

29 October 2012

URGENT FIELD SAFETY NOTICE ALL HOSPIRA PLUM™ A+ SINGLE CHANNEL FAMILY OF INFUSERS Volume Knob Rotation

Product name:	Plum A+ Single Channel Family of Infusers
List Number:	11005 – Plum A+ Hyperbaric infusion system. 11971 + 12391 – Plum A+ single channel infusion system. 20792 – Plum A+ infusion pump with Hospira MedNet™ software.
EMEA FA ID:	Q.FA.EMEA.2012.014
Date:	29 October 2012

Dear Healthcare Professional and Hospira Customer,

Hospira, Inc. is issuing this Field Safety Notice to inform you that the volume control knob on some Plum A+ single channel infusers (located on the back of the infuser) may not function as described in the System Operating Manual; the direction for “Loud” and “Quiet” may be reversed. The manual indicates a clockwise rotation of the knob decreases the volume; however, on some of the devices the alarm volume increases when the knob is turned clockwise.

In the event the healthcare professional rotates the volume control knob in the direction described in the System Operation Manual, the audible tone may be the opposite of the desired audio level. While the device will continue to alarm with an audible tone of at least 50 dBA at the lowest level, inadvertently setting a low tone when a louder level is actually intended may result in an audible alarm that is more difficult to hear. If this happens, it is possible the clinician may not be alerted when an alarm condition occurs and an interruption in therapy may occur.

To determine which direction to turn the knob to change and confirm the volume level, follow the directions below:

Before Beginning Therapy

To confirm that the audible alarm volume is acceptable for the environment where the infuser will be used, follow the steps below **before connecting to a patient**:

1. Turn the pump on with a cassette installed.
2. Look at the infuser display until the “Cassette test in progress” message is shown.
3. During the cassette test, open the cassette door. The pump will alarm.
4. Adjust the volume to the desired level, rotating the volume control knob (located on the back of the infuser), until the audible volume is acceptable, then close the cassette door.

During Therapy

The alarm volume may be adjusted during any alarm condition by rotating the knob to achieve the desired level.

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. Furthermore, Hospira will be creating a volume directional label as an additional improvement. Upon development and approval of the labels Hospira will contact all customers.

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 complete the attached reply form to acknowledge receipt of this FSN and return it via fax to the number on the form. It is important to indicate the number of system operating manuals at your location on the reply form so we can send the correct number once completed.

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.

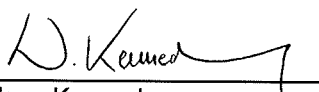
Please maintain awareness of this notice until Hospira notifies you of completion.

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,



Wilson Kennedy
EMEA Devices Quality Manager

URGENT FIELD NOTICE REPLY FORM

Product name:	Plum A+ Family of Infusers
List Number:	11005, 11971, 12391, 20792.
Lot Number/s:	

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:	29 October 2012

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 number of System Operating Manuals at your location.