Alaris™ Pump Module Model 8100
Bezel Assemblies with Separated Posts
Expansion of Affected Devices

Frequently Asked Questions (FAQs)

New Questions

1. Why is BD issuing a Press Release?

BD is issuing a Press Release because the U.S. FDA has designated this recall as a Class I recall.

2. Why is BD issuing another notification letter?

As a part of the Class I designation, BD has updated the instructions for customer actions as it relates to the inspection of bezels.

BD will not be differentiating between Priority 1a and Priority 1b pumps, BD will remediate all Priority 1 pumps at the same time. In addition, BD is on track to complete the remediation on an accelerated schedule with a target to complete Priority 1 in 12 months and Priority 2 in 24 months.

3. What are the updated customer actions for Biomedical Engineering?

Until the bezels affected by this recall are replaced, customers should inspect bezels of both Priority 1 and Priority 2 pumps as soon as feasible. If damage is found during the inspection, the pump should be removed from service and BD should be contacted for replacement bezels.

4. Has BD's risk assessment changed since the recall notification letter dated April 15, 2019?

No, BD's risk assessment has not changed. Affected pumps are still classified as Priority 1 or Priority 2.

5. Is the remediation plan with Priority 1 and Priority 2 pumps changing as a result of this update?

No, BD will continue to remediate Priority 1 pumps and any pumps with damaged bezels first. Once Priority 1 pumps are completed, BD will remediate Priority 2 pumps.

6. How is BD progressing on the remediation process?

BD has begun remediation and scheduling of customers for remediation of Priority 1 devices and is on track to complete this work within 12 months. Originally BD had estimated completion of Priority 1 devices in 18 months.

Once Priority 1 devices have been remediated, BD will remediate the Priority 2 devices and now expects to complete this work within 24 months. Originally BD estimated completion of Priority 2 devices in 36 months.

7. How will customers be notified?

On Thursday, July 18, 2019, BD posted an updated notification letter and this FAQ on the website at alaris.bdproductnotice.com, and BD will mail the updated notification letter and FAQ to the following recipients: Director of Nursing, Director of Biomedical Engineering, and Director of Risk Management. BD will mail the updated notification letters to customers by July 31st, 2019.

8. Do I need to submit another response card with this updated notification letter?

No.

9. Are there any changes to the instructions provided in Service Bulletin 621?

Service Bulletin 621 is being updated to be consistent with the instructions to inspect affected pumps as soon as feasible. The inspection directions are not changing and you may use Service Bulletin 621 for these directions until BD provides an update.

10. If my hospital is currently scheduled for remediation, are there any additional actions?

Until the bezels affected by this recall are replaced, customers should inspect bezels of both Priority 1 and Priority 2 pumps as soon as feasible. If damage is found during the inspection, the pump should be removed from service and BD should be contacted for replacement bezels.

Questions from the Notification Letter dated April 15, 2019

11. What products are affected by this recall?

The following products are affected by this recall as they are pumps or pump assemblies with bezels manufactured between April 2011 and June 2017 with the FR-110 plastic.

- Alaris™ Pump Modules model 8100 manufactured between April 2011 and June 2017 that include FR-110 bezels.
- Alaris™ Pump Modules serviced with LVP Mechanism Sub Assembly (P/N 10942012, P/N 49000007, and P/N 49000203).
- Alaris™ Pump Modules Bezel Kit Assembly (P/N 10964559 and P/N 49000204).

12. What is the issue associated with the Alaris™ Pump Module?

The component of the Alaris Pump module that is the subject of this recall is the bezel assembly, and the issue involves separation of the bezel posts. The bezel has 6 posts that connect the pumping mechanism frame to the bezel assembly and are critical to proper performance of the pump. BD's ongoing investigation has determined that the bezel manufacturing process for the FR-110 plastic may have resulted in its weakening. A bezel with weakened plastic may lead to separation of the bezel post (recall issue) as well as other damage to the bezel (i.e. external cracking). The separation of one or more bezel posts is a safety concern, therefore BD is initiating this voluntary recall.

13. What is the potential risk?

The separation of one or more bezel posts may result in free flow, over infusion, under infusion or interruption of infusion.

Affected pumps have different levels of risk. The risk is higher in older pumps and those with weakened plastic. BD is prioritizing remediation efforts based on risk.

14. What is the difference between Priority 1 and Priority 2 pumps?

Priority 1 pumps
- Pumps manufactured between April 2011 – October 2014, inclusive.
- All 14 injury reports to date are within Priority 1.
- BD will replace Priority 1 bezels within 12 months of the April 2019 notification.

Priority 2 pumps
- Pumps manufactured between November 2014 – June 2017, inclusive.
- To date, there have been no reported patient injuries associated with Priority 2 pumps.
- BD will replace Priority 2 bezels within 24 months of the April 2019 notification.
- NOTE: Priority 2 pumps have a reduced likelihood of weakened plastic leading to cracked bezel issues compared to the Priority 1 pumps.

15. What is the corrective action for affected devices?

BD has contacted customers with Priority 1 pumps to schedule remediation of those pumps. BD will replace Priority 1 bezels within 12 months of the April 2019 notification.

BD will contact customers to schedule replacement of bezels in Priority 2 pumps once Priority 1 pumps have been addressed. BD will replace Priority 2 bezels within 24 months of the issuance of this notification.

16. Are new BD branded Alaris™ Pump Modules affected?

No, new BD branded Alaris™ Pump Modules are not affected by this recall as their bezels are manufactured with a new design that utilizes an improved plastic material called Valox. BD began making bezels with Valox in June 2017 and these bezels have been tested extensively by BD to ensure reliability. There have been no patient injuries or complaints of cracking associated with Valox bezels to date.

17. Are the newer Bezel Kit Assemblies (P/N 49000270) manufactured after June 2017 affected by this recall?

No. The newer replacement Bezel Kit Assemblies (P/N 49000270) released in June 2017 are not affected by this recall as their design utilizes an improved plastic material called Valox. These bezels have been tested extensively by BD to ensure reliability. There have been no patient injuries or complaints of cracking associated with Valox bezels to date.

18. Why is BD expanding this recall?

BD has conducted an extensive investigation and determined that the bezel manufacturing process may have resulted in weakened plastic. Over time, further weakening of the plastic may lead to separation of the bezel post (recall issue) as well as other damage to the bezel (i.e. external cracking). BD is broadening this recall to include all pump modules manufactured or serviced with bezels manufactured using a different type of plastic material called FR-110 bezels.

19. Why was the first expanded recall so limited?

Conclusions from BD's initial investigation led to the previous expansion of this recall in April 2018. Throughout this process, BD continued extensive investigation and discovered the potential for this issue could occur in bezels molded from a specific plastic, called FR-110. These bezels were consumed for production of Pump Modules and Bezel Kit Assemblies between April 2011 and June 2017.

20. How did BD investigate the devices?

BD launched an extensive investigation bringing in some of the best engineering and scientific capabilities from within BD as well as external experts to determine the root cause and effects of the issue. BD discovered that the bezel manufacturing process may have resulted in weakened plastic.

BD also conducted accelerated life testing on bezels in the higher risk group (Priority 1), lower risk group (Priority 2), and on bezels manufactured from the new Valox material that was introduced in 2017.

Here are some important facts from the testing:

- None of the bezels from the lower risk months exhibited any cracking or separation throughout seven years of accelerated life testing
- None of the bezels manufactured after June 2017 with the new Valox material exhibited any cracking or separation throughout 10 years of accelerated life testing

- Bezels from the higher risk months exhibited cracking as early as the first year of life testing, but no separations were observed until year four

21. How has BD changed its manufacturing of these devices since discovering this issue?

BD is committed to quality improvement and changed the plastic material to Valox used in the Alaris Pump Module bezels in June 2017. Valox bezels have been tested extensively by BD to ensure reliability. Failure analysis and accelerated life testing have confirmed that Valox is not affected. There have been no reports of cracking with the new material.

22. Is this a recall?

This is not a new recall, but an update to the recall notification on April 15, 2019.

23. Has the FDA been notified?

Yes, the FDA has been notified.

Customer Notification Process

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

Customers will receive a Customer Letter, Customer Response Card, Service Bulletin 621, Recall Website Information flyer, and a list of affected Serial Numbers, by 2-day courier service delivered upon signed receipt. Notifications will be sent to the Director of Biomedical Engineering, Director of Nursing, and Director of Risk Management of each facility. Copies of this information can be found on our website at http://www.bd.com/en-us/support/alerts-and-notices.

25. Can an IDN submit an acknowledgement of the recall on behalf of all their facilities?

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

Customer Actions

26. What is the recommended action for Clinicians?

BD has assessed the risk of this issue and determined that affected pump modules, both Priority 1 and Priority 2 pumps, can be used until they are inspected.

27. What should the customer do if they serviced unaffected devices with an affected replacement bezel mechanical assembly?

Refer to Service Bulletin 621 for instructions to inspect the bezel assembly.

28. What should the customer do if they have serviced an affected device with an unaffected bezel kit assembly (part numbers 49000269 or 49000270)?

All pumps or bezel replacement kits containing part numbers 49000269 or 49000270 are NOT affected by this recall. Refer to Service Bulletin 621 for instructions on how to identify these pumps if no record of service with these bezels exist. Mark unaffected pumps for easy identification. Notify BD of Alaris™ Pump Modules that have had Valox replacement bezels installed. Instructions are available at http://alaris.bdproductnotice.com.

29. Can the customer visually identify an unaffected Valox bezel?

Yes. Refer to Service Bulletin 621 for instructions on how to identify unaffected Valox bezels. Additional resources to aid in identification of unaffected Valox bezels are also available at http://alaris.bdproductnotice.com.

30. Can the customer visually identify a bezel with separated posts without disassembling the device?

No. Separated bezel posts are not externally detectable by the user. Refer to Service Bulletin 621 for instructions on how to inspect the bezel for cracking.

31. Can the customer send affected pumps to the BD Service Depot for bezel replacement?

Yes. BD can replace the affected bezels at the BD Service Depot up to 25 devices per request.

32. How do customers order replacement bezel kit assemblies?

Replacement bezel kit assemblies (P/N 49000270) can be ordered through Customer Order Management at 1-800-482-4822. Small orders (3 or less) will be shipped within 5 business days based on availability. Bezel kit assembly orders of more than 3 will be reviewed daily. Customers who place bezel kit assembly orders of more than 3 will be called by the Service Contracts team to determine a shipping schedule.

33. What is BD doing to actively manage the supply of replacement bezels?

BD is actively working with our suppliers to increase our inventory of bezels to support increasing order volume resulting from this notification. In preparation for this action, BD has tripled the supply of bezels.

34. What is BD doing to ensure that this issue is not repeated?

Beginning in June 2017, BD began making bezels with a different plastic material called Valox. Valox bezels have been tested extensively by BD to ensure reliability. There have been no patient injuries or complaints of cracking associated with Valox bezels to date. Additionally, BD has expanded process controls with our suppliers.

35. How can the customer return unopened and unused affected bezel kit assemblies to BD?

- Affected Alaris™ Pump Module bezel kit assemblies are part numbers 10964559 and 49000204.

- Customers with unopened and unused affected kits can call the BD Support Center at 888-562-6018 to coordinate replacement of affected kit.
- BD Support Center will request a Return Good Authorization (RGA) for affected kits.
- BD Support Center will provide BD pre-paid shipping labels to the customers.
- Customers will pack and label the kits with RGA information and send it to the BD facility.
- BD will send replacement bezel kit assemblies, part number 49000270, back to the customer.

36. Who pays the shipping for affected devices or kits sent to the BD facility?

BD will pay all shipping costs.

37. Will BD provide loaner devices?

No. BD will not provide loaner Alaris™ Pump modules.

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

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

39. 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.bd.com/en-us/support/alerts-and-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@bd.com	General Follow-up Questions: RGA/ Affected Population/ 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@bd.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@bd.com	Product Complaints
Customer Order Management	Phone: 1-800-482-4822 Phone hours: 8:00 AM-5:00 PM Central Time Email: GMB-CTS-CustCareInfusion@bd.com	Order Bezel Kit Assemblies Replacements