



19 February 2013

URGENT FIELD SAFETY NOTICE ALL HOSPIRA PLUM™ A+ FAMILY OF INFUSERS E321 Error Code – Battery Not Fully Recharging

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.2013.005

Date:

19th February 2013

Dear Healthcare Professional and Hospira Customer,

Hospira, Inc. is issuing this Field Safety Notice to inform you of possible interruption of therapy which may occur when an E321 error code occurs while using a Plum A+/A+3 infuser. The E321 error code occurs when the Plum A+/A+3 infuser is operating on AC power and the software detects that the battery could not be fully recharged within eight hours. The root cause of this issue is a degraded battery that no longer has the storage capacity to be fully recharged. The error code is accompanied by both an audible alarm and a visual error message on the infuser's display.

If the E321 error code occurs during infusion, the infuser will stop delivery, which may 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. 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 in/of therapy could result in serious injury or death.**

When an E321 error code occurs, power cycle (turn off then on) to clear the error on the device or channel (in the case of a Plum A+3) and remove the infuser from service. While the infuser is out of service complete an eight hour charging cycle by plugging it into AC power and placing the device into standby mode as detailed in the Plum A+ System Operating Manual. If the E321 error code does not re-appear after the charging cycle, return the infuser to service. If the E321 error code re-appears after the charging cycle replace the battery as detailed in the Plum A+ Technical Service Manual and return the infuser to service. Note that on Plum A+3, E321 alarms on one channel do not affect the other channels.

There is no need to return your Plum A+/A+3 infuser. In Q3 2013, Hospira will be deploying a new battery with the same configuration that will mitigate the potential risk of interruption of therapy due to E321 errors. The new battery is expected to reduce but not completely eliminate instances of E321 malfunction and the "Warning: Replace Battery" alarm. The "Warning: Replace Battery" alarm does not interrupt therapy; it informs the health care provider that the battery should be replaced because its capacity may no longer be sufficient to meet Plum A+/A+3 product specifications.



In the event that your facility's ability to administer proper care is severely impacted by the issue, Hospira will provide loaner devices.

Please complete the attached Reply Form indicating the total 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,

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EMEA Devices Quality Manager

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URGENT FIELD NOTICE REPLY FORM

E321 Error Code – Battery Not Fully Recharging

Product name:	Plum A+ Family of Infusers
List Number:	11005, 11971, 12348, 12391, 12618, 20678, 20792.
Hospira ref:	Q.FA.EMEA.2013.005

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.