Abiomed, Inc.
22 Cherry Hill Dr.
Danvers, MA 01923 USA
Phone: +1 978-646-1400
Fax: +1 978-777-8411
www.abiomed.com

FSN Ref: 2026-FSN-0000154

FSCA Ref: 2026-FA-0000154

Date: 2026-08-01

URGENT Field Safety Notice
AIC Purge Flag Failures

For Attention of*: All Automated Impella Controller (AIC)

Contact details of local representative (name, e-mail, telephone, address etc.)*
E-Mail: DL-EUFSCA@its.jnj.com [redacted] **Abiomed Europe GmbH** **Neuenhofer Weg 3** **D-52074 Aachen** **Customer Service Tel.: +800 0 22 466 33**

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1. Information on Affected Devices*	
1.	1. Device Type(s)*
	All Automated Impella Controller (AIC)
1.	2. Commercial name(s)*
	Automated Impella Controller (AIC)
1.	3. Primary clinical purpose of device(s)*
	The Automated Impella Controller provides three functions to the operation of the Impella Catheter: • The controller provides an interface for monitoring and controlling the function of the Impella Catheter. • The controller provides a purge fluid to the Impella Catheter. • The controller provides backup power when the Impella Ventricular Support Systems are operated away from AC power.
1.	4. Device Model/Catalogue/part number(s)*
	0042-0000-EU; 0042-0000-UK; 0042-0010-EU; 0042-0010-UK; 0042-0040-EU; 0042-0040-UK (not all models apply to all countries)
1.	5. Software version
	All AIC Software version
1.	6. Affected serial or lot number range
	Not relevant – all AIC are impacted
1.	7. Associated devices
	All Impella heart pump models are run by the Automated Impella Controller (AIC). The user monitors the pump through the AIC user interface. The AIC also drives the Purge Cassette to provide purge fluid to the Impella pumps.

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	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 may be executed through annual preventative maintenance or individual outreach by Abiomed's service team. 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:

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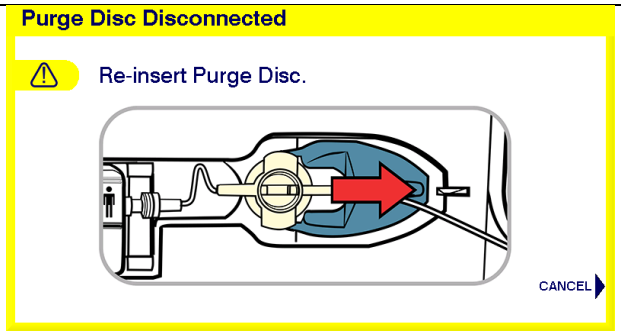
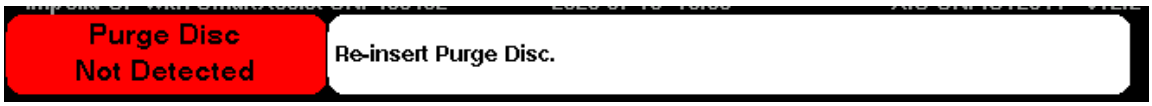


If a purge flag component failure were to occur during hemodynamic support, the user would see a “Purge Disc not Detected” alarm on the AIC. As per the Instructions for Use (IFU), first reinsert the purge disc to address the alarm. If that action does not clear the alarm, switch to a backup Automated 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 plan to implement this replacement. The replacement will be implemented through annual preventative maintenance or individual outreach.

ACTIONS TO BE TAKEN BY CUSTOMER/USER:

- **Hospital inventory can continue to be used while awaiting service from Abiomed to ensure continuity of care.**
- All AIC units globally are in scope of this removal, and as such, a phased removal approach is being implemented.
- Abiomed’s field service team will contact you to schedule the specified replacement, please work with them to return the identified device(s) to implement 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.

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	• 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 Field Safety Notification (FSN) to **fa-0000154-abiomed@iqvia.com**. • For any questions related to this Field Safety Notification, please contact **DL-EUFSCA@its.jnj.com** • 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 to Abiomed company. 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 notification, please contact **DL-EUFSCA@its.jnj.com** or your local clinical field staff. Thank you for your cooperation.
2.	2. Hazard giving rise to the FSCA*
	Exposure to AIC purge flag failures may reasonably be expected to result most frequently in user inconvenience (S1) due to troubleshooting, attempted purge cassette exchange and AIC exchange. If the failure occurs before initiation of support, exposure may result in a delay to procedure (S2), which is expected to remain clinically manageable in most cases. In the case of an urgent need for mechanical circulatory support or if the failure occurs during active Impella support, exposure may result in a temporary period of inadequate hemodynamic support (S3) during controller transition. Overall, the product issue does not introduce a new hazard but increases the documented severity or probability of harm. With existing alarms, monitoring, and mitigation actions, it is still not expected to overturn the product benefit-risk ratio. The life-sustaining benefit of Impella support is maintained regardless of action or inaction, whereas product removal would negatively affect benefit-risk because the AIC is required to operate Impella pumps and alternatives are limited.
2.	3. Probability of problem arising
	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).
2.	4. Predicted risk to patient/users

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	A purge flag failure leading to a "purge disc not detected" alarm will most frequently result in a user inconvenience (S1) as an AIC exchange is required to solve the situation and as this is only recognized after an (unnecessary) exchange of the purge cassette. If the failure occurs during case start, this may delay case start-up (S2). In the case of an urgent need for mechanical circulatory support, exposure may also result in a temporary period of inadequate hemodynamic support (S3) within the population at highest risk. If the failure occurs during active clinical support, typically after an attempted purge cassette exchange, a critical "purge disc not detected" alarm will be triggered and require immediate user action. Hemodynamic support continues during troubleshooting; however, purge flow may be interrupted while the issue is resolved. Because a purge flag failure requires exchange to a backup AIC, a temporary loss or reduction of support may occur during the transition. AIC exchange is an accepted clinical practice during standard use scenarios, such as patient transfers or therapy escalations, and is typically planned, prepared for, and performed in a controlled environment. Physicians are expected to exercise clinical judgment, stabilize the patient as needed before exchange, and determine whether transfer between devices is necessary and clinically tolerated. During the transition, patients may require additional support but may also have sufficient cardiac output to sustain circulation until Impella support is re-established. This is expected to result in a temporary period of inadequate hemodynamic support (S3), typically lasting approximately 1-2 minutes, which may be compensated by additional support therapies.
2.	5. Further information to help characterise the problem
	N/A
2.	6. Background on Issue
	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.
2.	7. Other information relevant to FSCA
	N/A

3. Type of Action to mitigate the risk*	
3.	1. Action To Be Taken by the User* ☐ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device ☐ On-site device modification / inspection ☐ Follow patient management recommendations.

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	☐ Take note of amendment / reinforcement of Instructions for Use (IFU) ☒ Other ☐ None **Follow the recommendations as specified in Section 2.1** To increase awareness of these recommendations: - **Keep the copy of this FSN together with your IFU.**	
3.	2. By when the action should be completed?	As soon as practical.
3.	3. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	**4. Action Being Taken by the Manufacturer*** ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☒ Other ☐ None Abiomed is addressing these failures by replacing the purge flag and purge retainer component within the purge pressure sensor assembly of the Automated Impella Controller ("AIC"). Abiomed will implement a phased approach to ensure continued patient support. **Until then, to ensure continuity of care, hospital inventory can continue to be used.**	
3.	5. By when the action should be completed?	As soon as practical.
3.	6. Is the FSN required to be communicated to the patient /lay user?	No

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	N/A
4.	3. For Updated FSN, key new information as follows:	
	N/A	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4.	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	N/A	
4.	6. Anticipated timescale for follow-up FSN	N/A
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Abiomed Inc.
	b. Address	22 Cherry Hill Drive, Danvers, MA, US

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	c. Website address	www.heartrecovery.com
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
4.	9. List of attachments/appendices:	None
4.	10. Name/Signature	[redacted]

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where Impella pumps have been transferred. Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action and keep this FSN together with the existing version of the product IFU. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback. *

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URGENT Field Safety Notice (FSN)
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Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	2026-FA-0000154
FSN Date*	2026-08-01
Product/ Device name*	Automated Impella Controller (AIC)
Product Code(s)	0042-0000-EU; 0042-0000-UK; 0042-0010-EU; 0042-0010-UK; 0042-0040-EU; 0042-0040-UK

2. Customer Details	
Account Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

If additional organizations are covered by your response, please ensure their details are recorded in the table on the next page.

3. Customer action undertaken on behalf of Healthcare Organisation		
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content*	Complete or enter N/A
☐	I performed all actions requested by the FSN*	Complete or enter N/A
☐	The information and required actions have been brought to the attention of all relevant users*	Complete or enter N/A
☐	I have a query please contact me	Enter contact details if different from above and brief description of query
Print Name*		
Signature*		
Date*		

4. Return acknowledgement to sender	
Email	fa-0000154-abiomed@iqvia.com
Customer Helpline	+800 0 22 466 33
Postal Address	Abiomed GmbH [redacted] Neuenhofer Weg 3 52074 Aachen -Germany
Web Portal	www.abiomed.eu; www.heartrecovery.eu
Deadline for returning the customer reply form*	**Please return within 7 working days**

Mandatory fields are marked with *

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This Customer reply form also applies to these additional organizations:

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.