

URGENT DEVICE RECALL
ALL PLUM A+™ Family of Infusers



Product	List Number
Plum A+ Hyperbaric Infusion Pump	11005
Plum A+ Infusion Pump	11971
Plum A+ Infusion Pump	11973
Plum A+3 Infusion Pump System	12348
Plum A+ Infusion Pump	12391
Plum A+3 Infusion Pump	12618
Plum A+3 with Hospira MedNet Software	20678
Plum A+ with Hospira MedNet Software	20679
Plum A+ Driver	20792

September 16, 2011

Dear Valued Customer:

Hospira, Inc. has received customer reports of two separate conditions affecting all Plum A+ infusers. One condition is the incorrect seating of the regulator closer. The second condition involves continuous reboot and/or recycling when the display settings have been changed from the default settings. The attached letters provide important information for both of these conditions.

Please read the information on the attached pages carefully, **complete the reply form at the end of each letter and fax it to the number on the form** to acknowledge receipt, communication and understanding of both issues.

The U.S. Food and Drug Administration has been notified of these recalls.

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

Hospira Contact	Contact Information	Areas of Support
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, option 4 (Available 24 hours a day/7 days per week)	Additional information Technical Assistance

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
- 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 regret any inconvenience this action may cause and ask your cooperation in this important matter.

Sincerely,

Ileana Quinones
Vice President, Device Quality Operations
2482_01_01AS

Hospira, Inc.
275 North Field Drive
Lake Forest, IL 60045
(224) 212-2000
www.hospira.com

FA107-02/FA108-01 C(3)

URGENT DEVICE RECALL
ALL PLUM A+™ Family of Infusers
Recycling/Rebooting



Product	List Number
Plum A+ Hyperbaric Infusion Pump	11005
Plum A+ Infusion Pump	11971
Plum A+ Infusion Pump	11973
Plum A+3 Infusion Pump System	12348
Plum A+ Infusion Pump	12391
Plum A+3 Infusion Pump	12618
Plum A+3 with Hospira MedNet Software	20678
Plum A+ with Hospira MedNet Software	20679
Plum A+ Driver	20792

September 16, 2011

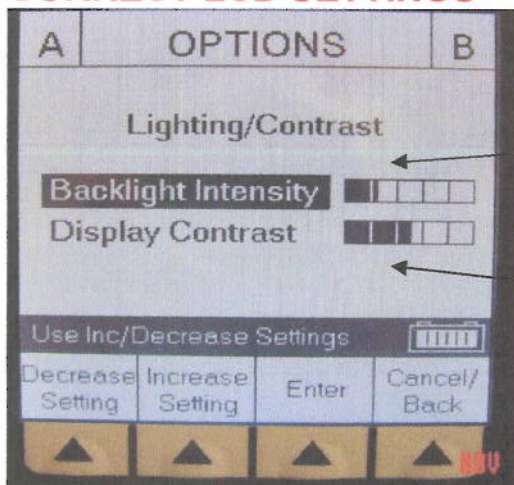
Dear Valued Customer:

Hospira has received customer reports involving continuous recycling and/or rebooting of Plum A+ devices (single and triple channel) when the “Backlight Intensity” and/or “Display Contrast” settings for the LCD display have been adjusted from the original default setting. **This condition could cause a delay in therapy because the clinician would not be able to start the device due to the continuous recycling and/or rebooting. This failure mode may contribute to patient adverse events;** however Hospira has not received any reports involving serious patient injury related to this condition.

To prevent an occurrence of continuous recycling/rebooting during start-up, adjust the backlight and contrast settings as described below:

- Go to the Lighting/Contrast Screen under “Options”.
- Backlight Intensity: Set to one (1) increment past one full bar from the left as shown in the picture below.
- Display Contrast: Set to five (5) decrements below three full bars as shown in the picture below.
- Press enter to save the settings.

CORRECT LCD SETTINGS



Backlight Intensity – One (1) increment above one full bar.

Display Contrast – Five (5) decrements below three full bars.

2482_01_02AS

Hospira, Inc.
 275 North Field Drive
 Lake Forest, IL 60045
 (224) 212-2000
 www.hospira.com

URGENT DEVICE RECALL
ALL PLUM A+™ Family of Infusers
Recycling/Rebooting



Product	List Number
Plum A+ Hyperbaric Infusion Pump	11005
Plum A+ Infusion Pump	11971
Plum A+ Infusion Pump	11973
Plum A+3 Infusion Pump System	12348
Plum A+ Infusion Pump	12391
Plum A+3 Infusion Pump	12618
Plum A+3 with Hospira MedNet Software	20678
Plum A+ with Hospira MedNet Software	20679
Plum A+ Driver	20792

In the event your device experiences this condition, immediately disconnect the device from A/C power and replace it with a unit that was confirmed to have its intensity and contrast settings at the default values so that therapy can continue. Have your biomed or support personnel disconnect the battery, as detailed in the Plum A+ Technical Service Manual, from the malfunctioning device and return the pump to Hospira for servicing.

Please inform users not to adjust the backlight intensity and display contrast settings from the default settings defined above. Until you have confirmed that the display settings for all Plum A+ devices in your facility have been set to their default settings, Hospira recommends that you have stand-by pumps available, particularly in critical care areas, that are set to the default settings should you experience the continuous recycling and/or rebooting condition.

A software upgrade to address the software timing issue is currently being developed by Hospira. Rollout of this upgrade is targeted to begin no later than the end of 1Q2012. Hospira will notify you when the software upgrade is available.

Please **complete the reply form at the end of this letter and fax it to the number on the form.** Please contact Stericycle at 1-866-899-7384 to obtain additional copies of the reply form.

The U.S. Food and Drug Administration has been notified of this recall.

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

Hospira Contact	Contact Information	Areas of Support
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, option 4 (Available 24 hours a day/7 days per week)	Additional information Technical Assistance

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
- Calling 1-800-FDA-1088
- Faxing at 1-800-FDA-0178
- Mailing to MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD, 20852-9787

2482_01_03AS

Hospira, Inc.
 275 North Field Drive
 Lake Forest, IL 60045
 (224) 212-2000
www.hospira.com

URGENT DEVICE RECALL
ALL PLUM A+™ Family of Infusers
Recycling/Rebooting



Product	List Number
Plum A+ Hyperbaric Infusion Pump	11005
Plum A+ Infusion Pump	11971
Plum A+ Infusion Pump	11973
Plum A+3 Infusion Pump System	12348
Plum A+ Infusion Pump	12391
Plum A+3 Infusion Pump	12618
Plum A+3 with Hospira MedNet Software	20678
Plum A+ with Hospira MedNet Software	20679
Plum A+ Driver	20792

Hospira is committed to providing our customers with the highest level of service and product quality. We regret any inconvenience this action may cause and ask your cooperation in this important matter.

Sincerely,

A handwritten signature in black ink, appearing to read "Ileana Quinones".

Ileana Quinones
Vice President, Device Quality Operations

2482_01_04AS

Hospira, Inc.
275 North Field Drive
Lake Forest, IL 60045
(224) 212-2000
www.hospira.com

**Urgent Device Recall – Reply Form
Recycling/Rebooting**



Product	List Number
Plum A+ Hyperbaric Infusion Pump	11005
Plum A+ Infusion Pump	11971
Plum A+ Infusion Pump	11973
Plum A+3 Infusion Pump System	12348
Plum A+ Infusion Pump	12391
Plum A+3 Infusion Pump	12618
Plum A+3 with Hospira MedNet Software	20678
Plum A+ with Hospira MedNet Software	20679
Plum A+ Driver	20792

Complete the form and fax it to 1-888-345-5358 or e-mail it to Hospira2491@stericycle.com

The following action has been taken:

I have received the Urgent Device Recall Letter regarding the regulator and recycling/rebooting conditions and have notified users in my facility of the precautions to be taken until the permanent corrections are completed by Hospira on our units.

YES _____ NO _____

If NO, provide reason:

Number of affected Plum A+ pumps at facility _____

Customer Information

Business Name _____

Address/City/State/Zip _____

Hospira Customer Number (if applicable) _____

Contact Name _____

Contact Phone/E-mail Address _____

Completed by: Printed Name/Signature/Date _____

2482_01_05AS

CID/SEQ

Event: 2491 CID:

Hospira, Inc.
275 North Field Drive
Lake Forest, IL 60045
(224) 212-2000
www.hospira.com

SAMPLE

URGENT DEVICE RECALL
ALL PLUM A+™ Family of Infusers
Regulator Closer



Product	List Number
Plum A+ Hyperbaric Infusion Pump	11005
Plum A+ Infusion Pump	11971
Plum A+ Infusion Pump	11973
Plum A+3 Infusion Pump System	12348
Plum A+ Infusion Pump	12391
Plum A+3 Infusion Pump	12618
Plum A+3 with Hospira MedNet Software	20678
Plum A+ with Hospira MedNet Software	20679
Plum A+ Driver	20792

September 16, 2011

Dear Valued Customer:

Hospira, Inc. has received customer reports related to incorrect seating of the regulator closer (flow regulator actuator) shown below.



Regulator closer
SEATED CORRECTLY



Regulator closer
NOT SEATED CORRECTLY

Regulator Closer



The regulator closer is attached to the mechanism chassis and is designed to close the flow regulator actuator when the device cassette door is opened.

If the regulator closer does not close the flow regulator actuator when the door is opened, and if the clinician has not engaged the clamp prior to opening the cassette door, unrestricted flow may occur. Unrestricted flow may contribute to life-threatening adverse events, including death. Hospira has received reports of this failure, including one event resulting in serious patient injury involving a drop in blood pressure requiring medical intervention.

2482_01_06AS

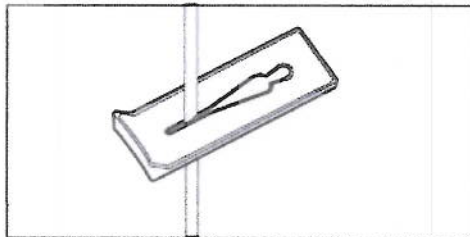
Hospira, Inc.
 275 North Field Drive
 Lake Forest, IL 60045
 (224) 212-2000
 www.hospira.com

URGENT DEVICE RECALL
ALL PLUM A+™ Family of Infusers
Regulator Closer



Product	List Number
Plum A+ Hyperbaric Infusion Pump	11005
Plum A+ Infusion Pump	11971
Plum A+ Infusion Pump	11973
Plum A+3 Infusion Pump System	12348
Plum A+ Infusion Pump	12391
Plum A+3 Infusion Pump	12618
Plum A+3 with Hospira MedNet Software	20678
Plum A+ with Hospira MedNet Software	20679
Plum A+ Driver	20792

To prevent unrestricted flow, you must be sure to close all slide clamps or CAIR™ (roller) clamps prior to opening the cassette door as shown in the illustrations below.



Our investigation of the customer reports found regulator closers that were not fully attached to the mechanism chassis. Hospira has implemented corrective/preventive measures to ensure the regulator is properly seated in all manufactured devices. Hospira will be performing inspections of the regulator closer on all Plum A+ pumps in the market and we will contact you to arrange for this inspection.

Please **complete the reply form at the end of this letter and fax it to the number on the form**. Please contact Stericycle at 1-866-899-7384 to obtain additional copies of the reply form.

The U.S. Food and Drug Administration has been notified of this recall.

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

Hospira Contact	Contact Information	Areas of Support
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, option 4 (Available 24 hours a day/7 days per week)	Additional information Technical Assistance

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
- Calling 1-800-FDA-1088
- Faxing at 1-800-FDA-0178
- Mailing to MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD, 20852-9787

2482_01_07AS

Hospira, Inc.
 275 North Field Drive
 Lake Forest, IL 60045
 (224) 212-2000
www.hospira.com

URGENT DEVICE RECALL
ALL PLUM A+™ Family of Infusers
Regulator Closer



Product	List Number
Plum A+ Hyperbaric Infusion Pump	11005
Plum A+ Infusion Pump	11971
Plum A+ Infusion Pump	11973
Plum A+3 Infusion Pump System	12348
Plum A+ Infusion Pump	12391
Plum A+3 Infusion Pump	12618
Plum A+3 with Hospira MedNet Software	20678
Plum A+ with Hospira MedNet Software	20679
Plum A+ Driver	20792

Hospira is committed to providing our customers with the highest level of service and product quality. We regret any inconvenience this action may cause and ask your cooperation in this important matter.

Sincerely,

A handwritten signature in black ink, appearing to read "Ileana Quinones".

Ileana Quinones
Vice President, Device Quality Operations

2482_01_08AS

Hospira, Inc.
275 North Field Drive
Lake Forest, IL 60045
(224) 212-2000
www.hospira.com

**Urgent Device Recall – Reply Form
Regulator Closer**



Product	List Number
Plum A+ Hyperbaric Infusion Pump	11005
Plum A+ Infusion Pump	11971
Plum A+ Infusion Pump	11973
Plum A+3 Infusion Pump System	12348
Plum A+ Infusion Pump	12391
Plum A+3 Infusion Pump	12618
Plum A+3 with Hospira MedNet Software	20678
Plum A+ with Hospira MedNet Software	20679
Plum A+ Driver	20792

Complete the form and fax it to **1-866-809-6038** or e-mail it to **Hospira2482@stericycle.com**

The following action has been taken:

I have received the Urgent Device Recall Letter regarding the regulator closer and have notified users in my facility of the precautions to be taken until the permanent corrections are completed by Hospira on our units.

YES _____ NO _____

If NO, provide reason:

Number of affected Plum A+ pumps at facility _____

Customer Information

Business Name _____

Address/City/State/Zip _____

Hospira Customer Number (if applicable) _____

Contact Name _____

Contact Phone/E-mail Address _____

Completed by: Printed Name/Signature/Date _____

Hospira, Inc.
275 North Field Drive
Lake Forest, IL 60045
(224) 212-2000
www.hospira.com

Event 2482

ID 33148125

Any Business Name

