

Patient Safety Alert

Veterans Health Administration Warning System Published by VA Headquarters

AL06-16

August 30, 2006

- Item:** All models of Alaris® SE infusion pumps - formerly the Signature Edition® Infusion System. Alaris is a subsidiary of Cardinal Health, Inc.
- Specific Incident:** On August 15, 2006 Cardinal Health initiated a voluntary field corrective action to address concerns about the sensitivity of the keypad that can lead to 'key bounce,' with a potential to result in over infusion. Key bounce occurs when a keyboard entry registers twice while pressing the key once. For example, an infusion rate intended to be 4.0 mL/hr where a key bounce occurs, results in an entry of 44.0 mL/hr.
- Subsequently, on August 28, 2006 Cardinal Health suspended manufacturing and distribution of the Alaris® SE infusion pumps resultant from FDA actions.
- Actions:** If your facility has an affected pump please assure the following:
1. Your facility has received the letters and warning labels sent by Cardinal Health for the Alaris® SE infusion pumps, and that the warning labels have been appropriately affixed.
 2. If your Alaris infusion pumps have the Guardrails® software, enforce the appropriate use of the software by always selecting "New Guardrails Drugs".
 3. If all your Alaris infusion pumps do not have the Guardrails® software, consider acquiring the software and implementing in locations where high risk medications are used.
 4. Assure that clinical staffs who program these pumps or any programmable medical device visually verify the intended device setting before beginning treatment and leaving the area.
- Addl. Information:**
1. FDA does not recommend removing these pumps from service and has provided additional guidance (attached).
 2. This issue does not apply to the Alaris® System - formerly the Medley® System; it only applies to the Alaris® SE pump.
- Source:** Manufacturer, FDA and VA Center for Engineering and Occupational Safety & Health (CEOSH)
- Contact:** Cardinal Health SE Recall Center (877)-552-4922
Paul Sherman, CEOSH (314)-543-6700



Cardinal Health
10221 Wateridge Circle
San Diego, CA 92121
858.458.7000 tel
858.458.7760 fax

www.cardinal.com

URGENT: MEDICAL DEVICE RECALL

August 15, 2006

**SUBJECT: Alaris[®] SE Pump (formerly Signature Edition[®] Infusion Pump) (All Models)
(Cardinal Health)**

Dear Valued Customer:

Director, Nursing
Director, Biomedical
Director, Materials Management
Hospital Administrator
Director, Purchasing

Cardinal Health, owner of Alaris[®] Products, is informing you of a potential for over infusion with all models of the Alaris[®] SE Pumps (formerly the Signature Edition[®] Infusion Pumps) caused by key bounce. If a key bounce occurs and is not detected during programming verification, it may result in an infusion rate at least 10 times (10X) the intended infusion rate. Key bounce occurs when a number registers twice although the operator only pressed the key once. For example, if an infusion rate is intended to be entered as 4.8 mL/hr and the key bounce occurs when the 4 is pressed the actual rate registered will be 44.8 mL/hr.

If not detected during programming verification, key bounce events may result in serious patient harm or death. You must check all programming parameters before starting any infusion therapy.

Cardinal Health will be sending you "Warning Labels" which must be placed on each device. These labels are intended to visibly reinforce the **critical** requirement of verifying programming accuracy prior to initiating infusion. (These labels will be sent to the Director of Biomed and Director of Nursing for each facility). They read as follows:

WARNING: Key bounce malfunction may cause data entry errors. It is critical to verify all programming parameters on the display screen prior to initiating RUN/HOLD during basic set up and following any changes to programming. Verify that flow in drip chamber appears appropriate for expected infusion rate.

Cardinal Health is also evaluating a design improvement to minimize the potential of key bounce occurring. When this solution becomes available we will immediately begin implementing the correction.

In addition, the following steps are recommended for programming any infusion device:


- **Proper Stance:**
When programming pumps, stand squarely in front of the keypad (ideally with the pump at eye level for best visibility) to facilitate proper depth of depressing each key.
- **Listen:**
Focus on listening to the number of beeps while programming IV pumps: each beep will correspond to a single digit entry. Unexpected double tone could indicate an unintended entry.
- **Verify Screen Displays:**
When programming pumps or changing settings, always compare the patient's prescribed therapy on the medication administration record, original order, or bar code device, to the displayed pump settings for verification before starting or restarting an infusion.
- **Independent Double Check:**
Require an independent double check of pump settings by another practitioner before starting or changing infusions with hospital-selected high alert drugs.
- **Look:**
Before leaving the patient's room, observe the IV tubing drip chamber to see if the observed rate of infusion looks faster or slower than expected, adjust accordingly.

If you should have any questions regarding this communication please contact us at (877) 552-4922. If you have any adverse reports related to key bounce you can contact Customer Advocacy at (800) 854-7128, extension 7812 or via email at customerfeedback@cardinal.com.

We also encourage you to report adverse events related to key bounce directly to MedWatch, the FDA's voluntary reporting program. You may submit reports to MedWatch by phone at 1-800-FDA-1088; by fax at 1-800-FDA-0178; by mail to MedWatch, Food & Drug Administration, 5600 Fishers Lane, Rockville, MD 20857-9787; or on line at <http://www.fda.gov/medwatch/report.htm>.

The US Food & Drug Administration has been notified of this communication.

Sincerely,



William H. Murphy, Jr.
Senior Vice President Quality & Regulatory Affairs
Clinical Technologies & Services
Cardinal Health
10221 Wateridge Circle
San Diego, CA 92121-2773

Alaris® SE pump* Recall Overview

Alaris® Products

On August 15, 2006, Cardinal Health initiated a voluntary field corrective action of the Alaris® SE pump* as a result of information indicating that a sensitive keypad posed a risk of 'key bounce' and could lead to the over-infusing of patients. As part of the field corrective action, Cardinal Health sent letters and warning labels to its customers.

On Monday, August 28, 2006, Cardinal Health announced that it suspended production, sales, repairs and installations of its Alaris® SE pump, after approximately 1,300 units were seized by the Food and Drug Administration (FDA).

As indicated in the August 15 Customer Letter, Cardinal Health is working with the FDA on a technical solution to this issue, and is currently testing a modification that reduces the sensitivity of the keypad. This modification will need to be validated on the device, and approved by the FDA. Once this issue is resolved with the FDA, the company will resume the manufacturing, distribution and service of the Alaris® SE pump.

Cardinal Health will continue to work directly with its Alaris® SE pump customers. Sales representatives are contacting each customer to ensure that they are aware of these actions. Any customers with questions are encouraged to contact the SE Recall Center at (877) 552 – 4922.

In the meantime, Cardinal Health recommends the following:

- Immediately implement the warning labels and follow the verification steps highlighted on the label
- Contact Customer Advocacy with any questions
- The company and the FDA have not recommended removing the Alaris® SE pumps from service.

Frequently Asked Questions

1. Why did the FDA seize inventory from Cardinal Health?

The FDA stated "this seizure was intended to ensure that infusion pumps located at Alaris' manufacturing facility are not distributed unless the problem is corrected." The steps we announced today were taken to further limit the distribution of the product in the field.

2. Why did Cardinal Health suspend production, sales, repairs and installations of the product?

Following the seizure of inventory by the FDA, we felt this was a prudent step until we reach a resolution on this issue.

3. Should hospitals stop using the product until the corrective action is implemented?

The FDA has advised "healthcare facilities can continue to use pumps in their possession, guided by these and further instructions." Please refer to the Cardinal Health August 15 letter, the warning label, and the Directions for Use (DFU) for proper verification procedures.

4. Why was the Alaris® SE pump recalled?

Cardinal Health initiated a voluntary field corrective action on August 15 to address a concern that the sensitivity of the keypad poses a risk of 'key bounce,' which could lead to over infusion. The FDA is appropriately sensitive to any potential issues involving direct infusion of medicine. This issue can be avoided with proper verification prior to infusion. We are testing a modification to the product to reduce the sensitivity of the keypad. This modification will need to be validated on the product and approved by the FDA.

5. Have any patients been harmed due to this issue?

We are not aware of any cases of a patient that was harmed as a direct result of this issue.

6. Is this an issue on other Cardinal Health products?

No, the keypad design is unique to the Alaris® SE pump.

7. Does this issue apply to the Alaris® System (formerly the Medley® System)?

No. This issue only applies to the Alaris® SE pump (formerly the Signature Edition® Infusion System).

8. How do I file a key bounce complaint?

If you have any adverse reports related to key bounce you can contact Customer Advocacy at 800.854.7128, extension 7812 or via email at customerfeedback@cardinal.com.

We also encourage you to report adverse events related to key bounce directly to MedWatch, the FDA's voluntary reporting program. You may submit reports to MedWatch by phone at 1.800.FDA.1088; by fax at 1.800.FDA.0178; by mail to MedWatch, Food & Drug Administration, 5600 Fishers Lane, Rockville, MD 20857-9787; or on line at <http://www.fda.gov/medwatch/report.htm>.

9. Is Guardrails® Suite MX available for Alaris® SE pump customers?

Yes. Guardrails® Suite MX will continue to be available for customers who already have the Alaris® SE pump installed.

*Alaris® SE Pump formerly known as Signature Edition® System.

Alaris®, Guardrails®, Medley® and Signature Edition® are registered trademarks of Cardinal Health, Inc. or one of its subsidiaries.

©2006 Cardinal Health, Inc. or one of its subsidiaries. All rights reserved. 3POC0894 (0806)

♻️ Printed on recycled paper with 10% post-consumer fiber.

Cardinal Health
Alaris® Products
10221 Wateridge Circle
San Diego, CA 92121

cardinalhealth.com/alaris





U.S. Food and Drug Administration



[FDA Home Page](#) | [Search FDA Site](#) | [FDA A-Z Index](#) | [Contact FDA](#) | [FDA Centennial](#)

FDA News

FOR IMMEDIATE RELEASE

P06-119

August 28, 2006

Media Inquiries:

Catherine McDermott, 301-827-6242

Consumer Inquiries:

888-INFO-FDA

United States Marshals Seize Defective Infusion Pumps Made by Alaris Products Pumps Can Deliver Excess Medication and Harm Patients

At the request of the U.S. Food and Drug Administration (FDA), the U.S. District Court for the Southern District of California issued a warrant for seizure of Alaris Signature Edition Gold infusion pumps, model numbers 7130, 7131, 7230 and 7231. The pumps are manufactured by Cardinal Health Care 303, Inc. and the seizure occurred August 25. The seized infusion pumps have a design defect called "key bounce" that may cause potential over-infusion of medications. This seizure was intended to ensure that infusion pumps located at Alaris' manufacturing facility are not distributed unless the problem is corrected.

Infusion pumps are electronic devices intended for controlled delivery of intravenous solutions and medications to patients. Key bounce occurs when a number pressed on the pump registers twice although the operator only pressed the key once. If a key bounce occurs and is not detected during programming verification, it may result in an infusion rate at least 10 times the intended infusion rate. For example, if an infusion rate is intended to be entered as 4.8 milliliters per hour and the key bounce occurs when the 4 is pressed, the actual rate registered will be 44.8 milliliters per hour. If not detected during programming verification, key bounce events may result in serious patient harm or death.

FDA inspections revealed that Alaris failed to follow FDA's medical device manufacturing regulations. The infusion pumps were seized by the U.S. Marshals Service at Alaris' manufacturing facility in San Diego, California. The seized devices valued at more than an estimated 1.8 million dollars. Alaris has distributed these products nationally and internationally. No products were seized from healthcare facilities or individual users, and there are no plans to do so.

Alaris was issued warning letters by FDA in August 1998 and October 1999 outlining the violations and was given opportunities to correct the violations, but failed to take appropriate actions.

In an August 15 recall letter, Alaris informed customers that it will provide a warning label for the pumps and a permanent correction for the key bounce problem once it is available. In the letter, Alaris also provided recommendations to pump users on steps they can take to minimize key entry errors until the problem can be corrected. The steps are as follows:

Proper Stance

When programming pumps, stand squarely in front of the keypad (ideally with the pump at eye level for best visibility) to facilitate proper depth of depressing each key.

Listen

Focus on listening to the number of beeps while programming IV pumps; each beep will correspond to a single digit entry. Unexpected double tone could indicate an unintended entry.

Verify Screen Display

When programming the pump or changing settings, always compare the patient's prescribed therapy or the medication administration record, original order, or bar code device to the displayed pump settings for verification before starting or re-starting the infusion.

Independent Double Check

Request an independent double check of pump settings by another practitioner before starting or changing infusions with hospital-selected high alert drugs.

Look

Before leaving the patient's room, observe the IV tubing drip chamber to see if the observed rate of infusion looks faster or slower than expected. Adjust accordingly.

Healthcare facilities can continue to use pumps in their possession, guided by these and further instructions.

For more information, check Alaris' Web site at: <http://www.cardinalhealth.com/alaris/>