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CardinalHealth

# 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,

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