Alaris™ Pump module Model 8100

Frequently Asked Questions (FAQ's)

BD is issuing this letter to inform you of a potential risk associated with the Alaris™ Pump module. We have identified a specific scenario that could cause unintended flow in the older, centered sear door latch design in the Alaris Pump module model 8100. This scenario is reproducible under the following situations: a) the user does not close the roller clamp on the IV administration set before the pump door is opened as recommended, and b) opening the pump door using an atypical technique with the door latch with the centered sear design. The following FAQs are for the customer letter dated on June 12, 2017.

General Questions

1. What device is affected?

Alaris Pump module model 8100 (Large Volume Pump) manufactured or serviced by the BD Service Depot from June 2002 to June 2004.

Alaris Pump module door latch kit (P/N 147503-000) shipped from June 2002 to June 2004.

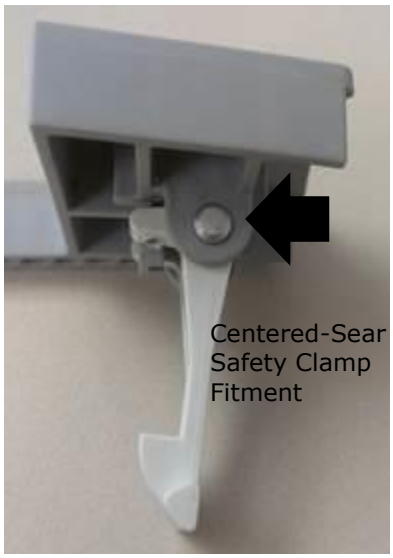
2. What is the issue associated with the Alaris Pump module?

User can reproduce a free-flow condition if the clinician does not close the roller clamp on the IV administration set prior to opening the pump door and the pump door is opened by using a "flick" of the door latch that causes the door to "pop" open instead of opening the door by slowly raising the latch. This flicking motion may cause the centered sear design to not effectively engage with the safety clamp fitment.

Both of these actions leave the roller clamp and safety clamp fitment in the open position which can cause unintended flow possibly resulting in an over infusion to the patient.

These two scenarios can be found on the centered sear door latch manufactured between June 2002 to June 2004.

Centered-Sear Safety Clamp Fitment Design
Manufactured 2002-2004



3. What is the potential risk?

Safety clamp fitment inactivation due to non-optimal engagement of sear to the slide clamp could result in an over infusion. Over infusion can result in serious life-threatening patient injury.

4. What is the probability of a centered sear door latch not effectively engaging the safety clamp?

The probability of occurrence based on the reports BD has received is 0.081%.

5. What is the corrective action for the Alaris Pump module model 8100 for this recall?

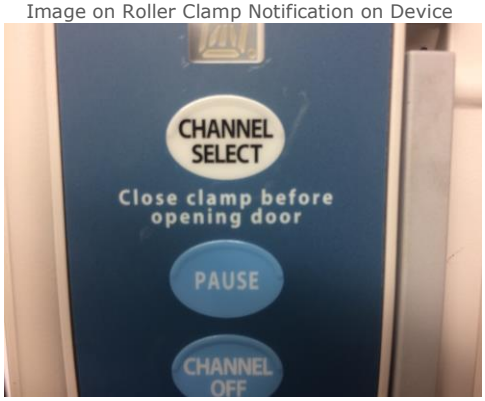
BD will contact all affected Alaris System Pump module customers by mail to notify them of this Medical Device Recall Notification. Customers will receive a customer letter, Frequently Asked Questions, and customer response card. The customer should sequester the device or kit so that Biomedical Engineering can verify the issue. If the door latch needs to be replaced, then Biomedical Engineering should contact BD to coordinate an onsite remediation or send the devices to the BD Service Depot.

6. What are the recommended best practices to prevent free flow infusions?

All Alaris Pump module administration sets have roller clamps. Recommended best practice is that all users close the roller clamp before opening the Pump module door. The labelling for the infusion set and packaging contains a warning indicating: "Warning: To prevent free-flow, close roller clamp when safety clamp is open". Additionally, the Alaris Pump module is labeled with "Close clamp before opening door". BD has provided these labeling indicators as reminders to close the roller clamp before opening the Alaris Pump module door.

Image of Roller Clamp Hang Tag

Image on Roller Clamp Notification on Device



7. Why has it taken BD more than 13 years to make customers aware of this issue?

In recent years, BD has received a larger than normal number of complaints which caused us to evaluate the issue further. After additional investigation, BD identified the complaints to come from the Pump modules manufactured or serviced between June 2002 and June 2004 with the older centered-sear design.

Customer Notification Process

8. How will affected customers be notified of this issue and to whom will the notification be addressed?

Customers will receive a Customer Letter, Frequently Asked Questions, affected Serial Numbers and kits, and a customer response card by overnight courier service delivered upon signed receipt. Notifications will be sent to the Director of Biomedical Engineering, Director of Nursing, Director of Risk Management of each facility. Copies of this information can be found on our website at http://www.carefusion.com/customer-support/alerts-and-notices.

9. Can an IDN submit a response card on behalf of all their facilities?

Yes. The IDN can sign on behalf of the affected facilities by identifying each facility it is representing. The IDN must acknowledge that they will notify their affected facilities on the response card.

Customer Actions

10. What is the recommended action for users?

All users should engage the roller clamp before opening the pump door. If the Alaris pump module has a centered sear door latch fitment, clearly mark and sequester (e.g. Biomed department) the module that exhibited the issue. Notify BD Support Center at 888-562-6018 or SupportCenter@carefusion.com.

11. What is the recommended action for users with unused affected Alaris door latch kits (P/N 147503-000)?

The user should sequester the unused parts and contact BD Support Center (CSC) at 888-562-6018 to coordinate an onsite remediation or send the devices to the BD Service Depot.

12. What is the recommended action for biomedical engineering?

If the pump or kit has been confirmed as having a centered-sear safety clamp fitment, contact BD Support Center at 888-562-6018 to schedule the remediation of your device(s).

If an affected pump has already been replaced with an off-centered safety clamp fitment, then the pump does not need to be remediated.

13. What should the customer do if they have centered-sear position door latch or kit?

The customer should sequester the device so that Biomedical Engineering can verify the issue. If the door latch needs to be replaced, then Biomedical Engineering should contact BD to coordinate an onsite remediation or send the devices to the BD Service Depot.

14. How can the customer return affected device(s) and kit(s) to a BD facility for remediation?

- Customers with the affected devices or kits shall call the BD Support Center (CSC) at 888-562-6018.
- CSC will receive a list of the affected serial numbers from the customers for return.
- CSC will create a Return Good Authorization for each serial number.
- CSC will send boxes and BD paid shipping labels.
- Customers will pack and label the devices with the boxes and labels provided by BD and send to a BD facility.
- BD will perform remediation activities.
- BD will send the devices back to the customer with updated documentation.

15. Who pays the shipping for affected devices sent to the BD facility?

BD will pay all of the shipping costs.

16. How can the user visually identify the Alaris Pump module door latch for a centered-sear?

The centered-sear safety clamp fitment is identified by the centered position of the metal pivot post located on the inside of the door latch assembly sear flange.

Image of Centered-Sear Safety Clamp Fitment (Affected Product)

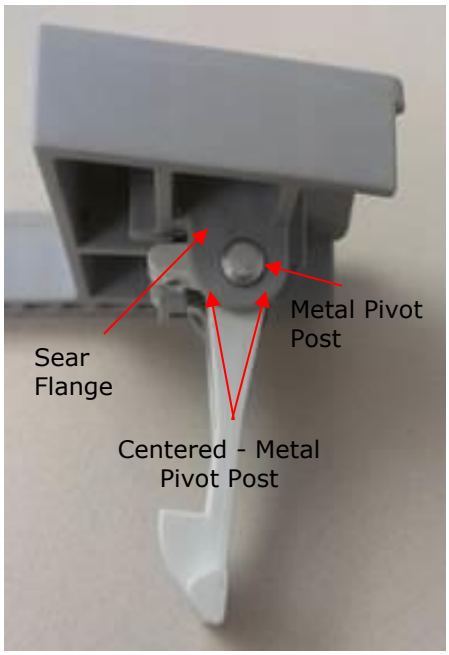
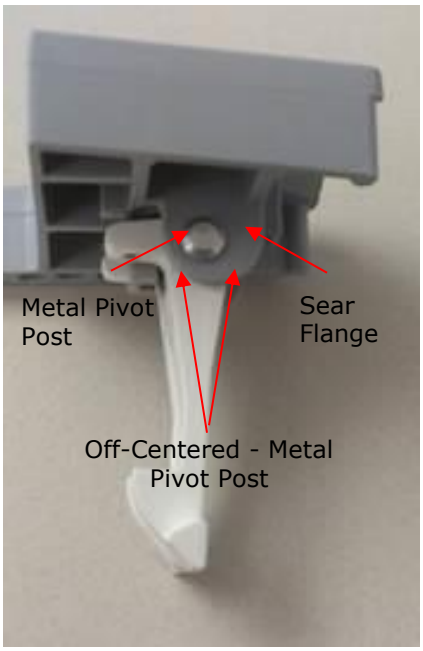


Image of Off-Centered-Sear Safety Clamp Fitment (Current Production)



17. Can the customer perform the corrective action for the affected device(s)?

No, BD must perform the corrective action.

18. How long will the remediation take for each customer?

Each door latch replacement will take approximately 20-25 minutes and will include a preventative maintenance.

19. What action should a customer take if the Alaris Pump modules have been taken out of service or destroyed?

The customer should check the "This facility no longer has any affected Alaris Pump modules model 8100" box on the Customer Response Card if their Alaris Pump modules have been taken out of service or replaced. Customers who check this box and return the response card to BD will not be remediated.

20. Will BD provide loaner devices?

No, BD will not offer additional Alaris Pump modules.

21. Will BD offer any compensation to customers for this remediation?

No, BD will not offer any customer compensation for the remediation.

22. Where can the customer find more details about this notification?

More details of this recall notification can be found on our website at http://www.carefusion.com/customer-support/alerts-notices/ or use the chart provided below for questions and support:

BD Contact	Contact Information	Areas of Support
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: RGA/ Affected Base/Field Remediation (Non-technical)
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