Abiomed, Inc.
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FSN Ref: 2026-FSN-0000140 FSCA Ref: 2026-FA-0000140

Date: 2026-06-01

URGENT Field Safety Notice
AIC EPC Software Error

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 **Malte Flory +49 172 4556857** **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 6.0.1, 6.0.2, 6.0.3, and 7.1 onwards
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 initiates a correction by informing users of a potential software error in the Automated Impella Controller (AIC) when used in conjunction with left ventricular Impella devices and to provide recommendations on what to do if the issue occurs. **Product is not being removed, and hospital inventory may continue to be used.** Abiomed has identified that when a patient is treated with a left ventricular Impella device and experiences an extended period (>80 minutes) with no residual pulsatility (<12 mmHg on the aortic placement signal), the Automated Impella Controller (AIC) may be forced to restart because of an internal software error. This can occur if there is a sudden change in left ventricular pressure (LVP) while the left ventricular pressure calculation is active (level of support above P-3). Disabling the aortic placement signal and the LVP display does not prevent the AIC from restarting.

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	During the restart, the AIC screen will turn black without further alert, and the pump will stop, during which the patient is unsupported by the Impella system and regurgitation via the cannula may occur. After the AIC restarts, the pump will automatically ramp up speed to the previous P-level. The total time from pump stop to reach the previous P-level may take up to 75 seconds based on preliminary data. Replacement of the AIC with another AIC would not resolve the potential for an AIC restart. **Recommendations for the customers:** • All Abiomed customers who have an Automated Impella Controller SW version 6.0.1, 6.0.2, 6.0.3, and 7.1 onwards will receive the notification. • Product is NOT being removed, and hospital inventory can continue to be used. • In the scenario of extended (>80 min) lack of pulsatility (< 12 mmHg), followed by a sudden change in LVP an AIC console restart will occur during support levels greater than P-3. Additional hemodynamic support may be required in this hemodynamically compromised population. • If such an episode is encountered, a console exchange is unnecessary as the phenomenon will recur on the exchange device. • In patients additionally supported with Veno-arterial ECMO, unloading of the ventricle at a level of support of P-3 or lower will avoid the restart from happening as the LVP calculator causing the issue is off. • Abiomed is actively working on a software update to the AIC to address this issue. 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 DL-EUFSCA@its.jnj.com or your local clinical field staff.
2.	2. Hazard giving rise to the FSCA*
	Health Hazard Evaluation Conclusion: Exposure to the failure of purge alarms to redisplay following an unintentional reboot of the Automated Impella Controller may result in delayed recognition of an underlying purge system abnormality. An unintentional reboot is a rare clinical scenario, and the hazard is limited to situations in which it occurs in the presence of a pre-existing purge alarm, resulting in a low probability of exposure. In most cases, delayed recognition would not be expected to result in patient harm due to continued display of purge pressure and flow parameters, standard visual inspection of infusion systems in intensive care and catheterization lab environments, and the presence of built-in air detection as an independent safeguard. Only under unusual circumstances, such as prolonged failure to recognize an existing purge abnormality, could exposure

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	potentially progress to inadequate or loss of hemodynamic support, which would be considered a life-threatening event. Patients without alternate mechanical support in place could be at increased risk for serious injury or death due to the resulting lack of hemodynamic support in the event of system reboot.
2.	3. Probability of problem arising
	An unintentional reboot is a rare clinical scenario, and the hazard is limited to situations in which it occurs in the presence of a pre-existing purge alarm, resulting in a low probability of exposure from January 1, 2024, to February 28, 2026, identified the software issue in 0.006% of cases (8 reported complaints out of 125,714 cases performed).
2.	4. Predicted risk to patient/users
	Based on available post-market data, no patient harms have been attributed to this failure mode to date, and when assessed within the total clinical system, the product issue does not result in a change to the overall benefit–risk profile of Impella therapy; the life-sustaining benefit of Impella support is maintained regardless of action or inaction. Hence, there is no perceived impact beyond the users.
2.	5. Further information to help characterise the problem
	Please follow instructions in section 2.1
2.	6. Background on Issue
	A review of global complaints from January 1, 2024, to February 28, 2026, identified the software issue in 0.006% of cases (8 reported complaints out of 125,714 cases performed). The complaints review determined that there has been one (1) patient death where the association of the above-described restart to the patient outcome could not be excluded. There have been two (2) cases where the failure resulted in a pump stop. In these two cases, the user chose to exchange the AIC console, which is considered a medical intervention and reportable as a serious injury. As a reminder, replacement of the AIC with another AIC would not resolve the potential for an AIC restart.
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. ☒ Take note of amendment / reinforcement of Instructions For Use (IFU) ☒ Other ☐ None Follow recommendations described in section 2.1 **ACTIONS TO BE TAKEN BY CUSTOMER/USER:** Please follow the recommendations described in **Section 2.1**. Such corrective actions will

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	be formally communicated to you in a timely manner. Until the corrective measures have been implemented, please note the following: • 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. • Review, complete all fields, sign, and return the attached Customer Reply Form to **DL-EUFSCA@its.jnj.com**. **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 ☐ Software upgrade ☒ Other ☐ On-site device modification/inspection ☐ IFU or labelling change ☐ None A Corrective and Preventive Action (CAPA) has been initiated, and Johnson and Johnson Heart Recovery is working diligently to confirm the root causes and to define an appropriate action plan to address the reported condition. Furthermore, we will provide estimated timelines for the implementation of the final solution in the finished products.	
3.	5. By when the action should be completed?	Abiomed is investigating and implementing appropriate corrective actions. The timeline is being established.
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	

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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	Malte Flory Senior Manager, Commercial Quality EMEA

	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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Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	2026-FA-0000140
FSN Date*	2026-06-01
Product/ Device name*	Automated Impella Controller (AIC)
Product Code(s)	0042-0000-EU, 0042-0010-EU, 0042-0040-EU, 0042-0000-UK, 0042-0010-UK; 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	DL-EUFSCA@its.jnj.com
Customer Helpline	+800 0 22 466 33
Postal Address	Abiomed GmbH Att. of Malte Flory 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.