URGENT: Medical Device Recall Notification

AFFECTED DEVICE: Alaris® PC unit (Model 8015)

March 12, 2015

Dear Valued Alaris® System Customer:

    Director of Biomedical Engineering
    Director of Nursing
    Director of Risk Management

CareFusion has identified an issue with the Alaris® PC unit model 8015. CareFusion has received reports of customers experiencing a system error on the Alaris PC Unit Model 8015. This product notification details the issue and recommended steps for users to take.

Affected Units: Alaris PC units model 8015. See Attachment A for a list of affected serial numbers.

Issue: CareFusion has received service reports of a system error on the Alaris PC unit 8015. The Alaris PC units were manufactured between September 1, 2012 through October 22, 2013. Error code 110.6021 is displayed on the PC unit with an audio and visual alarm. The error code may occur upon power on during the “Power-On Self Test” (Figure 1) due to a keypad issue. The Power-On Self Test is designed to occur during power on in order to detect issues prior to initiation of an infusion.

Figure 1: System Error message
**Potential Risk:** The system error occurs upon power on during the "Power-On Self Test". The system error will cause an audible and visual alarm displaying the Error code 110.6021. The system cannot be cleared by restarting or rebooting the PC unit. When the error code occurs this can cause a delay of infusion. A delay of infusion at start up is unlikely to cause harm. There have been no reports of serious injury or death.

**Required Action for Users:**

If system error code 110.6021 occurs;

1. Clinician can utilize another Alaris System PC unit.
2. Clinician can utilize gravity infusions outside the pump or IV syringe push in certain clinical applications.
3. Clearly mark and sequester (e.g. Biomed department) the PC Unit that exhibited the error code.
4. Notify CareFusion Support Center at 888-562-6018 or SupportCenter@carefusion.com.

**Follow-up Actions by CareFusion:** CareFusion has identified the root cause of this issue and will replace the affected front keypad assembly on the Alaris PC unit. CareFusion will contact all affected customers within 60 days to initiate the scheduling process for the remediation.

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:

<table>
<thead>
<tr>
<th>CareFusion Contact</th>
<th>Contact Information</th>
<th>Areas of Support</th>
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</thead>
<tbody>
<tr>
<td>CareFusion Support Center</td>
<td>Phone: 888-562-6018</td>
<td>Recall Related Questions</td>
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<tr>
<td></td>
<td>Phone hours: 7:00am to 4:00pm PT, Monday - Friday</td>
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<tr>
<td></td>
<td>Email: <a href="mailto:SupportCenter@carefusion.com">SupportCenter@carefusion.com</a></td>
<td></td>
</tr>
<tr>
<td>Customer Advocacy</td>
<td>Phone: 888-812-3266</td>
<td>Adverse Event Reports</td>
</tr>
<tr>
<td></td>
<td>Phone hours: 24 hours a day, 7 days a week</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Email: <a href="mailto:customerfeedback@carefusion.com">customerfeedback@carefusion.com</a></td>
<td></td>
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<tr>
<td>Technical Support</td>
<td>Phone: 888-812-3229</td>
<td>Technical Questions Regarding the Alaris System</td>
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<tr>
<td></td>
<td>Phone hours: 6:00am to 5:00pm PT, Monday – Friday</td>
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<tr>
<td></td>
<td>Email: <a href="mailto:DL-US-INF-TechSupport@carefusion.com">DL-US-INF-TechSupport@carefusion.com</a></td>
<td></td>
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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.

Sincerely,

Chuck Donlon
Vice President, Quality and Regulatory Affairs
Infusion Technologies

Enclosures:
- Affected Serial Numbers
- Customer Response Card