Dear Valued Alaris™ System Customer:

Director of Biomedical Engineering
Director of Nursing
Director of Risk Management

BD is issuing this Safety Notification letter to inform you of reports of customers experiencing a System Error (error code: 255-16-275) with Alaris System PC unit model 8015 that can result in interruption of infusions. The following information details the scenarios in which this system error can occur and the actions to avoid this error. Your Alaris System will not need to be remediated.

Products included in this notification:

- Alaris System PC unit model 8015.

Issue:
System Error 255-16-275 can occur when a user selects two functions at the same time/rapid succession or not following typical workflows. This results in a synchronization issue between the PC unit and the modules. Below are five examples:

1. Closing the pump module door and in rapid succession (less than 1 second apart) pressing START.
2. Priming and starting system in PAUSE state and then attempting to remove the new syringe.
3. Starting an infusion using the DELAY OPTIONS. Then confirming the delay entry and pressing CHANNEL SELECT on another module at the same time.
4. Locking PCA door before confirming on screen popup that occurs on another module.
5. Pressing CHANNEL OFF on two syringe modules after completion of infusions at the same time.

The enclosed FAQ provides an explanation for this Safety Notification and the User Manual Addendum provides instructions on how to avoid the System Error.

Potential Risk:
The System Error would result in a non-silenceable, high priority alarm and status indicator lights on modules will flash red. The PC unit displays an error code of 255-16-275. If the system error occurs, all attached modules that are actively infusing will continue to infuse without the ability to titrate infusion parameters. The user may decide to reboot the system or re-program the device to titrate the infusion and/or to silence the alarms. This could
result in the clinical decision to interrupt the infusions. An interruption in infusion can result in serious injury.

**Required Action for Users:**
Your Alaris System will not need to be remediated. Refer to the User Manual Addendum to avoid the occurrence of this System Error.

If the System Error occurs, the Alaris System modules will continue as programmed. Do not interrupt critical infusions if infusion parameters do not need to be edited. If it is safe to do so, manually stop the infusion in order to reprogram and re-start the pump following the instructions in the User Manual Addendum to avoid this error.

Power down the PC unit by pressing the SYSTEM ON key. Restart the device by pressing the SYSTEM ON key. Restart previous infusions and/or monitoring settings. If the System Error returns, power down the PC unit and replace it immediately. Return the PC unit to your Biomedical Engineering department for troubleshooting and data log retrieval.

**Follow-up Actions by BD:**
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

If you have any questions regarding the products, please contact:

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<tr>
<th>BD Contact</th>
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| BD Support Center | Phone: 888-562-6018
                     | Phone hours: 7:00am to 4:00pm PT, Monday - Friday
                     | Email: SupportCenter@carefusion.com                                               | General Follow-up Questions                           |
| Technical Support | Phone: 888-812-3229
                     | Phone hours: 5:00am to 5:00pm PT, Monday - Friday
                     | Email: DL-US-INF-Tech-Support@carefusion.com                                      | Technical Questions related to this notification      |
| 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                                                            |

Please promptly complete and return the enclosed Customer Response Card to acknowledge receipt of this notification.

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BD sincerely regrets the inconvenience this may cause you. BD is committed to serving your infusion product needs and our primary objectives are patient safety, exceptional product reliability, and the highest level of customer support. Thank you for your continued support while we address these challenges.

Sincerely,

[Signature]

Keith McLain
Vice President, Quality
Infusion Systems

Enclosures:
- FAQs
- User Manual Addendum
- Customer Response Card