URGENT: Medical Device Recall Notification

AFFECTED DEVICE: Alaris® PC unit (Model 8015) software version 9.17

May 13, 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 software version 9.17 related to the cancel functionality when used with the Pump module or Syringe module. This does not affect the PCA module. The issues only occur if the clinician programs an infusion outside the Guardrails limits established by the hospital and uses a specific sequence of steps using the cancel key. This notification details the issue and recommended steps for users to take.

Affected Product: Alaris PC unit model 8015 (PC unit) with software version 9.17. PC unit is used in conjunction with all Alaris System modules including the Pump, Syringe, and PCA modules. The PC unit is used to program the modules as well as provide information regarding module status. This information includes infusion parameters, alarms, and Guardrails limit information. Guardrails software is used in conjunction with the PC unit. It allows hospitals to establish limits for infusion parameters (i.e., medication specific minimum or maximum rates). Hospitals can choose to utilize hard limits which will not allow an infusion to begin if outside the established limits or soft limits that allow starting an infusion only after acknowledgement of being outside the established limits.

Issue: CareFusion has identified an issue related to canceling user inputted values. The issue was identified by CareFusion during routine internal testing of the cancel logic software and does not occur during normal programming. If a clinician programs an infusion outside the hospital established limits, then uses a specific sequence of programming steps using the cancel key, then presses the start key on the infusion parameters verification screen, then the Alaris System will start to infuse the medication outside of Guardrails limits established by the hospital without providing a Guardrails popup notification on the PC unit display. If the issue occurs, an infusion may start that is greater than or lower than the hospital established limits for the specific medication (rate or dose). This could lead to an injury depending on the patient's condition, infusion parameters programmed outside of hospital defined limits, and type of drugs being infused at the time.

This issue has not been reported by customers.

Potential Risk: The issues can be duplicated under atypical manual programming. There have been no reports from customers of this issue and no adverse events reported.

Required Action for Users:

1. Verify all infusion parameter values on the infusion parameters verification screen to ensure proper programming prior to beginning an infusion.
2. For running infusions, infusions outside the Guardrail limits can be identified as follows:
   a. The yellow G icon associated with the channel being outside Guardrails limits is correctly displayed (see Picture 1).
b. The Guardrails summary screen displays the correct soft or hard Guardrails limits (see Picture 2).

3. In the unlikely event of observing this anomaly, the clinician can reprogram the infusion parameters and the pump will function as intended.


Picture 1. Yellow G icon

Picture 2. Guardrails summary screen and channel indicators of Guardrails limit being passed

Follow-up Actions by CareFusion: CareFusion has released a software upgrade to address this issue. CareFusion will contact all affected customers within 60 days to initiate the scheduling process for the software upgrade installation.

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>
</tr>
</thead>
<tbody>
<tr>
<td>CareFusion Support Center</td>
<td>Phone: 888-562-6018&lt;br&gt;Phone hours: 7:00am to 4:00pm PT, Monday - Friday&lt;br&gt;Email: <a href="mailto:SupportCenter@carefusion.com">SupportCenter@carefusion.com</a></td>
<td>Recall Related Questions</td>
</tr>
<tr>
<td>Customer Advocacy</td>
<td>Phone: 888-812-3266&lt;br&gt;Phone hours: 24 hours a day, 7 days a week</td>
<td>Adverse Event Reports</td>
</tr>
</tbody>
</table>

©2015 CareFusion Corporation or one of its subsidiaries All rights reserved. Alaris is a registered trademark of CareFusion Corporation or one of its subsidiaries. All other trademarks are property of their respective owners.
Email: customerfeedback@carefusion.com

Technical Support  Phone: 888-812-3229
Phone hours: 6:00am to 5:00pm PT,
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.

Sincerely,

Chuck Donlon
Vice President, Quality and Regulatory Affairs
Infusion Technologies

Enclosures:
- Affected Serial Numbers
- Customer Response Card
- Frequently Asked Questions (FAQ)