



**URGENT DEVICE RECALL**  
**ALL PLUM XL™ Family of Infusers**

Product	List Number
Plum XL Infusion Pump	11555
Plum XL3 Infusion Pump	11781
Plum XL3M Infusion Pump	11845
Plum XLM Infusion Pump	11846
Plum XL3M with Dataport Infusion Pump	11855
Plum XLD, Infusion Pump	11859

February 14, 2011

Dear Healthcare Professional and Valued Hospira Customer:

Hospira, Inc. has received customer reports of the Plum XL, XLM and XLD™ infusion pumps 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's investigation concluded the root causes to be an electrical short between pins due to contamination of the surface of the piezo electric transducer ("buzzer") and lifted legs at the buzzer. (The buzzer is designed to create an audible tone during any device alarm condition). Contamination is caused by fluid ingress, which occurs when cleaning or other fluids come in contact with the buzzer inside the infuser (e.g. spraying cleaning solution directly on the infuser) resulting in an electrical short in the buzzer. To avoid occurrence of alarm failure, it is essential to follow Hospira's Technical Service Manual for cleaning the pumps. All fluid ingress into the device must be avoided during cleaning or operation, as exposure of contaminants can impact buzzer performance.

Alarm failures caused by lifted legs at the buzzer are not related to contamination. These failures may occur even when cleaning has been performed correctly.

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



If you elect to continue to use the devices, Hospira recommends the following actions:

**Perform Alarm Tests Prior to Each Clinical Use (during your pump cleaning process).**

**For Plum XL and XL3 infusion pumps (one buzzer configuration for high and low volume settings):** Hospira recommends that trained personnel perform the audible alarm test prior to each clinical use (during your 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 pump alarm will not fail during the next clinical use.

- a. Turn the pump on – without a cassette.
- b. Set the volume switch to the ‘low volume position’.
- c. Turn the rotary knob to the ‘set rate’ position.
- d. Listen for the audible alarm.
- e. If the alarm is audible, continue to use the infuser. If the alarm is not audible, discontinue use of the infuser and contact Hospira Global Product Safety and Complaints at 1-800-441-4100.
- f. For XL3 devices, be sure to test each infusion channel separately.

**For Plum XLM, XL3M and XLD (two buzzer configuration/high volume buzzer and low volume buzzer):** Hospira recommends that trained personnel perform the audible alarm test prior to each clinical use (during your 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 pump will not fail during the next clinical use.

- a. In the interim, turn the pump on – without a cassette.
- b. Set the volume switch to the ‘low volume position’.
- c. Turn the rotary knob to the ‘set rate’ position.
- d. Listen for the audible alarm. If the low volume alarm is not audible, discontinue use of the infuser and contact Hospira Global Product Safety and Complaints at 1-800-441-4100.
- e. If the alarm is audible, test the high volume setting.
- f. Set the volume to the highest level. Follow the System Operating Manual or the Technical Service Manual to adjust the audio level. If the alarm is audible, continue to use the infuser.
- g. For XL3M devices, be sure to test each infusion channel separately.
- h. If the high volume alarm is not audible, discontinue use of the infuser and contact Hospira Global Product Safety and Complaints at 1-800-441-4100.

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.

Ensure that all personnel in your facility are following Hospira's Technical Service Manual for routine decontamination of the pumps and cleaning of the buzzers during preventive maintenance.

**Buzzer Cleaning.** During each preventive maintenance, to remove potential for contamination on the surface of the buzzer caused by fluid ingress, **clean the buzzer in accordance with the instructions contained in the Technical Service Manual, for all devices.**

#### 5.1.2

### CLEANING THE BUZZER

Recommended materials are cotton swabs and pure isopropyl alcohol.

Under certain circumstances, residue will build up on the buzzer located on the MCU board. This residue can prevent the buzzer from alarming, but can be easily removed.

To remove any residue, see [Figure 5-1](#), then proceed as follows:

1. Separate the front and rear enclosures as described in [Section 7.2.5](#). Leave the main chassis in the rear enclosure.
2. Inspect the buzzer for any physical damage. If damage is found, discontinue cleaning and [contact Hospira](#).
3. Moisten the cotton swab with the isopropyl alcohol and clean any residue from the entire rear surface of the buzzer.
4. Reassemble the infuser in the exact reverse order of disassembly, then perform the PVT in [Section 5.2](#).

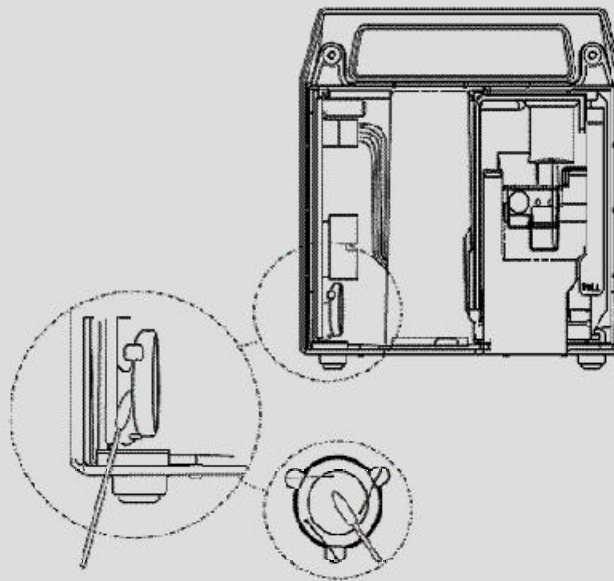
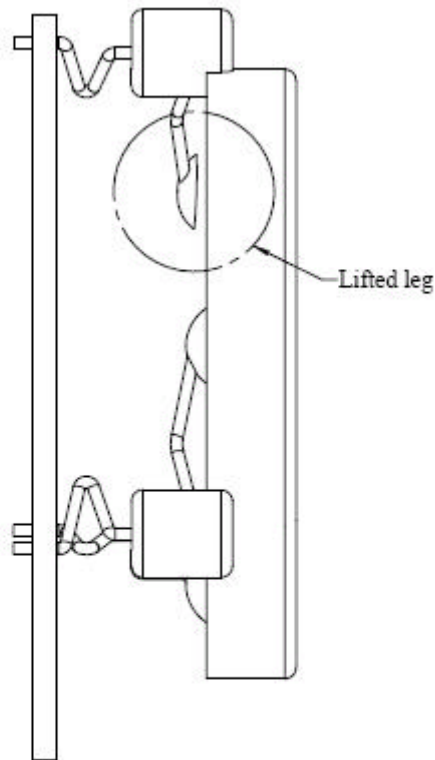


Figure 5-1. Cleaning the Buzzer

**Inspect for Leg Lifting.** Also during each preventive maintenance, please also be sure to inspect the buzzer assembly for any evidence of physical damage including a lifted leg on the ceramic surface of the buzzer. A figure of a lifted leg is shown below. In the event that the buzzer assembly demonstrates any physical damage, please remove the pump from service and contact Hospira Global Product Safety and Complaints.



**Figure: Buzzer with lifted leg**

**In the event the device does not produce an audible alarm, either in a clinical setting or during alarm testing, remove the device from service and contact Hospira Global Product Safety and Complaints.** Please report all product problems using the contact 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 (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 XL™ Family of Infusers**

**COMPLETE THE INFORMATION AND FAX THE COMPLETED FORM TO 866-382-4228**

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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

---

Contact Phone/e-mail Address

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Completed by: Printed Name/Signature/Date

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