



URGENT: Medical Device Recall Notification [Expansion of Affected Units]
AFFECTED DEVICE: Alaris™ Pump Module Model 8100

April 15, 2019

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

BD is announcing a recall expansion¹ of the Alaris™ Pump Module to include all bezels manufactured between April 2011 and June 2017. All of the bezels subject to this recall expansion were manufactured with a specific type of plastic, called FR-110.

Issue

The component of the Alaris Pump module that is the subject of this recall is the bezel assembly (*Attachment A, Figure 1*), and the issue involves potential separation of the bezel posts (*Attachment A, Figure 2*). 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, over time, 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 potential safety concern and, therefore, BD is initiating this voluntary recall.

Affected Products

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 Module Bezel Kit Assembly (P/N 10964559 and P/N 49000204).

A serialized list of affected pumps is provided in *Attachment E* and will identify pumps in Priority 1 and Priority 2 as described below. And, if applicable, *Attachment E* includes the quantity of replacement kits affected by this recall.

Risk

The separation of one or more bezel posts may result in free flow, over infusion, under infusion or interruption of infusion. To date, BD has received 364 reports of separated bezel posts with 12 resulting in injury reports without lasting harm or death.

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

1. Priority 1 pumps:

- Pumps manufactured between April 2011 – October 2014, inclusive.
- All 12 injuries reported to date are within Priority 1.
- BD will inspect all Priority 1 pumps. This inspection will enable identification of bezels that may have weakened plastic or are damaged resulting in two subpopulations that are prioritized based on risk:

¹ Initial recalls were announced Sept 1, 2017 and April 13, 2018



- **Priority 1A pumps:** BD will replace Priority 1A bezels at the time of the inspection.
- **Priority 1B pumps:** BD will replace Priority 1B bezels within 18 months of the inspection.
- **NOTE:** The difference between pumps designated as Priority 1A versus 1B, is that the Priority 1A product has demonstrated to be more prone to weakened plastic leading to cracked bezel issues.

2. **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 36 months of the issuance of this notice.
- NOTE: Priority 2 pumps have a reduced likelihood of weakened plastic leading to cracked bezel issues compared to the Priority 1 pumps.

Until the bezels affected by this recall are replaced by BD, customers should inspect bezels of both Priority 1 and Priority 2 pumps during their annual preventative maintenance schedule. Any pumps with bezel post separation should be removed from service.

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.

Actions by BD

BD will contact customers of Priority 1 pumps within 60 days of this notification to initiate scheduling of the inspection of those pumps. BD will contact customers to schedule replacement of bezels in Priority 2 pumps once Priority 1 pumps have been addressed.

BD will cover the replacement of all bezels under warranty (if applicable) or under this recall at no charge to the customer.

Follow-Up Actions for Biomedical Engineering

Share this recall notification with all users of the product within your facility to ensure that they are also aware of this recall.

1. Until the bezels affected by this recall are replaced by BD, customers should inspect bezels of both Priority 1 and Priority 2 pumps during their annual preventative maintenance schedule. BD will offer oversight and training on the bezel inspection process. **Contact the BD Support Center to coordinate training.** Additionally, customers can refer to Service Bulletin 621 (*Attachment D*) for inspection instructions or view the bezel inspection training video at <http://alaris.bdproductnotice.com>
2. Damaged bezels must be replaced before the pump can be returned to service. Contact the BD Support Center to schedule bezel replacement.
3. Priority 1B and Priority 2 pumps that pass this inspection at each preventive maintenance interval may be returned to clinical use until BD replaces the bezel. BD will replace bezels in Priority 1B and Priority 2 pumps as supply of replacement bezels are available.

Identifying Non-Affected Pumps

The recall DOES NOT include Alaris™ Pump Modules or bezel replacement kits (P/N 49000270 or P/N 49000269) manufactured after June 2017. 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.

If your facility has installed Valox replacement bezels into affected pumps, these pumps are not affected by the current recall. To identify such pumps, consult your maintenance records and/or perform the following visual inspection.



1. See *Attachment A, Figures 3 and 4*, or Service Bulletin 621, to determine if you have installed a replacement Valox bezel. Refer to *Attachment E* for the quantity of unaffected Valox replacement bezels shipped to your facility.
2. Mark unaffected pumps for easy identification.
3. Notify BD of Alaris™ Pump Modules that have had Valox replacement bezels installed. Instructions are available at <http://alaris.bdproductnotice.com>.

Contact Information:

BD has established a website to support customers with this recall. Please visit <http://alaris.bdproductnotice.com> (*Attachment C*).

The US 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

If you have any questions regarding the products, please contact:

| 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 or Recall Related Questions |
| BD Customer Advocacy | Phone: 888-812-3266 Phone hours: 7:00am to 5:00pm PT Monday - Friday Email: customerfeedback@bd.com | Product Complaints |
| BD 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 on the Alaris System |

Please promptly complete and return the enclosed Customer Response Card to acknowledge receipt of this notification.

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, but we are committed to achieving the highest levels of customer satisfaction and serving your infusion product needs.

Sincerely,

Keith McLain
Worldwide Vice President of Quality for Medication Management Solutions

Enclosures:

- **Attachment A: Images of Alaris Pump module and bezel assemblies**
- **Attachment B: Customer Response Card**
- **Attachment C: Recall website information**
- **Attachment D: Service Bulletin 621**
- **Attachment E: List of Affected Devices**

ATTACHMENT A: Figures



Figure 1a: Pump Module with door open showing the front of the bezel

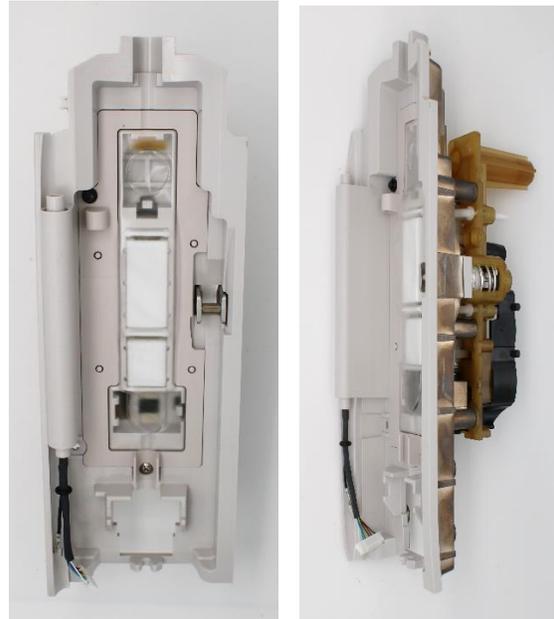


Figure 1b: Front and side views of the bezel assembly



Figure 2a: Back side of bezel assembly highlighting the bezel posts



Figure 2b: Bezel post with NO separation



Figure 2c: Bezel post WITH separation



Figure 3: Side view of affected bezel, FR-110



Figure 4: Side view of non-affected bezel, Valox