URGENT: Medical Device Recall Notification
[Expansion of Affected Units]

AFFECTED DEVICE: Alaris® Syringe Module (Model 8110)

October 15, 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® Syringe module model 8110 after receiving reports of customers experiencing a channel error on the Alaris Syringe module Model 8110. This recall notification is an expansion of affected units outlined in the CareFusion recall previously issued on July 20, 2015. The following information details the issue and recommended steps for users to take.

Affected Units: Alaris Syringe module model 8110. This notification expands the affected units identified in July 2015, from those manufactured between March 2014 through September 2014, to units shipped prior to July 13, 2015, and in addition of replacement kits for the BOM Housing Assembly Service (Part Number 10010997), Kit Lower Housing / Carriage Block Assembly ROHS (Part Number 49000226), and Kit Lower Housing / Carriage Block Assembly (Part Number 148188-100). See Attachment A for a list of affected serial numbers.

Issue: CareFusion has received customer reports of a channel error on the Alaris Syringe module model 8110 which occurs during an infusion. Error code 351.6740 is displayed on the PC unit with an audio and visual alarm (Figure 1), and a channel error is displayed on the Alaris Syringe module (Figure 2). After the error is cleared on the PCU, the syringe pump is unresponsive to key presses until the next power cycle, or until the module is detached and re-attached.
Potential Risk: The error code will cause an audible and visual alarm on the Alaris PC unit and a channel error on the Alaris Syringe module. After the channel error is cleared on the PC unit, the syringe pump is unresponsive to key presses until the next power cycle, or until the module is detached and re-attached, or clinician finds an alternative pump. The error code can occur during an infusion and can result in an interruption of infusion. An interruption of infusion could result in serious injury or death. There have been reports where medical intervention was required as a result of the interruption of infusion, but there have been no reports of serious injury or death.

Required Action for Users:

For the Alaris Syringe Pump module model 8110:

If system error code 351.6740 occurs:

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

For Alaris Syringe Pump replacement kits:

- BOM Housing Assembly Service (Part Number 10010997)
- Kit Lower Housing / Carriage Block Assembly ROHS (Part Number 49000226)
- Kit Lower Housing / Carriage Block Assembly (Part Number 148188-100)

Contact CareFusion Support Center at 888-562-6018 or SupportCenter@carefusion.com to return the kit and receive a replacement.

Follow-up Actions by CareFusion for the Alaris Syringe Pump module: CareFusion will perform an assessment of the drive train on the affected Alaris Syringe modules, and adjust or replace if necessary. 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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<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>
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<tr>
<td>Customer Advocacy</td>
<td>Phone: 888-812-3266</td>
<td>Adverse Event Reports</td>
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<tr>
<td></td>
<td>Phone hours: 24 hours a day, 7 days a week</td>
<td></td>
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<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</td>
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<td></td>
<td>Phone hours: 6:00am to 5:00pm PT, Monday – Friday</td>
<td>Regarding the Alaris</td>
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<td></td>
<td>Email: <a href="mailto:DL-US-INF-TechSupport@carefusion.com">DL-US-INF-TechSupport@carefusion.com</a></td>
<td>System</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 quality, and the highest level of customer satisfaction. Thank you for your prompt attention to this important matter.

Sincerely,

Chuck Donlon
Vice President, Quality and Regulatory Affairs
Infusion Technologies

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