Johnson&Johnson MedTech

Abiomed Inc.
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URGENT MEDICAL DEVICE CORRECTION

AIC Purge Pressure Sensor Assembly Failures

PLEASE DISTRIBUTE THIS INFORMATION TO APPROPRIATE PERSONNEL AT YOUR FACILITY WHO MAY USE THE PRODUCT THAT IS THE SUBJECT OF THIS NOTICE

Product Code(s)	Product Description(s)	Affected Lots / Serial No.
0042-0000-AU	Impella Controller, Packaged, AU	All lots and serial numbers are affected
0042-0000-CA	Impella Controller, Packaged, CA	
0042-0000-EU	Impella Controller, Packaged, EU	
0042-0000-IN	Impella Controller, Packaged, IN	
0042-0000-JP	Impella Controller, Packaged, JP	
0042-0000-UK	Impella Controller, Packaged, UK	
0042-0000-US	Impella Controller, Packaged, US	
0042-0010-AU	Impella Optical Controller, Packaged, AU	
0042-0010-EU	Impella Optical Controller, Packaged, EU	
0042-0010-IN	Impella Optical Controller, Packaged, IN	
0042-0010-UK	Impella Optical Controller, Packaged, UK	
0042-0010-US	Impella Optical Controller, Packaged, US	
0042-0040-AU	Optical, AIC, Impella Connect, Pkgd, AU	
0042-0040-CA	Optical AIC w/Impella Connect,Pack'd, CA	
0042-0040-EU	Optical AIC w/Impella Connect,Pack'd, EU	
0042-0040-JP	Optical AIC w/Impella Connect, Pkgd, JP	
0042-0040-KR	Optical, AIC, Impella Connect, Pkgd, KR	
0042-0040-UK	Optical, AIC, Impella Connect, Pkgd, UK	
0042-0040-US	Optical, AIC, Impella Connect, Pkgd, US	

August 13, 2026

Dear Valued Customer,

Abiomed, Inc. has issued a voluntary device correction (notification). **Hospital inventory can continue to be used to ensure continuity of care.**

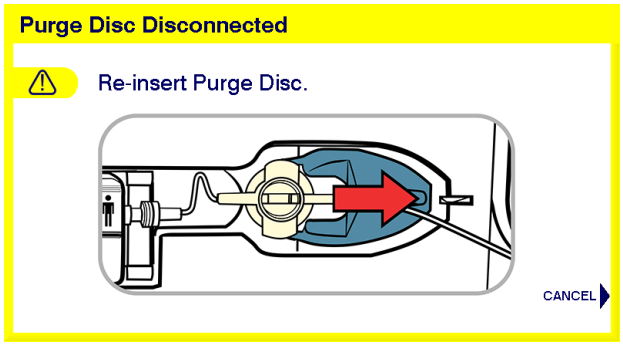
Abiomed is informing customers of a correction of the purge pressure sensor assembly within the Automated Impella Controller ("AIC"). Abiomed servicing team will contact you to coordinate the implementation of this correction.

REASON FOR NOTIFICATION:

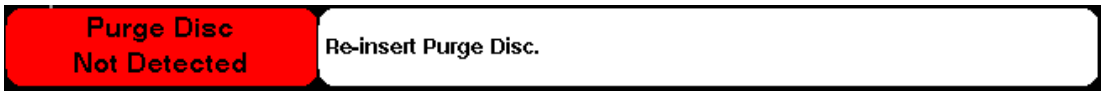
Abiomed has identified an increase in complaints due to purge cassette recognition issues resulting from failures of the purge flag component within the purge pressure sensor assembly. The purge flag engages with the purge disc and allows the AIC to recognize that the purge disc is inserted properly. Abiomed is addressing these failures by replacing the purge flag and purge retainer components within the purge

pressure sensor assembly of the AIC. **Implementation of this replacement will be executed either through annual preventative maintenance or individual outreach by Abiomed's service team. Abiomed will contact you to coordinate scheduling of the replacement.**

If a purge flag component failure were to occur during set up of clinical procedure, the user would see a "Purge Disc Disconnected" alarm on the AIC. As per the Instructions for Use (IFU), first reinsert the purge disc to address the alarm. If that action does not clear the alarm, switch to a backup Automated Impella Controller. Refer to below for an example of the alarm:



If a purge flag component failure were to occur during hemodynamic support, the user would see a "Purge Disc not Detected" alarm on the AIC. As per the Instructions for Use (IFU), first reinsert the purge disc to address the alarm. If that action does not clear the alarm, switch to a backup Automated Impella Controller. Refer to below for an example of the alarm:



Improper cleaning can cause damage to plastic components including the purge flag. Ensure cleaning of the AIC housing with a mild detergent as specified in the IFU.

Hospital inventory can continue to be used to ensure continuity of care. The Abiomed service team is working on a schedule to implement this replacement. The replacement may be implemented through annual preventative maintenance or individual outreach.

POTENTIAL PATIENT IMPACT:

Exposure to these AIC purge flag component failures requires an AIC exchange to solve the issue. If the failure occurs before initiation of support, there may be a delay to the procedure. In cases involving hemodynamic instability, this delay may result in a prolonged period without mechanical circulatory support.

If the failure occurs during active Impella support, it will usually occur during an elective exchange of the purge cassette, but might in rare occasions also happen during ongoing support. In the case of ongoing support, mechanical circulatory support will continue while purge delivery is stopped and the AIC exchange is planned. Albeit urgent, exchange of the AIC can be prepared for, including additional hemodynamic stabilization of the patient for the brief interruption of support.

A review of global complaints from January 01, 2025 to June 28, 2026 found purge flag component

failure in 0.2% of cases (193 complaints of 96,729 usages). This complaint review identified thirty-seven (37) complaints where there was a delay of therapy and were reported as a serious injury. Additionally, three (3) patient deaths were identified where the issue resulted in a console exchange. All 3 patients had cardiogenic shock. Although the available information suggested that the patients' underlying clinical condition more likely contributed to the deaths, the contribution of the delay caused by the console exchange could not be definitively excluded.

With existing alarms, monitoring, and mitigation actions, the overall benefit of the Impella system continues to outweigh the risk.

ACTIONS TO BE TAKEN BY CUSTOMER/USER:

- **Hospital inventory can continue to be used while awaiting service from Abiomed to ensure continuity of care.**
- Abiomed's field service team will contact you to schedule the specified replacement, please work with them to implement this replacement of the purge flag and purge retainer components within the purge pressure sensor assembly of the AIC.
- In the event of these purge flag component failures and associated alarms, as per IFU, first reinsert purge disc to address the alarm. If that action does not clear the alarm, switch to a backup Automated Impella Controller.
- Improper cleaning can cause damage to plastic components including the purge flag. Ensure cleaning of the AIC housing with mild detergent as specified in the IFU.
- Ensure future routine preventive maintenance is performed annually on your AIC(s) following the guidance in the IFU
- Review, complete all fields, sign, and return the attached business reply form (BRF) (refer to Attachment 1) to your local Abiomed representative.
- Forward this notice to anyone in your facility that needs to be informed (i.e., those who manage, transport, store, stock, or use the subject products).
- If any of the subject products have been forwarded to another facility, contact that facility and provide them with this notice.
- Post a copy of this notice in a visible area for awareness.
- As with any medical device, adverse reactions or quality problems experienced with the use of this product should be reported according to your procedures and applicable regulatory requirements.

At Abiomed, our priority is to our customers and their patients, and that includes the safe and effective use of our products. If you have questions or concerns regarding this notice, please contact your local clinical field staff. Thank you for your cooperation.

Attachments:
Attachment 1 – Business Reply Form

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Attachment 1 – Business Reply Form (BRF)

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Please complete this Business Reply Form **within 3 business days upon receipt of the notification** and return this form to your local Abiomed representative.

By signing this form, I am confirming that I have read and understand the correction (notification) provided in this letter and actions were appropriately taken.

Acknowledgement Signature		**Date**	14 AUG 2026
Print Name	Cheah Ming Xuan	**Telephone**	016-3561588
Account Name & Address	DCH Auriga (Malaysia) Sdn. Bhd. Lot 6, Persiaran Perusahaan, Seksyen 23, 40300 Shah Alam, Selangor, Malaysia.		
Email	mingxuancheah@dchauriga.com		
Comments:			