

Patient Safety Alert

Veterans Health Administration Warning System
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AL06-10

March 6, 2006

- Item:** Alaris IV Tubing sets, including commonly used 72023E and 72033E sets, manufactured by Cardinal Health, Alaris Products.
- Specific Incident:** Several VA facilities report failures when loading administration sets in Alaris Signature series infusion pumps. The sets are difficult to load, and, when they do load, may malfunction or become occluded.
- Gen'l Information:** Production runs from the latter part of calendar year 2005 into January 2006 of **all** Alaris tubing sets, including 72023E and 72033E (commonly used in VA), for Alaris Signature infusion pumps, may be affected by this problem.

Traditionally, caregivers could use a one handed installation technique to load the administration set into the Alaris Signature series pump; the sets manufactured in 2005 and early 2006 require users to use a two handed loading technique (see attachment). However, even when using two hands to load the set, some sets (estimate up to 10%) will not function properly in the Alaris Signature pumps. In these cases the following problems may occur:

- 1) The door will not close
- 2) The flow regulator thumb clamp (blue thumb clamp) will not be in the open position resulting in no flow of medication and activation of the pumps occlusion alarm, indicating a problem.

A recall is not being conducted on these administration sets because:

- 1) The majority of impacted administration sets will work properly when installed using the two hand technique.
- 2) The pump occlusion alarm will indicate when the set is not installed correctly.
- 3) There is an insufficient supply of administration sets manufactured after January 2006 available to meet demand.

- Actions:** If you use the Alaris Signature series pump:
- 1) By close of business Friday, March 10, 2006, disseminate the attached "AccuSlide® flow regulator loading guide" to all caregivers that utilize the Alaris Signature infusion pump, and train all users to use the two hand technique to load the sets to prevent tubing malfunction.
 - 2) Save sets that do not function properly despite using the two handed loading technique, and involve your local CLO, materiel management, and/or SPD to return the sets to your supplier for credit. (DO NOT return sets to Cardinal Health, Alaris Products without trying to load them using the two hand technique.)

3) By close of business, Friday, March 17, 2006, develop a contingency plan in the event that Cardinal Health, Alaris Products exhaust their tubing administration set inventory (e.g. working with a local medical device rental company to have alternate brand infusion pumps and compatible sets on reserve).

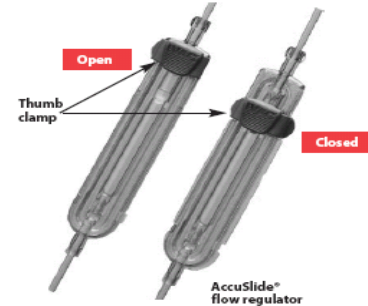
Addl Information: Cardinal Health, Alaris Products is working with the suppliers of the components of their sets to find the root cause of the problem; meanwhile, they are increasing production of sets that will not fail in the Alaris Signature infusion pumps.

Source: Several VA facilities and Cardinal Health, Alaris Products.

Contact: Cardinal Health, Alaris Products at (800) 659 3292, or Mr. Bryanne Patail or Ms. Lori King at the VA National Center for Patient Safety (734) 930 5890.

AccuSlide® flow regulator loading guide

Alaris® SE Pump*



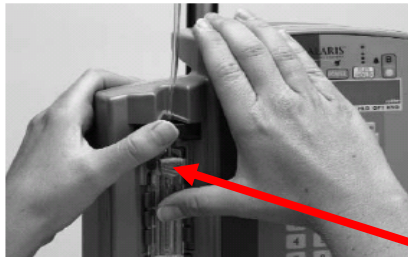
Prepare set:

- Prime set.
- Slide the AccuSlide® flow regulator thumb clamp down until an audible "click" verifies it is in the fully closed position.



Load set:

- Using both hands, press the top and bottom of the AccuSlide® flow regulator straight into the instrument until it snaps into place.
- Verify 3 gray "fingers" (clamp arms) on each side of pumping mechanism have engaged the AccuSlide® flow regulator.
- Let go of the set. A properly loaded set will stay in the instrument.



Close latch:

- Press firmly just below the blue thumb clamp on the AccuSlide® flow regulator with one hand while using the other hand to close the latch fully to the left.
- If resistance is met while closing latch, remove set, verify AccuSlide® flow regulator is fully closed and then reinstall set.

NOTE: Verify that the blue thumb clamp has moved to the open (up) position before starting the infusion.

Verify flow from the IV container after starting the infusion.

*Alaris® SE pump formerly known as Signature Edition® Infusion System.

For more information, please contact Customer Advocacy at 800.854.7128, ext. 7812. In Canada at 800.387.8309.

Or visit our website at www.cardinalhealth.com.

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