the Technical Service Manual (TSM) which includes the annual inspections detailed in the table above. Additionally, in Section 5.2.14, a required Preventive Maintenance Checklist has been added to provide a robust maintenance program to be followed over the useful life of the Plum A+/A+3 infusion pump. The safety related information added to the manuals is critical for the continued safe use of the pump.

Actions to be taken:

Hospira began distributing the updated Plum System Operating Manual (SOM) to customers in May 2014 and the distribution of the updated Technical Service Manual (TSM) is to start in September 2015. Customers can find the details for the changes that were added to the SOMs and the TSMs listed above and should ensure all previous versions of the manuals are discarded.

Please complete the attached Reply Form indicating your receipt and understanding of this Field Safety Notice and, if applicable, indicate the number of Plum SOMs and TSMs still required 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.

For further inquiries, please contact Hospira using the information provided below.

Hospira contact	Contact details	Areas of support
Local Contacts	T: 0800 0287 304 Email to: custserv@hospira.com	Local contacts
Hospira EMEA Product Safety	T: 0800 088 5133 Email to: emeadevicecomplaints@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

Please be assured that maintaining a high level of safety, quality and service is Hospira's highest priority. We appreciate your cooperation and we regret any inconvenience this action may cause.

Thank you,

W. J. Kennedy 29/JUL/15

Wilson Kennedy
EMEA Quality Manager – Medical Devices

Urgent Field Safety Notice – Reply Form
ALL HOSPIRA PLUM A+ FAMILY OF INFUSERS
UPDATE TO SYSTEM OPERATING MANUAL
AND TECHNICAL SERVICE MANUAL

Product name:	**Plum A+/A+3 Family of Infusers**
List Number:	**11971, 12348, 12391, 12618, 20678, 20792, 20677**
Hospira ref:	**Q.FA.EMEA.2015.007**

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 Urgent Device Field Safety 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 received updated Plum A+ System Operating Manuals and provided/made available a copy to users in my facility. **Number received:** ☐ **Numbers needed:** ☐

☐ I have received updated Plum A+ System Technical Service Manuals and provided/made available a copy to users in my facility. **Number received:** ☐ **Numbers needed:** ☐

Section D

Have you distributed the product further to the retail level? YES ☐ NO ☐

- If yes, have you notified your retail customers? YES ☐ NO ☐ (if NO, please provide further detail)