



CareFusion  
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[www.carefusion.com](http://www.carefusion.com)

## **URGENT: Medical Device Recall Notification**

### **IMPORTANT INFORMATION UPDATE TO PREVIOUS RECALL NOTIFICATION – ACTION REQUIRED:**

#### **AFFECTED DEVICES:**

**Alaris® PC unit (8000, 8015) (formerly Medley™ PC unit)  
- Syringe Volume Warning Message for Alaris® PCA module (formerly Medley™ PCA module)**

July 29, 2009

Dear Valued Customer:

Chief Administrative Officer  
Director of Pharmacy  
Director of Biomedical Engineering  
Director of Nursing  
Director of Risk Management

CareFusion Corporation (formerly Cardinal Health) is providing an update to the Medical Device Recall Notification issued by Cardinal Health on June 12, 2009, that identified five (5) potential risks associated with the Alaris® System modules. This update letter provides an additional risk mitigation step when the syringe volume warning message appears for the Alaris® PCA module.

The June 12, 2009, notice informed you to take the following steps to mitigate the risk of the Syringe Volume Warning Message on the Alaris® PCA module:

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Users should take the following steps when the warning message "*The volume in the syringe is inadequate to deliver the programmed PCA Dose*" appears on the screen:

- Press the CONFIRM key when the warning message "The volume in the syringe is inadequate to deliver the programmed PCA Dose. PRESS CONFIRM" is displayed on the screen.
- Immediately press the PAUSE button to pause the infusion.
- Remove syringe from the pump, verify concentration and reprogram the infusion. (be sure to enter either a drug amount per 1 mL or total drug amount per total volume—for example, 1 mg/1 mL or 30 mg/30 mL).

Note: DO NOT press RESTART. Doing so will deliver the remaining volume in the syringe.

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We are now recommending the following **revised** risk mitigation steps. (The new steps have been added in **bold text**.)

- **Remove the Dose Request Handset from the patient to prevent inadvertent dose activation by the patient.**
- Press the CONFIRM key when the warning message “The volume in the syringe is inadequate to deliver the programmed PCA Dose. PRESS CONFIRM” is displayed on the screen.
- Immediately press the PAUSE button to pause the infusion.
- Remove syringe, verify concentration and reprogram the infusion. (be sure to enter either a drug amount per 1 mL or total drug amount per total volume—for example, 1 mg/1 mL or 30 mg/30 mL).
- **After confirming that the infusion has been programmed correctly, resume operation of the device.**

**NOTE: Provide the patient with the Dose Request Handset ONLY after reprogramming the infusion and confirming that the infusion has been programmed correctly.**

CareFusion does not require that you return your devices. We will contact your facility through phone or in person within 60 days of the original notification (dated June 12, 2009), to provide an Alaris® PC unit software update to address this risk.

The US Food and Drug Administration has been notified of this update to the June 12, 2009, notification letter. Any adverse reactions 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, or by
- Mailing to: MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787

Please contact the CareFusion Recall Center (see contact information below) for further details. Please use the chart provided below for questions and support:

CareFusion Contact	Contact Information	Areas of Support
CareFusion Recall Center	888-562-6018 7am to 5pm (Pacific)	-General Questions
Customer Advocacy	800-854-7128, Option 1, Option 1, Option 3 OR Email at <a href="mailto:customerfeedback@carefusion.com">customerfeedback@carefusion.com</a> 24 hours a day, Sunday -Saturday	-Adverse Reports
Technical Support	888-812-3229 6am to 5pm (Pacific)	-Technical Questions Regarding the Alaris® System

**Please promptly complete and return the enclosed Customer Response Card within two weeks of receipt of this letter to expedite the correction process.**

CareFusion is committed to serving your infusion product needs and our primary objectives are patient safety, exceptional product reliability, and the highest level of customer satisfaction. Thank you for your prompt support on this important matter. We appreciate your cooperation.

Sincerely,



**Krishna Uppugonduri**  
Vice President, Quality and Regulatory Affairs  
Infusion Technologies

**Enclosures:**

- **Customer Response Card**