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™ PC Unit Model 8015
PC Unit Front Case with Keypad 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™ PC Unit to inform you that the PC unit keypad may exhibit unresponsive or stuck keys as a result of fluid ingress potentially resulting in a delay to the start of infusion or interruption of infusion.

Affected Products
BD Alaris™ PC Unit model 8015 manufactured from April 7, 2017 to present
PC Unit Front Case with Keypad Replacement Kits

- TC10008389 ASSY CASE FRONT W/KEYPAD 8015LS
- TC10010217 ASSY FRT CASE W/ KEYPAD 8015 M2
- TC10012515 ASSY FR CASE W/ KEYPAD 8015 M2
- TC10013702 ASSY, CASE, FRONT W/KEYPAD, 8015LS
- TC10013664 ASSY FR CASE W/ KEYPAD 8015 M2

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

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

In both situations, the modules continue to infuse as programmed; however, there is an inability to make programming changes.

- The PC unit will not alarm for the unresponsive keypad.
- If the keys become stuck, the PC unit will alarm and exhibit a System Error.

Potential Risks:
BD has assessed the risk of this issue and determined that the Alaris™ PC unit can continue to be used until BD replaces the affected keypads.

An unresponsive keypad or stuck key could result in a delay to the start of an infusion or an inability to titrate medication. If editing of programmed settings is critical, it may be necessary to interrupt and restart the infusion using a different PC unit. High-risk patient populations who are receiving life-sustaining infusions are at the greatest risk of harm. For these patients, delays or interruption of infusion can cause serious injury or death.

Between April 7, 2017, and July 30, 2020, BD has received one report of serious injury that is potentially related to this issue. No reports of permanent injury or death have been attributed to this issue.

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Actions for Clinical Users:
If the PC unit keypad becomes unresponsive or a key gets stuck, clinicians should remove the device from service and send to Biomedical Engineering. If you are administering a critical medication, continue the infusion until it is safe to replace the PC unit.

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:
If an affected PC unit has an unresponsive keypad or stuck key, please remove the unit from service and contact BD at 1-800-482-4822 to order a replacement keypad at no charge or call the BD Recall Support Center at 1-888-562-6018 to send the module to the BD Service Depot for repair at no charge. Until the release of a redesigned PC unit keypad and 510(k) clearance, the affected PC unit keypad design will continue to be provided for replacement or repair.

Inspect all PC unit keypads for bubbling, cracks, damage, layer separations, and holes. Replace the front case keypad if it fails inspection.

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:

Please provide a copy of this letter and enclosures to your customers who are currently renting BD Alaris™ System devices.

Actions by BD:
BD is currently working on a design change for the PC unit keypad and will notify customers when replacement keypads are available. BD will contact all affected customers to schedule remediation upon 510(k) clearance of the BD Alaris™ System, including the addition of the redesigned PC unit keypad. Alaris™ PC unit keypads on the affected units and replacement kits will be provided at no charge.

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

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Medical Device Recall
Customer Response Form
Alaris™ PC Unit model 8015
PC Unit Front Case with Keypad Replacement Kits:
(P/N TC10008389, TC10010217, TC10012515, TC10013702, TC10013664)
MMS-20-3845

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: _____