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FSN Ref: 2026-FSN-000127

FSCA Ref: 2026-FA-000127

Date: 2026-03-03

URGENT Field Safety Notice

“Purge System Blocked” alarm delay with AIC Old Software version

For Attention of*: Users of Automated Impella Controller (AIC) with software version below 10.1 (Specifically versions 8.2.2 and 8.5) in conjunction with Impella 5.5 first generation (Code 0550-0002)

Contact details of local representative (name, e-mail, telephone, address etc.)*

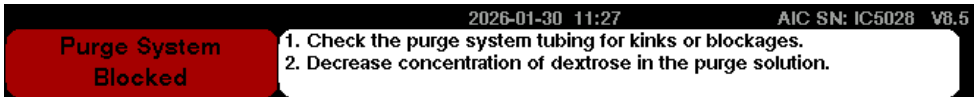
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1. Information on Affected Devices*	
1.	1. Device Type(s)* All Automated Impella Controller (AIC)
1.	2. Commercial name(s)* Automated Impella Controller (AIC)
1.	3. Primary clinical purpose of device(s)* The Automated Impella Controller provides three 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)* 0042-0010; 0042-0040; 0042-0000. (not all models apply to all countries)
1.	5. Software version Versions below 10.1 (Specifically versions 8.2.2 and 8.5)
1.	6. Affected serial or lot number range See Customer reply form
1.	7. Associated devices All Impella heart pump models are run by the Automated Impella Controller (AIC). 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 that AICs with software version below 10.1 (Specifically versions 8.2.2 and 8.5), when used in conjunction with an Impella 5.5 first generation (product code 0550-002), have a delayed “Purge System Blocked” alarm. Software versions V10.1 or above, and Impella 5.5 second generation (product code: 1000482) have this issue addressed. A review of global complaints from September 1, 2019 to January 16, 2026 found a delay in “Purge System Blocked” alarms in 0.35% of cases. The complaints review determined that there have been no patient deaths attributed to this issue; however, in 10 cases there was a pump / console exchange due to events such as a pump stop or high purge pressure, and it was later determined there was also a delayed “Purge System Blocked” alarm. If the purge flow stops completely, the controller displays the “Purge System Blocked” alarm; see below for an example of the alarm.
 <p>The screenshot shows a red alarm box with the text "Purge System Blocked". To the right, a white box contains the following instructions: "1. Check the purge system tubing for kinks or blockages." and "2. Decrease concentration of dextrose in the purge solution." Above the instructions, the date and time "2026-01-30 11:27" and the device ID "AIC SN: IC5028 V8.5" are visible.</p>	

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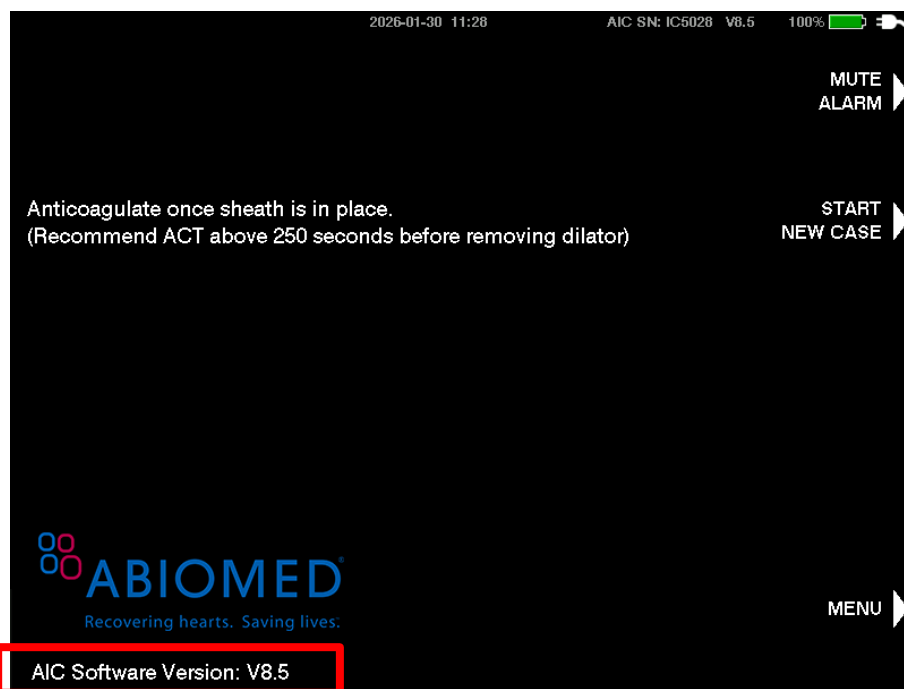
POTENTIAL PATIENT IMPACT:

In the event that high purge pressure is not detected, it may result in the failure of the purge system which may potentially result in a complete pump stop. A pump stop may result in a loss of hemodynamic support and lead to an outcome of death.

ACTIONS TO BE TAKEN BY CUSTOMER/USER:

- Abiomed recommends that you do not use the AIC with an Impella 5.5 first generation (product code 0550-002) unless AIC software is updated to V10.1 or above.
- AIC software version can be identified in the lower left corner of the initial AIC display screen, see Figure 1 below for example.

Figure 1: AIC Software Identification on Example Startup Screen



- Where required, please contact Abiomed at RA-ABM-EUFieldServic@ITS.JNJ.com to schedule your software update.
- Review, complete all fields, sign, and return the attached Customer Reply Form to 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.

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2.	2. Hazard giving rise to the FSCA*
	Health Hazard Evaluation conclusion: The potential consequences of exposure to the hazard of the delayed alarm of the purge system blockage on the Impella 5.5 pump's revolve around the concern of having adequate time to intervene to prevent a purge system failure and eventual pump stop. The clinical interventions and harms resulting would include user inconvenience(S1), inadequate hemodynamic support (during the period of pump exchanges) (S3) or loss of hemodynamic support (from an un-anticipated pump stop) (S5). Pump stop is not exclusively related to delayed alarm recognition. If the pump stop result from a delayed purge pressure alarm, it may reasonably be expected to result in temporary hemodynamic instability—considered a reversible injury if promptly recognized and managed. When the patient in cardiogenic shock is dependent on the Impella pump and there is a pump stop due to a delayed alarm resulting in a purge system failure, this failure could lead to more severe outcomes such as organ damage, which presents a life-threatening injury with the potential for permanent impairment. The probability of exposure to this hazardous situation indicates that the occurrence rate of 0.35%. The probability of the hazardous situation is low although higher than previously predicted. This rate has effectively dropped to zero with the release of the new software version which eliminates the chance of delayed alarms. The identified product issue does not materially change the overall risk-versus-benefit ratio of using the Impella5.5 pump in indicated populations, particularly with the new software system where implemented. Actions or inactions related to this issue do not materially affect the overall benefit-risk ratio of the products.
2.	3. Probability of problem arising
	A review of global complaints from September 1, 2019 to January 16, 2026 found a delay in “Purge System Blocked” alarms in 0.35% of cases. The complaints review determined that there have been no patient deaths attributed to this issue; however, in 10 cases there was a pump / console exchange due to events such as a pump stop or high purge pressure, and it was later determined there was also a delayed “Purge System Blocked” alarm.
2.	4. Predicted risk to patient/users
	Impact beyond users: No impact beyond the user.
2.	5. Further information to help characterise the problem
	Please follow instructions in section 2.1
2.	6. Background on Issue
	The need for this correction was identified through retrospective reviews that were performed in January 2026.
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*
	<input checked="" type="checkbox"/> Identify Device <input type="checkbox"/> Quarantine Device <input type="checkbox"/> Return Device <input type="checkbox"/> Destroy Device <input type="checkbox"/> On-site device modification / inspection <input type="checkbox"/> Follow patient management recommendations.

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<input checked="" type="checkbox"/> Take note of amendment / reinforcement of Instructions For Use (IFU) <input checked="" type="checkbox"/> Other <input type="checkbox"/> None Follow recommendations described in section 2.1 ACTIONS TO BE TAKEN BY CUSTOMER/USER: Please follow the recommendations described in Section 2.1 . <ul style="list-style-type: none"> • Please contact Abiomed at RA-ABM-EUFieldServic@ITS.JNJ.com to schedule your software update. • Review, complete all fields, sign, and return the attached Customer Reply Form to DL-EUFSCA@its.jnj.com. Until the corrective measures have been implemented, please note the following: <ul style="list-style-type: none"> • Product is NOT being removed from the field and does not need to be returned. • Review this notice carefully, and forward 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. <p>To increase awareness of these recommendations: * Keep the copy of this FSN together with your IFU.</p>							
3.	<table border="1"> <tr> <td>2. By when should the action be completed?</td> <td>As soon as practical.</td> </tr> </table>	2. By when should the action be completed?	As soon as practical.				
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3.	<table border="1"> <tr> <td>3. Is customer Reply Required? * (If yes, form attached specifying deadline for return)</td> <td>Yes</td> </tr> </table>	3. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes				
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3.	<table border="1"> <tr> <td colspan="2">4. Action Being Taken by the Manufacturer*</td> </tr> <tr> <td> <input type="checkbox"/> Product Removal <input checked="" type="checkbox"/> Software upgrade <input type="checkbox"/> Other </td> <td> <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> IFU or labelling change <input type="checkbox"/> None </td> </tr> <tr> <td colspan="2">All AIC with software Version older than 10.1 will be updated.</td> </tr> </table>	4. Action Being Taken by the Manufacturer*		<input type="checkbox"/> Product Removal <input checked="" type="checkbox"/> Software upgrade <input type="checkbox"/> Other	<input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> IFU or labelling change <input type="checkbox"/> None	All AIC with software Version older than 10.1 will be updated.	
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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
	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	Mariano Santos Senior Manager, Commercial Quality

Transmission of this Field Safety Notice	
	<p>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.</p> <p>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.*</p>

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URGENT Field Safety Notice (FSN)
“Purge System Blocked” alarm delay with AIC Old Software version
Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	2026-FA-000127
FSN Date*	2026-03-03
Product/ Device name*	Automated Impella Controller (AIC)
Product Code(s)	0042-0000, 0042-0010; 0042-0040.
Serial Number	All Customers SN impacted: IC5403; IC5404; IC5801; IC5904; IC10408; IC10425; IC3099; IC3102; IC5918; IC5921; IC5666; IC5667; IC4329; IC4358;

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		
<input type="checkbox"/>	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Complete or enter N/A
<input type="checkbox"/>	I performed all actions requested by the FSN.	Complete or enter N/A
<input type="checkbox"/>	The information and required actions have been brought to the attention of all relevant users.	Complete or enter N/A
<input type="checkbox"/>	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	DL-EUFSCA@its.jnj.com
Customer Helpline	+800 0 22 466 33
Postal Address	Abiomed GmbH Att. of Mariano Santos 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

