



**URGENT DEVICE RECALL**  
**ALL PLUM A+™ Family of Infusers**

<b>Product</b>	<b>List Number</b>
Plum A+ Hyperbaric Infusion Pump	11005
Plum A+ Infusion Pump	11971
Plum A+ Infusion Pump v10.3	11973
Plum A+3 Infusion Pump System v10.3	12348
Plum A+ Infusion Pump v11.3	12391
Plum A+3 Infusion Pump v11.3	12618
Plum A+3 with Hospira MedNet Software	20678
Plum A+ with Hospira MedNet Software	20679
Plum A+ Driver	20792

February 14, 2011

Dear Healthcare Professional and Valued Hospira Customer:

Hospira, Inc. has received customer reports of the Plum A+™ infusers in which the audible alarm has failed. **If 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 has received reports of this failure, including events resulting in serious patient injury.**

Hospira's investigation concluded 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.

**Clinicians should weigh the risk associated with continued use of the device versus removal from service.**

If you elect to continue using the devices, Hospira recommends that trained personnel perform an audible alarm test prior to each clinical use of the device (during the pump cleaning process). **Do not perform this test while the pump is being used on a patient.** Note that this test will identify if the alarm has already failed. However, even if a pump successfully passes this test, this does not guarantee that the alarm will not fail during the next clinical use.



To perform the test:

1. Install an empty (dry) set or an empty (dry) test cassette.
2. Turn on the infuser.
3. When the pump detects the empty cassette, listen for the audible alarm.
4. 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 Global Product Safety and Complaints.
5. For Plum A+3 devices, be sure to test each infusion channel separately.

Hospira personnel will provide additional training support as needed to ensure staff members have a clear understanding of the alarm test procedure. Please contact your Hospira representative or the Advanced Knowledge Center to request training support.

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.

If a device fails, or you elect to remove an infuser from service, please contact Hospira using the information provided below.

<b>Hospira Contact</b>	<b>Contact Information</b>	<b>Areas of Support</b>
Hospira Global Product Safety and Complaints	1-800-441-4100 (8am-5pm CST, M-F) (ProductComplaintsPP@hospira.com).	To report adverse events or product complaints
Hospira Advanced Knowledge Center	1-800-241-4002 (Available 24 hours a day/7 days per week)	Additional information Technical Assistance

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

This communication is being made with the knowledge of the U.S. Food and Drug Administration.

Any adverse events experienced with the use of this product, and/or quality problems should also be reported to the FDA's MedWatch Program by:

- Linking to the MedWatch website at [www.fda.gov/medwatch](http://www.fda.gov/medwatch)
- Calling 1-800-FDA-1088
- Faxing at 1-800-FDA-0178
- Mailing to MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD, 20852-9787



Hospira is committed to providing our customers with the highest level of service and product quality. We appreciate your cooperation, and we regret any inconvenience this action may cause.

Sincerely,

A handwritten signature in black ink, appearing to read "Ileana Quinones", written in a cursive style.

Ileana Quinones  
Vice President, Device Quality Operations



**Urgent Device Recall Reply Form. - RESPONSE REQUIRED  
No Audible Alarm**

**PLUM A+™ Family of Infusers**

**COMPLETE THE INFORMATION AND FAX THE COMPLETED FORM TO 888-216-7330.**

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1. I have received the Customer Notification and distributed it to users throughout the facility:

YES\_\_\_ NO\_\_\_

If NO, state reason:

**Customer Information**

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Business Name

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Address/City/State/Zip

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Hospira Customer Number (if applicable)

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Contact Name

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Contact Phone/e-mail Address

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Completed by: Printed Name/Signature/Date

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