URGENT: Medical Device Recall Notification

AFFECTED DEVICE: Alaris® Pump module (Model 8100) “Delay Until” Option and “Multidose” Feature

April 23, 2014

Dear Valued Alaris® System Customer:

Director of Pharmacy
Director of Biomedical Engineering
Director of Nursing
Director of Risk Management

CareFusion has identified a potential risk with the Alaris® Pump module (model 8100). CareFusion has received a report of a customer experiencing an issue with the “Delay Until” when using the Pump module. This recall notification details the potential risk and recommended steps for users to take.

Affected Units: Alaris Pump module (model 8100) v9.1.18. See Attachment A for a list of affected serial numbers.

Issue: CareFusion has identified a software issue with the Alaris Pump that results in a situation where the Pump module will not properly delay an infusion when the “Delay Until” option or “Multidose” feature is used.

This issue does not impact the “Delay For” option. This issue does not impact the Alaris Syringe Module “Delay Until” option or “Multidose” feature. This issue only impacts the Alaris Pump module software version 9.1.18.

Potential Risk: If the Infusion starts earlier or later than intended and is not immediately detected and stopped by the clinician this could result in serious injury or death.

Required Action for Users: Although no adverse events or deaths have been reported there is a potential for this risk. Do NOT use the Alaris Pump module “Delay Until” option (Figures 1-4).

![Infusion Setup](Figure 1)

![Delay Options](Figure 2)

![Delay Options](Figure 3)

![Delay Options](Figure 4)

© 2014 CareFusion Corporation or one of its subsidiaries. All rights reserved. Alaris, CareFusion and CareFusion logo are trademarks or registered trademarks of CareFusion Corporation or one of its subsidiaries.
Do NOT use the “Multidose” feature (Figure 5).

Included you will find a Tip Sheet which may be used to alert staff that the “Delay Until” option and “Multidose” feature should not be utilized. You may obtain an electronic copy of the Tip Sheet at http://www.carefusion.com/customer-support/alerts-notices. A FAQ is also attached to help address any specific questions related to this issue.

If you experience this issue while using the Alaris Pump module contact CareFusion Customer Advocacy at 888-812-3266.

Follow-up Actions by CareFusion: CareFusion has identified the root cause of this issue and is recommending installation of the previous Alaris Pump module software version 9.1.17 to address this recall. 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>
</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 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 Email: <a href="mailto:customerfeedback@carefusion.com">customerfeedback@carefusion.com</a></td>
<td>Adverse Event Reports</td>
</tr>
<tr>
<td>Technical Support</td>
<td>Phone: 888-812-3229&lt;br&gt;Phone hours: 6:00am to 5:00pm PT, Monday - Friday Email: <a href="mailto:DL-US-INF-TechSupport@carefusion.com">DL-US-INF-TechSupport@carefusion.com</a></td>
<td>Technical Questions Regarding the Alaris System</td>
</tr>
</tbody>
</table>

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 Technologies

Enclosures:
- Affected Serial Numbers
- FAQs
- Tip Sheet
- Customer Response Card