Patient Safety Alert

Veterans Health Administration Warning System
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Item: Model 8100 infusion pump modules shipped before September 27, 2007; a component of the Alaris Medley infusion pump system, distributed by Cardinal Health.

Specific Incident: Cardinal Health reports that some of the 8100 pump modules may have mis-assembled occluder springs. The springs can be missing, bent or broken, risking medication over-infusion. Cardinal Health identified 5,560 units of the model 8100 module at 30 VA Medical Centers and sent notices to Biomedical Engineering, Materials Management, Nursing and Risk Management via certified letter. Cardinal Health is establishing teams to visit each hospital and arrange for definitive testing of all modules that is expected to be completed over the next several months. The only definitive test is an x-ray of each module to examine the occluder springs.

Action: 1. By close of business (COB) on Friday, December 7, 2007:

a. If you have Alaris Medley pumps and have not received notification from Cardinal Health, check Attachment 1 to see if your facility is affected.

b. If your facility is affected and did not receive Cardinal Health's customer letter (Attachment 2), contact Cardinal Health at (800) 625-6627 and the VA Center for Engineering and Occupational Safety & Health (CEOSH).

2. Where possible, arrange to send modules not currently in use to Cardinal Health for x-ray testing. Cardinal Health will bear the cost of shipping and testing. Ensure you have enough infusion pumps and modules on hand for use before sending modules to Cardinal Health for x-ray.

3. Monitor the modules impacted by this notification for potential inaccurate flow. If you suspect inaccurate flow with a particular device, remove the device from service and contact Cardinal Health at (800) 854-7128 (select option 3) to arrange for a device failure investigation.

Addl. Information: Cardinal Health recommends customers immediately perform an occluder pressure test on all modules but preliminary field results indicate little value from this action. VHA does not recommend performing the occluder test. The test is not definitive, must be repeated at frequencies no greater than every six months, and hospitals that have performed the recommended occlusion test have come up with numerous false positives and false negatives from the test.

The only definitive test is x-ray of the modules that must be performed by Cardinal Health. For reference only, a copy of the occlusion test protocol is on the CEOSH website at http://vaww.ceosh.med.va.gov/biomedical/Patient_Safety_Alerts.shtml

Due to the high volume of units affected (200,000 worldwide) and the limited time since discovery of the issue, Cardinal Health does not have enough stock on hand to provide loaner units.

Source: Manufacturer and CEOSH

Contact: Cardinal Health Technical Support at (800) 625-6627, or
Paul Sherman, VA CEOSH at (314) 543-6700

Attachments:
1. List of VA facilities with affected pump modules.
2. Cardinal Health customer letter dated November 5, 2007.

ATTACHMENT 1

List of VA facilities with affected pump modules

VISN	City	State	Description	Quantity
1	BEDFORD	MA	LVP V7.2 COMMERCIAL RELEASE	10
1	BEDFORD	MA	LVP V7.5.5.0 Commercial Release	5
1	BOSTON	MA	8100 Pump Module, V8	100
1	BOSTON	MA	LVP V7.2 COMMERCIAL RELEASE	10
1	BOSTON	MA	LVP V7.5.5.0 Commercial Release	440
1	LEEDS	MA	LVP V7.2 COMMERCIAL RELEASE	22
1	MANCHESTER	NH	LVP V7.2 COMMERCIAL RELEASE	10
1	MANCHESTER	NH	LVP V7.5.5.0 Commercial Release	23
1	PROVIDENCE	RI	8100 Pump Module, V8	10
1	PROVIDENCE	RI	LVP V7.2 COMMERCIAL RELEASE	120
1	TOGUS	ME	8100 Pump Module, V8	15
1	TOGUS	ME	LVP V7.2 COMMERCIAL RELEASE	10
1	TOGUS	ME	LVP V7.5.5.0 Commercial Release	87
1	WEST HAVEN	CT	8100 Pump Module, V8	35
1	WEST HAVEN	CT	LVP V7.2 COMMERCIAL RELEASE	10
1	WEST HAVEN	CT	LVP V7.5.5.0 Commercial Release	311
1	WHITE RIVER JUNCTION	VT	LVP V7.2 COMMERCIAL RELEASE	150
2	BUFFALO	NY	8100 Pump Module, V8	760
2	CANANDAIGUA	NY	8100 Pump Module, V8	10
2	SYRACUSE	NY	MEDLEY PUMP MODULE 5.0	18
2	SYRACUSE	NY	MEDLEY PUMP MODULE 5.0	10
4	LEBANON	PA	8100 Pump Module, V8	149
5	WASHINGTON	DC	8100 Pump Module, V8	0
7	ASHEVILLE	NC	8100 Pump Module, V8	290
7	AUGUSTA	GA	8100 Pump Module, V8	370
7	CHARLESTON	SC	LVP V7.2 Commercial Release	202
7	COLUMBIA	SC	8100 Pump Module, V8	0
7	MONTGOMERY	AL	8100 Pump Module, V8	100
8	GAINESVILLE	FL	8100 Pump Module, V8	0
8	LAKE CITY	FL	8100 Pump Module, V8	0
11	ANN ARBOR	MI	MEDLEY PUMP MODULE 5.0	30
17	SAN ANTONIO	TX	8100 Pump Module, V8	340
18	NORTH LAS VEGAS	NV	8100 Pump Module, V8	24
18	PHOENIX	AZ	8100 Pump Module, V8	250
18	TUCSON	AZ	LVP V7.2 Commercial Release	488
18	TUCSON	AZ	MEDLEY PUMP MODULE 5.0	5
20	ANCHORAGE	AK	8100 Pump Module, V8	2
20	PORTLAND	OR	8100 Pump Module, V8	440
20	ROSEBURG	OR	8100 Pump Module, V8	80
23	MINNEAPOLIS	MN	8100 Pump Module, V8	329
23	OMAHA	NE	8100 Pump Module, V8	295
			Total =	5,560

ATTACHMENT 2

Cardinal Health
10221 Wateridge Circle
San Diego, CA 92121
858.458.7000 tel
858.458.7760 fax
www.cardinalhealth.com

URGENT: Medical Device Recall Notification

November 5, 2007

SUBJECT: Alaris® Pump Module (a.k.a. Medley™ Pump Module) (Model 8100)

Dear Valued Customer:
Director of Biomedical
Director of Materials Management
Director of Nursing
Director of Risk Management

Cardinal Health has received reports of inaccurate flow rate with the Alaris® Pump module (a.k.a Medley™ Pump module) (Model 8100) related to misassembled (missing, bent or broken) springs during the manufacturing or servicing of the mechanism assembly. Within the mechanism assembly there is an upper and lower occluder finger, each with two posts. On each post, a single spring is placed during the assembly process for a total of four springs. The coordinated opening and closing of the two occluder fingers controls the flow through the pump tubing segment. **If a spring is misassembled, there is a potential for inaccurate flow rate which may lead to patient harm due to an overinfusion.**

All Alaris® Pump modules shipped prior to September 27, 2007 are subject to this recall. Cardinal Health implemented a new inspection process in manufacturing for each Alaris® Pump module that eliminates this potential issue for **new product shipped** as of September 27, 2007.

The Alaris® Pump module was commercially released in 2001 and has an installed base of approximately 200,000 devices. To date, the number of reported devices which have been determined to be related to this issue is low.

Short Term Actions (Pending Completion of Field Remediation Plan at Customer Site)

Cardinal Health is recommending the following actions for continued use of the Alaris® Pump module to minimize the potential for inaccurate flow delivery which may lead to overinfusion:

- Until all devices can be inspected per Cardinal Health's field remediation plan (Long Term Actions), Cardinal Health recommends customers perform the Occluder Pressure Test (see attached Service Bulletin) in order to confirm that the occluders are functioning properly as of the date of the test. The lack of occluder pressure is a strong indicator of a misassembled spring warranting removal from patient use for further inspection. As this test cannot detect all misassembled springs, Cardinal Health is recommending that customers perform the Occluder Pressure Test at least every 6 months until such time as the devices are inspected by Cardinal Health.

- If customers suspect inaccurate flow on a particular device they should follow normal hospital protocol, remove the device from service and contact Cardinal Health Customer Advocacy at 800-854-7128, Option 3, or via e-mail at customerfeedback@cardinalhealth.com for failure investigation to take place.

Long Term Actions

Cardinal Health is developing a field remediation plan that includes a field inspection team to examine each Alaris® Pump module at the customer site. Each device will be inspected and any device found with misassembled springs will be sent to Cardinal Health for appropriate servicing. Acceptable devices (devices without misassembled springs) may be placed back in use. Once the field remediation plan has been finalized, Cardinal Health will be contacting each customer to coordinate the inspection of each device.

In addition, customers may choose to send devices directly to Cardinal Health for inspection related to this issue at the service depot. This effort can be arranged through the Alaris® Pump module Call Center at 800-625-6627. Cardinal Health will provide this service and standard shipping at no cost to the customer.

Please promptly complete the enclosed Customer Response Card to expedite the remediation process.

If you have any questions regarding this communication, please contact the Alaris® Pump module Call Center at 800-625-6627. The hours of operation for the Call Center are 7 a.m.-5 p.m. PST. If you have any adverse reports related to the Alaris® Pump module you can contact Customer Advocacy at 800-854-7128, Option 3, or via email at customerfeedback@cardinalhealth.com

Thank you for your support in this important matter.

Sincerely,

Donald M. Abbey
Senior Vice President, Quality and Regulatory Affairs
Clinical Technologies & Services
Cardinal Health
10221 Wateridge Circle
San Diego, CA 92121-2773

Enclosures:
- Customer Response Card
- Occluder Pressure Test service bulletin