CareFusion, a wholly-owned subsidiary of
Becton, Dickinson and Company (BD)
10020 Pacific Mesa Blvd
San Diego, CA 92121

www.bd.com

Urgent Medical Device Recall
BD Alaris™ Pump Module Model 8100
Pump Module Door Assembly Replacement Kits

August 4, 2020

Dear Valued BD Alaris™ System Customer:
Director of Biomedical Engineering
Director of Nursing
Director of Risk Management

BD is initiating a voluntary recall for the BD Alaris™ Pump Module Model 8100 to inform you that the keypad may exhibit unresponsive or stuck keys as a result of fluid ingress. This issue may potentially result in a delay to the start of infusion or an interruption of infusion.

Affected Products
- BD Alaris™ Pump Module Model 8100 manufactured from December 1, 2016, to January 23, 2019
- Pump Module Door Assembly Replacement Kits labeled with a date prior to January 25, 2019. Affected part numbers: 49000239; 49000346; 49000438; 49000439

See *Attachment A* for a list of affected Alaris™ Pump Module 8100 serial numbers. If applicable, *Attachment A* will also include the quantity of replacement kits shipped.

Issue:
The affected BD Alaris™ Pump Module keypads may have one or more keys that become unresponsive or stuck (i.e., constantly pressed state) due to fluid ingress.

- If the keys become unresponsive, the module will continue to infuse as programmed. The unresponsive keypad on the module will not trigger an alarm on the PC unit, and all programming changes must be made on the PC unit.
- If a key gets stuck, the Alaris™ PC unit will alarm and the module will exhibit a Channel Error on the scrolling marquee, which will result in an interruption of infusion.

Potential Risks:
An unresponsive keypad could result in a delay to the start of an infusion or inability to titrate medication. If editing of programmed settings is critical, it may be necessary to interrupt and restart the infusion using a different Pump Module.

A stuck key on the Alaris™ Pump Module keypad could result in a delay to the start of an infusion or interruption of infusion.

High-risk patient populations who are receiving life-sustaining infusions are at the greatest risk of harm. For these patients, delay or interruption of an infusion can cause serious injury or death. BD has assessed the risk of this issue and determined that the Alaris™ Pump Modules can still be used until the affected keypads are replaced.

Between December 1, 2016, and July 30, 2020, BD received no reports of permanent injury or death that are potentially related to this issue.

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Actions for Clinical Users:
Clinicians should remove the pump from service and send to Biomedical Engineering if the Pump Module keypad becomes unresponsive or stuck. If a critical medication is being administered, continue the infusion until it is safe to replace the Pump Module. In an urgent situation, clinicians can close the roller clamp on the IV administration set to stop an infusion.

Actions for Cleaning Personnel:
Follow the cleaning instructions provided in the current Directions for Use to minimize the potential for fluid ingress during cleaning.

- Do not use a cloth that drips. Be sure to wring out the cleaning cloth to squeeze out excess fluid.
- Do not spray fluids directly onto the device.

Actions for Biomedical Engineering:
Inspect all uninstalled Pump Module Door Assembly Replacement Kits noted above. All kits dated prior to January 25, 2019 are affected. If affected kits are found upon inspection, dispose per facility guidelines. An example of how to identify the date on the keypad is provided below:

- Contact BD at 1-800-482-4822 to order replacement Pump Module keypad kits at no charge (either discarded by your facility or needed for remediation of the Pump Module),
- Contact the BD Recall Support Center at 1-888-562-6018 to schedule remediation of the pump module at no charge if unable to perform at your location.
- Maintain a list of all Pump Module serial numbers remediated to provide to BD upon completion of the activity.

Please promptly complete and return the enclosed Customer Response Form to acknowledge receipt of this notification and the recall instructions provided in this letter.

Actions for BD Alaris™ System rental providers:
Provide a copy of this letter to your customers who are currently renting BD Alaris™ System devices.

Actions by BD:
BD redesigned and implemented the Alaris™ Pump Module keypad in January 2019. The Alaris™ Pump Module keypads on the affected units will be replaced at no charge. BD will contact all affected customers to confirm or schedule remediation.

The U.S. 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

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

Contact	Contact Information	Areas of Support
BD Customer Advocacy	Phone: 888-812-3266 Phone hours: 7:00am to 5:00pm PT Monday – Friday Email: customerfeedback@bd.com	Product Complaints
Training Resources	BD has established a website for easy access to resources and to support customers with this recall. Please visit www.bd.com/alaris-system-hardware-recall	Resources to support this notification
BD Recall Support Center	Phone: 888-562-6018 Phone hours: 7:00am to 4:00pm PT, Monday – Friday Email: SupportCenter@bd.com	Recall Related Questions
Technical Support	Phone: 888-812-3229 Phone hours: 6:00am to 5:00pm PT, Monday – Friday Email: DL-US-INF-TechSupport@bd.com	Technical Questions
Customer Order Management	Phone: 1-800-482-4822 Phone hours: 8:00 AM-5:00 PM CT Email: GMB-CTS-CustCareInfusion@bd.com	Replacement Parts Orders

BD's actions are guided by our commitment to patient safety and minimizing disruption of patient care. We regret the inconvenience that may result from this recall and are committed to achieving the highest levels of customer satisfaction and serving your infusion product needs.

Sincerely,

Mark Neal
Vice President of Quality Assurance

Idal Beer, MD
Vice President of Medical Affairs
Medication Management Solutions

Enclosures:
- Attachment A: Affected Serial Numbers and Replacement Kits
- Attachment B: Customer Response Form

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Attachment B

Medical Device Recall
Customer Response Form
Alaris™ Pump Module Model 8100
Pump Module Door Assembly Replacement Kits:
(P/N 49000346, 49000239, 49000438, 49000439)
(MMS-20-3817)

Please assist us in making this Medical Device Recall Notification follow-up process efficient and convenient for you by completing and returning this form to BD via email or fax. This response form serves as a confirmation that you have read and understood this notification and will take the recommended actions. A cover sheet is not required.

EMAIL: BDRC21@bd.com **FAX: 1-312-949-0437**

(PLEASE PRINT)

Facility Name: _____

Facility Address: _____

_____

_____

Completed By: _____

Title: _____ Phone: _____

Email: _____

Signature: _____ Date: _____