CareFusion 303, Inc.
10020 Pacific Mesa Blvd
San Diego, CA 92121
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URGENT MEDICAL DEVICE RECALL: UPDATED NOTICE
MMS-25-5311-FA

BD Alaris™ Pump Module Model 8100 associated with all BD Alaris™ Guardrails Suite MX software versions up to v12.5

BD Alaris™ Compatible Pump Infusion Sets

December 2025 Update: BD is notifying customers of new information regarding a subset of impacted BD Alaris™ Pump infusion sets. This is an update to the recall notice provided on September 11, 2025.

Date: December 12, 2025

For the Attention of:
Director of Nursing
Director of Risk Management
Director of Pharmacy
Director of Supply Chain and Inventory Management

On September 11, 2025, BD issued an updated recall notice (MMS-25-5311-FA, Attachment A) which included revised performance data and important safety information for certain BD Alaris™ compatible pump infusion sets when used with the BD Alaris™ Pump Module Model 8100.

In this notice, BD is providing important updates regarding product discontinuation and new labeling for a subset of BD Alaris™ compatible pump infusion sets.

Discontinuation of Infusion Sets:
BD previously communicated the discontinuation of fifteen (15) BD Alaris™ Pump Infusion Sets in scope of this recall (**Table 1**). Subsequently, BD has made the commercial decision to discontinue seven (7) additional BD Alaris™ Pump Infusion Sets (**Table 2**) for a total of twenty-two (22) discontinued sets. The decision to discontinue these seven (7) additional BD Alaris™ Pump Infusion Sets was made to streamline the BD Alaris™ Pump Module Infusion Set portfolio.

Table 1:

Previously Discontinued Sets	Catalog No.	UDI
BD Alaris™ Pump Infusions Set, Amber Tubing, 15 Micron Filter, 0.2 Micron Filter, SmartSite™ Y-Site	C24101E	10885403235528
BD Alaris™ Pump Infusion Blood Set, 180 Micron Filter	10015414	10885403233999
BD Alaris™ Pump Infusion Burette Set Ball Valve SmartSite™ Port (Burette) 2 SmartSite™ Y-Sites	2447-0007	10885403235078
BD Alaris™ Pump Infusion Set, 2 SmartSite™ Y-sites	24201-0007	10885403476341
BD Alaris™ Pump Infusion Set, Back Check Valve, Non-vented, SmartSite™ Y-site	10012645	10885403233753
BD Alaris™ Pump Infusion Set, Back Check Valve, 3 SmartSite™ Y-sites	2426-0500	7613203020992

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BD Alaris™ Pump Infusion Set Back Check Valve 2 Ganged 3-Way Stopcocks 3 SmartSite™ Y-sites	2450-0500	10885403235115
BD Alaris™ Pump Infusion Set, Ball Valve, Back Check Valve, 3 SmartSite™ Y-sites	11522558	10885403232305
BD Alaris™ Pump Infusion Set, 2 SmartSite™ Y-Sites	2410-0500	7613203012492
BD Alaris™ Pump Infusion Set, 0.2 Micron Filter	2232-0007	10885403463969
BD Alaris™ Pump Infusion Burette Set, 0.2 Micron Filter, Ball Valve, SmartSite™ Port (Burette), 2 SmartSite™ Y-sites	11613191	10885403276026
BD Alaris™ Pump Infusion Set, 3 SmartSite™ Y-Sites, Check Valve	10012144	7613203021159
BD Alaris™ Pump Infusion Set, 3 SmartSite™ Y-Sites, Check Valve, 2-Ganged 4-way Stopcock	10013034	10885403232312
BD Alaris™ Pump Blood Set, Non-Vented, 180 Micron Filter, Low Sorbing Tubing Segment, 1 SmartSite™, Y-Site	10013037	10885403233784
BD Alaris™ Pump Infusion Set: 3 SmartSite™ Y-Sites, Check Valve, 2-Ganged 3-way Stopcock	11582773	10885403239588

Table 2:

Newly Discontinued Sets	Catalog No.	UDI
BD Alaris™ Pump Infusion Set, 0.2 Micron Filter, Back Check Valve, SmartSite™ Y-site	2434-0007	07613203019682
BD Alaris™ Pump Infusion Set, Back Check Valve, 3 SmartSite™ Y-sites	10013186	07613203021173
BD Alaris™ Pump Infusion Set, 2 Back Check Valves, 3 SmartSite™ Y-sites	2452-0007	10885403219870
BD Alaris™ Pump Infusion Set, Back Check Valve, SmartSite™ Y-site	24001-0007	10885403238666
BD Alaris™ Pump Infusion Set, 15 Micron Filter	10863358	10885403232466
BD Alaris™ Pump Infusion Set, Back Check Valve, 2 Ganged 4-Way Stopcocks, 3 SmartSite™ Y-sites	10015896	10885403234064
BD Alaris™ Pump Infusion Set, Half Set, SmartSite™ Y-site	2403-0007	10885403232473

For the twenty-two (22) discontinued BD Alaris™ Pump Infusion Sets, BD is requesting that customers transition to alternative infusion sets and remove and discard any remaining discontinued SKUs within their inventory. Customers can reach out to BD Clinical Consultants and Account Executives for help with identifying alternative sets based on their clinical needs.

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Updated Labeling:

BD is updating the labeling of the following BD Alaris™ Pump Infusion Sets (**Table 3**) that were included within the scope of the September 11, 2025 recall notice:

Table 3:

Product Description: Updated Labeling	Catalog No.	UDI
BD Alaris™ Pump Infusion Set, 1.2 Micron Filter	2202-0007	10885403274039
BD Alaris™ Pump Infusion Set	2204-0007	10885403199363
BD Alaris™ Pump Infusion Set, 0.2 Micron Filter, Back Check Valve, 3 SmartSite™ Y-sites	2432-0007	10885403232329
BD Alaris™ Pump Infusion Set, 15 Micron Filter, Back Check Valve, 3 SmartSite™ Y-sites	10561554	10885403232565
BD Alaris™ Pump Infusion Set, 2 Back Check Valves, 3 SmartSite™ Y-sites	11171447	07613203021234
BD Alaris™ Pump Infusion Set, Back Check Valve, 5 SmartSite™ Y-sites	11426965	10885403232558

The infusion set product labeling will contain the following **new warnings** related to the performance of the infusion sets with the Pump Module:

- DO NOT use with flow rates below 1 mL/h unless clinically indicated and no alternatives, such as the syringe module, are available.
- DO NOT administer bolus volumes below 5 mL on the Pump Module unless clinically indicated and no alternatives, such as manual IV push or the syringe module, are available.
- ALWAYS USE the lowest occlusion pressure setting possible and consider disconnecting the tubing or relieving excess pressure when a downstream occlusion is cleared to minimize the creation of an unintended bolus (over infusion).

The above warnings are particularly important when infusing high-risk or life sustaining medications to high-risk patient population groups. Failure to adhere to these warnings may lead to serious adverse events including patient harm or death.

The infusion set product labeling will also be updated to contain performance values specific to each set relating to rate accuracy, bolus accuracy, upstream and downstream occlusion time to alarm, and post-occlusion bolus volume. The set-specific performance data is included in Attachment B. ***Please note that the set-specific data in Attachment B supersedes the values previously communicated in the September 11, 2025, recall notification.***

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Actions For Customers and Distributors:

1. Review your inventory for the catalog numbers listed in Tables 1 and 2 above. Remove and discard any remaining inventory per your facility guidelines.
2. To receive credit for discarded product, please return the completed customer response form attached to this notice.
3. Please contact your BD Clinical Consultants and Account Executives for alternative sets information.
4. Review the updated sets performance data in Attachment B.
5. Circulate this notice within your facility network to ensure that all concerned personnel are made aware of this issue.
6. Distributors should provide a copy of this notice to all customers who may have purchased a BD Alaris™ Pump Module.

Actions Taken by BD:

1. BD has discontinued sales of the catalog numbers listed in Table 1 and Table 2 above, effective immediately.
2. BD Clinical Consultants and Account Executives can help with identifying alternative sets, where available.
3. BD will issue credit for all unused inventory upon receipt of the completed customer response form.
4. BD will be implementing updated labeling in manufacturing for the infusion sets listed above in Table 3.

Attachments:

Attachment A: Customer Letter September 11, 2025
Attachment B: Updated Performance Data

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Contact Information:
If you require further assistance, please contact:

BD Contact	Contact Information	Areas of Support
Post Market Quality Operations	Email: BDRC49@bd.com	Customer Response Forms
BD Alaris™ Medical Affairs	Email: Alarismedicalaffairs@bd.com	Clinical Questions
BD Technical Support	Phone: 866-488-1408 Phone hours: 5:00 am to 5:00 pm PT Monday – Friday **Create a case at:** https://bd.com/self-service	Technical Service / Customer Service

BD is committed to advancing the world of health. Our primary objectives are patient and user safety and providing you with quality products. We apologize for any inconvenience this issue may have caused you and thank you in advance for helping us to resolve this matter as quickly and effectively as possible.

Sincerely,

Chad Modra
Vice President, Quality Management
Medication Management Solutions

Idal Beer
SVP, Medical Affairs
Medication Management Solutions

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Attachment B: Updated Performance Data

SKU 2202-0007 Pump Set Performance Values

Rate Accuracy[1] [Flow Rates]	Bolus Accuracy – Loading Dose[1,3] [Bolus Volumes]	Bolus Accuracy – Subsequent Doses[1,4] [Bolus Volumes]	Downstream Occlusion Time to Alarm[1,2] [Flow Rates]	Upstream Occlusion Time to Alarm[1] [Flow Rates]	Post- Occlusion Bolus Volume[1] [Flow Rates]
±5% [1 - 999 mL/h] **-8% to +5.5%** [Less than 1 mL/h]	**-3.5% to +3.8%** [greater than or equal to 5 mL] **-11.7% to +6.8%** [1 - less than 5 mL] **-9.2% to +49.8%** [Less than 1 mL]	**±5%** [5 - 999 mL] **±10%** [1 - less than 5 mL] **0% to +55%** [Less than 1 mL]	**5 min 8 sec or less** [1 - 999 mL/h] **1 h 7 min or less** [Less than 1 mL/h]	**5 min or less** [5 - 999 mL/h] **22 min or less** [1 – less than 5 mL/h] **3 h 43 min or less** [Less than 1 mL/h]	**0.5 mL or less** [0.1 - 999 mL/h]

1. Test data applicable to infusion set SKU 2202-0007
2. Downstream occlusion time to alarm tested with "Pump Mode" pressure setting
3. A bolus delivered by the Pump Module at the beginning of an infusion is also known as a loading dose
4. Subsequent bolus dose worst case data is collected without a running continuous infusion

Note: Data represents performance at environmental standard operating conditions

SKU 2204-0007 Pump Set Performance Values

Rate Accuracy[1] [Flow Rates]	Bolus Accuracy – Loading Dose[1,3] [Bolus Volumes]	Bolus Accuracy – Subsequent Doses[1,4] [Bolus Volumes]	Downstream Occlusion Time to Alarm[1,2] [Flow Rates]	Upstream Occlusion Time to Alarm[1] [Flow Rates]	Post-Occlusion Bolus Volume[1] [Flow Rates]
±5% [1 - 999 mL/h] **-8.7% to +5.5%** [Less than 1 mL/h]	**-3.5% to +3.6%** [greater than or equal to 5 mL] **-11.7% to +6.1%** [1 - less than 5 mL] **-11.2% to +52.7%** [Less than 1 mL]	**±5%** [5 - 999 mL] **±10%** [1 - less than 5 mL] **0% to +55%** [Less than 1 mL]	**5 min or less** [1 - 999 mL/h] **1 h 25 sec or less** [Less than 1mL/h]	**5 min or less** [5 - 999 mL/h] **24 min 51 sec or less** [1 – less than 5 mL/h] **3 h 40 min or less** [Less than 1 mL/h]	**0.5 mL or less** [0.1 - 999 mL/h]

1. Test data applicable to infusion set SKU 2204-0007
2. Downstream occlusion time to alarm tested with "Pump Mode" pressure setting
3. A bolus delivered by the Pump Module at the beginning of an infusion is also known as a loading dose
4. Subsequent bolus dose worst case data is collected without a running continuous infusion

Note: Data represents performance at environmental standard operating conditions

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SKU 2432-0007 Pump Set Performance Values

Rate Accuracy[1] [Flow Rates]	Bolus Accuracy – Loading Dose[1,3] [Bolus Volumes]	Bolus Accuracy – Subsequent Doses[1,4] [Bolus Volumes]	Downstream Occlusion Time to Alarm[1,2] [Flow Rates]	Upstream Occlusion Time to Alarm[1] [Flow Rates]	Post-Occlusion Bolus Volume[1] [Flow Rates]
±5% [1 - 999 mL/h] **-9% to +5.5%** [Less than 1 mL/h]	**-4.7% to +3.4%** [greater than or equal to 5 mL] **-11.7% to +11.5%** [1 - less than 5 mL] **-15.1% to +102.4%** [Less than 1 mL]	**±5%** [5 - 999 mL] **±10%** [1 - less than 5 mL] **0% to +55%** [Less than 1mL]	**5 min or less** [2 - 999 mL/h] **8 min 25 sec or less** [1 – less than 2 mL/h] **1 h 57 min or less** [Less than 1 mL/h]	**5 min or less** [5 - 999 mL/h] **22 min or less** [1 – less than 5 mL/h] **3 h 44 min or less** [Less than 1mL/h]	**0.5 mL or less** [0.1 - 999 mL/h]

1. Test data applicable to infusion set SKU 2432-0007
2. Downstream occlusion time to alarm tested with "Pump Mode" pressure setting
3. A bolus delivered by the Pump Module at the beginning of an infusion is also known as a loading dose
4. Subsequent bolus dose worst case data is collected without a running continuous infusion

Note: Data represents performance at environmental standard operating conditions

SKU 10561554 Pump Set Performance Values

Rate Accuracy[1] [Flow Rates]	Bolus Accuracy – Loading Dose[1,3] [Bolus Volumes]	Bolus Accuracy – Subsequent Doses[1,4] [Bolus Volumes]	Downstream Occlusion Time to Alarm[1,2] [Flow Rates]	Upstream Occlusion Time to Alarm[1] [Flow Rates]	Post-Occlusion Bolus Volume[1] [Flow Rates]
-5.1% to +5.0% [1 - 999 mL/h] **-9.6% to +5.5%** [Less than 1 mL/h]	**-4.0% to +5.0%** [greater than or equal to 5 mL] **-11.7% to +9.7%** [1 - less than 5 mL] **-3.3% to +87.8%** [Less than 1 mL]	**±5%** [5 - 999 mL] **±10%** [1 - less than 5 mL] **0% to +55%** [Less than 1 mL]	**5 min 21 sec or less** [1 - 999 mL/h] **1 h 32 min or less** [Less than 1 mL/h]	**4 min 29 sec or less** [5 - 999 mL/h] **22 min 24 sec or less** [1 – less than 5 mL/h] **3 h 55 min or less** [Less than 1 mL/h]	**0.3 mL or less** [0.1 - 999 mL/h]

1. Test data applicable to infusion set SKU 10561554
2. Downstream occlusion time to alarm tested with "Pump Mode" pressure setting
3. A bolus delivered by the Pump Module at the beginning of an infusion is also known as a loading dose
4. Subsequent bolus dose worst case data is collected without a running continuous infusion

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SKU 11171447 Pump Set Performance Values

Rate Accuracy[1] [Flow Rates]	Bolus Accuracy – Loading Dose[1,3] [Bolus Volumes]	Bolus Accuracy – Subsequent Doses[1,4] [Bolus Volumes]	Downstream Occlusion Time to Alarm[1,2] [Flow Rates]	Upstream Occlusion Time to Alarm[1] [Flow Rates]	Post-Occlusion Bolus Volume[1] [Flow Rates]
±5% [1 - 999 mL/h] **-8% to +5.5%** [Less than 1 mL/h]	**-4.3% to +5.8%** [greater than or equal to 5 mL] **-11.7% to +8.3%** [1 - less than 5 mL] **-22.7% to +73.3%** [Less than 1 mL]	**±5%** [5 - 999 mL] **±10%** [1 - less than 5 mL] **0% to +55%** [Less than 1 mL]	**5 min or less** [1 - 999 mL/h] **1 h 6 min or less** [Less than 1 mL/h]	**5 min or less** [5 - 999 mL/h] **23 min or less** [1 – less than 5 mL/h] **3 h 46 min or less** [Less than 1mL/h]	**0.3 mL or less** [0.1 - 999 mL/h]

1. Test data applicable to infusion set SKU 11171447
2. Downstream occlusion time to alarm tested with "Pump Mode" pressure setting
3. A bolus delivered by the Pump Module at the beginning of an infusion is also known as a loading dose
4. Subsequent bolus dose worst case data is collected without a running continuous infusion

Note: Data represents performance at environmental standard operating conditions

SKU 11426965 Pump Set Performance Values

Rate Accuracy[1] [Flow Rates]	Bolus Accuracy – Loading Dose[1,3] [Bolus Volumes]	Bolus Accuracy – Subsequent Doses[1,4] [Bolus Volumes]	Downstream Occlusion Time to Alarm[1,2] [Flow Rates]	Upstream Occlusion Time to Alarm[1] [Flow Rates]	Post-Occlusion Bolus Volume[1] [Flow Rates]
±5% [1 - 999 mL/h] **-8% to +5.5%** [Less than 1 mL/h]	**-5.0% to +6.6%** [greater than or equal to 5 mL] **-11.7% to +9.9%** [1 - less than 5 mL] **-12.2% to +96.4%** [Less than 1 mL]	**-5.6% to +5%** [5 - 999 mL] **±10%** [1 - less than 5 mL] **0% to +55%** [Less than 1 mL]	**5 min 34 sec or less** [1 - 999 mL/h] **1 h 50 min or less** [Less than 1 mL/h]	**5 min or less** [5 - 999 mL/h] **23 min or less** [1 – less than 5 mL/h] **3 h 44 min or less** [Less than 1mL/h]	**0.3 mL or less** [0.1 - 999 mL/h]

1. Test data applicable to infusion set SKU 11426965
2. Downstream occlusion time to alarm tested with "Pump Mode" pressure setting
3. A bolus delivered by the Pump Module at the beginning of an infusion is also known as a loading dose
4. Subsequent bolus dose worst case data is collected without a running continuous infusion

Note: Data represents performance at environmental standard operating conditions

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CUSTOMER RESPONSE FORM- UPDATED NOTICE

BD Alaris™ Pump Module Model 8100 associated with all BD Alaris™ Guardrails Suite MX software versions up to v12.5

BD Alaris™ Compatible Pump Infusion Sets

Please assist BD by acknowledging this field action using one of the following methods:

URL:https://bdx.my.site.com/CC360/s/impactedproducts?rn=MMS-25-5311

Email: BDRC49@bd.com
Fax No.: (312) 949-0068

Facility:

Please print full, current facility name. Do not use initials.

Street Address: _____

City:_____ **State**: _____ **Zip**: _____

Response Form Completed By:	
Name:	
Title:	
Telephone No.:	
Fax No.:	
Email Address:	

Please check all that apply:

☐ I have read and understood the attached notice and taken appropriate actions.

☐ **For distributors:** I have provided a copy of this recall notification to all customers who have purchased BD Alaris™ Pump Modules.

☐ We do not have any of the affected product(s) on hand.

☐ I have discarded all affected product indicated below as available inventory at the time of receipt of this notification and request credit for the following units:

Product Description: Newly Discontinued Sets	Catalog No.	QTY in Eaches
BD Alaris™ Pump Infusion Set, 0.2 Micron Filter, Back Check Valve, SmartSite™ Y-site	2434-0007	
BD Alaris™ Pump Infusion Set, Back Check Valve, 3 SmartSite™ Y-sites	10013186	
BD Alaris™ Pump Infusion Set, 2 Back Check Valves, 3 SmartSite™ Y-sites	2452-0007	

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BD Alaris™ Pump Infusion Set, Back Check Valve, SmartSite™ Y-site	24001-0007	
BD Alaris™ Pump Infusion Set, 15 Micron Filter	10863358	
BD Alaris™ Pump Infusion Set, Back Check Valve, 2 Ganged 4-Way Stopcocks, 3 SmartSite™ Y-sites	10015896	
BD Alaris™ Pump Infusion Set, Half Set, SmartSite™ Y-site	2403-0007	

If a specific Catalog No. is not applicable, please enter 'N/A' in the table above

Please assist BD with assuring that these communications are delivered to the appropriate person/function within your facility if that is not you.

Name:	
Title:	
Telephone No.:	
Fax No.:	
Email Address:	

This response includes responses for the following locations as well:

Facility	Street Address	City	State	Zip

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