Hospira

URGENT FIELD SAFETY NOTICE
ALL PLUM A+ ™ Family of Infusers

Product	List number
Plum A+ Infusion Pump	11971
Plum A+ 3 Infusion Pump System v10.3	12348
Plum A+ Infusion Pump v 11.3	12391
Plum A+3 Infusion Pump v11.3	12618
Plum A+3 with Hospira MedNet Software	20678
Plum A+ Driver	20792

Date: xx / month / 2011

Dear Healthcare Professional and Valued Hospira Customer,

Hospira Inc. has received customer reports of Plum A+ infusers in which the audible alarm has failed. Should the audible alarm fails and the user does not notice the visual alert, the user may not be aware of the change in pump status such as air-in-line or occlusion. This may result in a delay or interruption of therapy which may result in serious injury and/or death.

Hospira's investigation concluded that the primary root cause is associated with failure of the piezoelectric assembly ("buzzer") due to improper mounting of components on the board assembly, poor solder application and breakage of internal wiring connections.

Hospira is developing a design improvement to resolve this issue. Validation of this solution for all device configurations is in progress. Once the redesign and testing activities are complete and inventory is available, Hospira will notify you to schedule replacement of your buzzer assemblies.

In the interim, we recommend that you perform an audible alarm test prior to each clinical use of the device. Note that these tests will identify if the alarm has already failed. Three options for testing the device are described below:

1. Dry cassette test (do not perform this test while the pump is being used on a patient).
To perform the test:

a. Install an empty (dry) cassette or an empty (dry) test cassette.
b. Turn on the infuser.
c. When the pump detects the empty cassette, listen for the audible alarm.

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www.hospira.com Registered in England No. 1923357

d. If the alarm is audible, remove the empty cassette and continue to use the infuser. If the alarm is not audible. Discontinue use of the infuser and contact Hospira.
e. For Plum A+3 devices, be sure to test each infusion channel separately.

We will be supplying dry cassettes for this test free of charge in the coming weeks

2. Proximal Occlusion Simulation Test

a. Turn on the infuser
b. Insert primed set
c. Close door and let infuser initialize
d. If infuser alarms for error codes E378, E379 or E380, take infuser out of service and contact Hospira Global Product Safety and Complaints.
e. If infuser passes initialization and cassette test with no alarm, do the following:
    ii. Open door lever.
    iii. Pinch tubing proximally (5 to 10 cm above the cassette)
    iv. With the tubing still pinched, close door lever and let infuser initialize.
    v. Verify the N185 Proximal occlusion and audible alarm sounds. If the audible alarm does not sound, remove the infuser from service and contact Hospira Global Product Safety and Complaints.

3. Open door test

To perform the test:

a. Start the infusion and immediately open the cassette door. This will cause an alarm code whereby the audible alarm can be verified.
b. The screen will display the message N250 Door open while pumping.
c. Close the door lever and restart the infusion. The pump will retest the cassette which takes approximately 12 seconds and then start the infusion.
d. If the alarm is not audible, discontinue use of the infuser and contact Hospira.

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Hospira personnel can provide additional training support as required to ensure staff members have a clear understanding of the alarm test procedure. Please contact your Hospira representative to request training support.

Please complete the attached Reply Form and return it via fax to the number on the form.

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 this may have caused you.

Please forward this Field Safety Notice to all colleagues within your organisation who need to be aware of it or to any organisation where the potentially affected devices have been transferred. Should you have any further questions please do not hesitate to contact your local Hospira office:

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Hospira contact	Contact details	Areas of support
Hospira Medical Information	+44 1926 834 400 *SafetyEMEA@hospira.com.*	To report adverse events or product complaints
Hospira EMEA Factory Service Centre	+353 - 71 917 424 *(office hours)*	Additional information and technical assistance
Hospira EMEA Quality	T +31 (0)36 527 4700 F +31 (0)36 527 4701 Email to*: devicesfieldactions@hospira.com*	Additional information and technical assistance

The Competent Authorities in all countries affected by this action have been informed.

Yours sincerely,

Mike Murphy 2nd March 2011

Mike Murphy

Mike Murphy
EMEA Regional QA Director

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Urgent Device Field Safety Notice Reply Form

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Please fill out the information below and fax the completed form to Hospira at [*local fax number*].

I have read and understood this Field Safety Notice, and circulated it to all staff/departments that use this product.

_____

Hospital/Distributor Name

_____

Address

_____

Phone Number

_____

Completed by: Printed name/signature/title/date

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