UPDATED - URGENT FIELD SAFETY NOTICE

Plum A+ Infusion Pumps with Audible Alarm Failures

Product name:	Plum A+ Infusion Pump Plum A+ Infusion Pump v11.3 Plum A+3 Infusion Pump v11.3 Plum A+3 with Hospira MedNet Software Plum A+ Driver Plum A+ Hyperbaric infusion system
List Number:	**11971, 12391, 11005, 12618, 20678, 20792**
Lot Number:	**Alarm component (Piezo) – Lot: 6142**
EMEA FA ID:	**Q.FA.EMEA.2014.008**
Date:	**17th June 2014**

Dear Healthcare Professional and Hospira Customer,

Hospira, Inc. is voluntarily notifying that the audible alarming component (Piezo) within the Plum A+ infusion pumps may fail to sound at various positions of the volume spectrum. **Please ensure that all potential users in your facility, and other facilities for which the device has now been distributed, are made aware of this safety notification and the recommended actions.**

Issue: Hospira initiated a field correction on 14th June 2011 to replace the alarm component (Piezo) in the Plum A+ infusion pumps. Since that time, through complaint trending, Hospira has identified one lot of alarm assemblies that may fail to sound, at all volume levels, at a higher failure rate than the other lots of alarm assemblies. Should the audible alarm fail and the user not notice the visual alert, the user may not be aware of the change in pump status, such as air-in-line or occlusion. To date, no complaints associated with this issue resulting in serious injury or death have been reported.

Risk to Health: Failure of an audible alarm may result in a delay or interruption of therapy. If the audible alarm fails and the user does not notice the visual alert, the user may not be aware of the alarm. Death or serious injury is possible in the patient population at greatest risk. The most reasonable harm expected in both patient populations is an injury that is reversible with medical intervention.

Affected Product Details:

The components impacted by this issue can only be identified by an identification number located on the alarm assembly within the casing of the device. Hospira is **not** recommending customers open the casing or attempt to locate the impacted alarm assemblies.

The following Plum A+ infusion pumps may contain the affected alarm assembly:

List Numbers	Product Name
11971	Plum A+ Infusion Pump
12391	Plum A+ Infusion Pump v 11.3
20792	Plum A+ Driver
11005 (Plum Hyperbaric)	Plum A+ Hyperbaric infusion system
12618	Plum A+3 Infusion Pump v11.3
20678	Plum A+3 with Hospira MedNet Software

Actions to be taken:

Attached to this letter, please find the Plum A+ Remediation - Data Capture Log which includes a list of potentially impacted devices, which Hospira's records identify are located at your facility. To determine if your device is impacted, a trained biomedical professional should test the pumps to confirm the audible alarm can be heard at all volume levels. *This test only needs to be performed once* and **should not be performed while the pump is being used on a patient**.

Audible Alarm Test

1. Remove the battery from the device but keep it connected to the Power supply PWA.
2. Device must **not** be plugged in to AC power.
3. Turn the power on the pump. Disconnect the battery harness from the Charger Circuit Cable while the Self Test is occurring and the device goes into alarming mode.
4. Re-connect the battery cable to the Charger Circuit Cable and turn the power on the device.
5. Device will display an error code with a **constant audible alarm**.
6. While the constant alarm is occurring, slowly adjust the volume control knob from the lowest setting to the highest setting and back to the lowest setting, as viewed from the rear of the device. Listen carefully for any loss of audible alarm over the volume adjustment range.
7. For Plum A+3™ devices, be sure to test each infusion channel separately following these instructions for each individual alarm assembly.
8. **If the audible alarm cannot be heard throughout the entire range, remove the infuser from service and contact your local Hospira office.**
9. Document results of Audible Alarm Test on the Plum A+ Remediation - Data Capture Log next to the appropriate serial number and return.

Additionally, please take the following actions related to this important product information:

1. Forward this Field Safety Notice to all colleagues within your organisation who need to be aware of it or to any organisation or persons where the affected devices have been transferred.
2. *Complete the attached reply form and return it to the fax number or e-mail address on the form*, even if you **do not have** the affected product.
    - **Indicate on the attached reply form whether you prefer to perform the test identified above yourself or if you would prefer Hospira to perform the test.**
    - **If you perform the test yourself, please document the outcomes of your tests on the Plum A+ Remediation - Data Capture Log and return it to the fax number or e-mail address on the form.**
        - Without completion of the attached form, Hospira will require the device be retested should the serial number be identified as potentially impacted.

A volume test should be completed on each potentially impacted infusion device, as stated in the instruction section of this letter. As part of the field correction activities initiated in August 2013,

Hospira has been performing the same volume test outlined above on alarm assemblies of Plum A+ single devices in accordance with the procedures associated with a separate field action and replaced those that have failed to sound at all volume levels. The Plum A+ Remediation - Data Capture Log attached to this letter outlines the serial numbers of Plum A+ infusion pumps that Hospira has identified as still requiring attention related to this issue, Hospira will be contacting your facility regarding completion of an audible alarm test and will replace any alarm assemblies that fail the audible alarm test.

In addition to quality control tests performed during recent field correction activities, corrective actions were implemented at the supplier level to enhance reliability of components.

Additionally, as part of establishing a streamlined and modernised device portfolio that addresses customer needs, Hospira is in the process of retiring the Plum Hyperbaric devices (including list number 11005) as communicated in the details of the Important Infusion Pump Discontinuation Notice announced 5th March 2014. As of 30th June 2014, Hospira will consider Plum Hyperbaric devices retired and will no longer support them.

Please complete the attached Reply Form and return it **to the fax number or e-mail address on the form**, *even if you do not have the affected devices.*

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 this may cause you.

Please forward this Field Safety Notice to all colleagues within your organisation who need to be aware of it or to any organisation or persons where the affected devices have been transferred.

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,

Simon Baker
European Authorised Representative

URGENT FIELD SAFETY NOTICE REPLY FORM

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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 impacted devices.

Or

Section C

☐ I have read and understood the contents of this Field Action, and circulated it to all staff/departments that use this device. I confirm that all affected products have been located and tested accordingly.

Or

Section D

☐ I have read and understood the contents of this Field Action, and circulated it to all staff/departments that use this device. I confirm that all affected products have been located and would like the following devices to be tested by Hospira accordingly.

Number of Plum A+^{TM} at facility: _____

Number of Plum A+3^{TM} at facility: _____