



URGENT: FIELD SAFETY NOTICE – MMS-21-3991

**BD Alaris™ Pump Module Model 8100
Pump Module Door Assembly Replacement Kits**

March 3, 2021

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

BD is initiating an advisory Field Safety Notice for the BD Alaris™ Pump Module Model 8100 due to potential lifting of the keypad, which could result in one or more keys becoming unresponsive or stuck (i.e., constantly pressed state) due to fluid ingress. This issue may potentially result in a delay to the start of infusion or an interruption of infusion. BD has identified this unique supplier manufacturing issue for Alaris™ System pump modules manufactured between January 23, 2019 to December 5, 2019.

Please note, this Field Safety Notice is separate from the BD Alaris Pump Module 8100 keypad Field Safety Notice dated August 4, 2020.

If you had previously remediated devices affected by the August 4, 2020 Pump Module Keypad Field Safety Notice, those devices will not need to be remediated a second time, as a result of this Field Safety Notice. Please be advised your action is still needed to remediate the devices affected by this Field Safety Notice.

Affected Products:

- BD Alaris™ Pump Module Model 8100 manufactured January 23, 2019 to December 5, 2019.
- Pump Module Door Assembly Replacement Kits labeled with a date range of January 15, 2019 to November 14, 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.

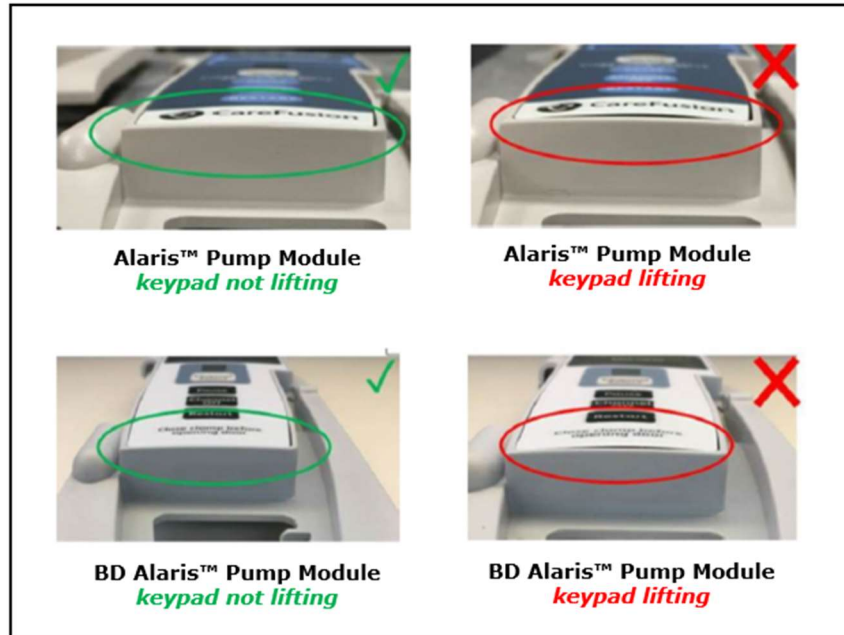
Issue:

The affected BD Alaris™ Pump Module keypads may exhibit keypad lifting, which could result in one or more keys becoming unresponsive or stuck (i.e., constantly pressed state) due to fluid ingress. Please see Figure 1 for an example of a keypad with no lifting compared to a keypad exhibiting lifting.

- 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.



Figure 1. Alaris™ Pump Module and BD Alaris™ Pump Module demonstrating keypad without lifting compared to a keypad exhibiting lifting.



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.

BD has received no reports of permanent injury or death that are potentially related to this issue.

Actions for Clinical Users:

Clinicians should remove the pump from service and send to Biomedical Engineering if the Pump Module keypad shows signs of lifting, 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.

If Pump Module keypad lifting or stuck or unresponsive keys are observed, remove the pump from service and send to Biomedical Engineering.

Actions for Biomedical Engineering:

1) Remediation of Pump Module Door Assembly Replacement Kits

All Pump Module Door Assembly Replacement Kits dated from January 15, 2019 to November 14, 2019, should be disposed per facility guidelines. Contact BD to order replacement Pump Module keypad kits at no charge. An example of how to identify the date on the keypad is provided below:



2) Remediation of Pump Module Keypads

Please refer to *Attachment A* for a list of affected serial numbers or visit bd.com/mms-21-3991

3) Customer Reply Form

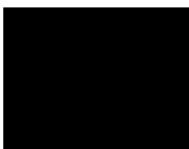
Please promptly complete and return the enclosed Customer Reply Form to acknowledge receipt of this notification and the Field Safety Notice instructions provided in this letter and send it to DL-EMA-INF-Tech-Support@bd.com

Actions by BD:

The root cause was identified as a supplier manufacturing process issue and has been resolved. Corrective actions have been validated and implemented. Any Alaris™ Pump Module keypads on the affected units will be replaced at no charge. BD local representative will coordinate the replacement process.

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 Field Safety Notice and are committed to achieving the highest levels of customer satisfaction and serving your infusion product needs.

Sincerely,



Jeff Fecho
Vice President, Quality Management
Medication Management Solutions



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



Customer Acknowledgement Form – MMS-21-3991

BD Alaris™ Pump Module Model 8100 Pump Module Door Assembly Replacement Kits

Please read in conjunction with Product Notification MMS-21-3991 and return the completed and signed form as soon as possible or **no later than March 31st, 2021**, to DL-EMA-INF-Tech-Support@bd.com

By completing the information below you confirm you have read, understood, and distributed the contents of this Product Notification accordingly.

Name of Company	
Email Address	
Telephone Number	
Name	
Signature	
Date	

Serial#	Material	Manufacture Date
15527072	8100TDXEN933	03/22/2019
15527083	8100TDXEN933	03/22/2019
15527088	8100TDXEN933	03/22/2019
15527089	8100TDXEN933	03/22/2019
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