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www.carefusion.com

CareFusion
has joined BD

Medical Device Recall Notification

AFFECTED DEVICE: Alaris™ PC unit (model 8000)

February 25, 2016

Dear Valued Alaris System Customer:

Director of Biomedical Engineering
Director of Nursing
Director of Risk Management

CareFusion will be conducting a corrective action to mitigate a potential risk with the Alaris PC unit model 8000. The following information details the issue and recommended steps to take.

Affected Units: Alaris PC units model 8000 where power supply boards serviced between May 10, 2013 and May 14, 2015 and Alaris PC unit model 8000 power supply boards (Part Number TC10005092) shipped between May 10, 2013 and May 14, 2015 may be affected. See **Attachment A** for a list of affected serial numbers.

Issue: If it fails, a component on the PC unit power supply board may cause a "System Error" or "Missing Battery" error code (120.4630). The error code is accompanied by both an audible alarm and visual error messages on the PC unit screen.

If this error code occurs at start-up, the PC unit cannot be programmed and a new device has to be used to provide infusion therapy. If this error code occurs during infusion, the attached modules providing infusion will continue to infuse and the buttons on the modules will operate as expected. However, clinicians will be unable to titrate infusions.

Potential Risk: The "System Error" or "Missing Battery" error code (120.4630) could cause a delay of therapy at start up. If the error code is observed during an infusion, you will not be able to make programming changes to current infusions, which could result in serious injury. We have not received any reports of the error code occurring with the Alaris System PC unit model 8000.

Required Action For Users:
If you observe either of these error messages, remove the PC unit from use and contact the CareFusion Support Center.

Follow-up Actions by CareFusion: CareFusion will contact your facility by phone within 60 days of receiving this notification to schedule a visit to replace your affected power supply board on your PC unit.

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	Phone: 888-562-6018 Phone hours: 7:00am to 4:00pm PST, Monday - Friday Email: SupportCenter@carefusion.com	Recall Related Questions
Customer Advocacy	Phone: 888-812-3266 Phone hours: 24 hours a day, 7 days a week Email:customerfeedback@carefusion.com	Clinical Inquiries Product Complaints Clinical Troubleshooting
Technical Support	Phone: 888-812-3229 Phone hours: 6:00am to 5:00pm PST, Monday – Friday Email: DL-US-INF-TechSupport@carefusion.com	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,

Chuck Donlon
Vice President, Quality and Regulatory Affairs
Infusion Systems

Enclosures:

- **Affected Serial Numbers**
- **External FAQs**
- **Customer Response Card**