3750 Torrey View Court
San Diego, CA 92130
888-562-6018 (toll-free)

carefusion.com

CareFusion

URGENT: Medical Device Recall Notification

AFFECTED DEVICE: Alaris® Pump Module (model 8100)

July 20, 2012

Dear Valued Alaris® System Customer:

Director of Biomedical Engineering
Director of Nursing
Director of Risk Management

CareFusion has identified a potential risk associated with the Alaris® Pump module model 8100. CareFusion has received reports of customers experiencing motor stalls during infusion with Alaris Pump Module (model 8100) manufactured between August 2010 and July 2011. This recall notification details the potential risk and recommended steps for users to take.

Affected Units: Alaris Pump module model 8100 manufactured between August 2010 and July 2011. See **Attachment A** for a list of affected serial numbers.

Issue: The Alaris Pump module may experience intermittent motor stall. Most of the motor stalls reported appear to occur intermittently at high infusion rates (typically over 900 ml/hr) but CareFusion cannot rule out the possibility of occurrence at lower infusion rates.

Potential Risk: When a motor stall occurs, the Alaris PC unit and the Alaris Pump module displays the visual error code 242.4030 with an audible alarm and is followed by a termination of infusion. This is an intermittent error and re-powering the PC unit may not recover the device every time. Termination of infusion could result in serious injury or death.

Required Action For Users:
For high risk patients undergoing infusions at high rates, consider having additional devices as back up. Clinicians should weigh the risk/benefit to the patients before continuing to use the device. If you experience a motor stall at high infusion rates, remove the Pump module from use and contact the CareFusion Support Center.

Follow-up Actions by CareFusion: CareFusion is currently investigating these reports and has not identified a root cause for these incidents. CareFusion continues to monitor these incidents and investigate the root cause and is working to identify actions to address these errors. CareFusion will notify you as new information becomes available.

The US Food and Drug Administration has been notified of this action. 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:

- Web: MedWatch website at www.fda.gov/medwatch
- Phone: 1-800-FDA-1088
- Fax: 1-800-FDA-0178, or by
- Mail: MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787

Please use the chart provided below for questions and support:

CareFusion Contact	Contact Information	Areas of Support
CareFusion Support Center	888-562-6018 7am to 5pm (Pacific)	Recall Related Questions
Customer Advocacy	800-854-7128, Option 1, Option 1, Option 3 OR Email at customerfeedback@carefusion.com 24 hours a day, 7-days per week	Adverse Event Reports
Technical Support	888-812-3229 7am to 5pm (Pacific)	Technical Questions Regarding the Alaris System

Please promptly complete and return the enclosed Customer Response Card to expedite the corrective action 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:

- **Attachment A: Affected Serial Numbers**
- **FAQs**
- **Customer Response Card**