Abiomed, Inc.
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www.abiomed.com

FSN Ref: 2025-FSN-0000105 FSCA Ref: 2025-FA-0000105

Date: 2025-08-21

URGENT Field Safety Notice
Pump Driver Circuit Assembly that does not meet current specifications

For Attention of*: Automated Impella Controller (AIC)

- Customer Name -

Contact details of local representative (name, e-mail, telephone, address etc.)*
Mariano Santos Senior Manager, Commercial Quality Msant169@its.jnj.com +49 1525 8193604

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1. Information on Affected Devices*	
1.	1. Device Type(s)*
	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
1.	5. Software version
	All AIC Software versions.
1.	6. Affected serial or lot number range
	IC2243(DE); IC1775(DE); IC1383(DE); IC1350(DE); IC4002(IT); IC1547(IT); IC1546(NL); IC1548(NL); IC1549(NO); IC1542(GB); IC1519(GB)
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 specific AICs that have a Pump Driver Circuit Assembly that does not meet current specifications. These Pump Driver Circuit Assemblies contain 25V-rated tantalum capacitors instead of 35V-rated tantalum capacitors, failure of which may lead to decreased pump performance or pump stop and trigger an “Impella Failure” or “Impella Stopped. Controller Failure.” alarm.
2.	2. Hazard giving rise to the FSCA*
	Delayed or unanticipated capacitor failure, resulting in pump stops and cessation of mechanical circulatory support, has the potential to compromise patient hemodynamic stability, which may influence the overall benefit-risk profile of the device. Based on available data and technical assessments, the potential clinical consequences of exposure to this hazard mostly include an un-anticipated console exchange where there may be a transient period of inadequate hemodynamic support which is a reversible tissue

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	injury if identified early. However, in exceptionally rare cases where failure is unrecognized or intervention is delayed, there is a risk of irreversible organ damage or severe organ ischemia secondary to loss of hemodynamic support, which could be potentially life-threatening.
2.	3. Probability of problem arising
	An occurrence rate of 0.006% (27 complaints / 393,776 uses) was identified from global complaints related to alarms caused by this issue from January 01, 2011, to June 30, 2025. One (1) complaint over this date range reported a patient death in the United States related to this Pump Driver Circuit Assembly issue. This issue impacts 69 AIC units out of a total 10,084 AIC units distributed to customers as of July 29, 2025. The probability of patients experiencing harm based on this issue is rare. In the case of capacitor failure in the AIC, an abrupt pump stoppage or decreased performance of the AIC may occur, potentially resulting in transient hemodynamic instability, loss of circulatory support, and/or death.
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
	Complaint investigation confirmed a tantalum capacitor failure (C319.2) on console IC1531 which led to an unexpected pump stop and an adverse event reported under the complaint. Investigation determined that this complaint console (IC1531) had an Impellatronic Printed Circuit Assembly (PCA) with 25V-rated tantalum capacitors instead of 35V-rated, and that there are other AICs in the field that also have the Impellatronic PCA board with 25V-rated tantalum capacitors instead of 35V-rated. These under rated capacitors may result in a pump stop and failure alarm(s) as reported in the complaint.
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 **ACTIONS TO BE TAKEN BY CUSTOMER/USER:** Please follow the recommendations provided to minimize the risk associated with this

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	issue while Abiomed implements appropriate corrective actions. Such corrective actions will be implemented through console servicing. • **Quarantine immediately and do not use the subject products.** • 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) • Review and complete all fields and sign the Field Safety Notification (FSN) and send it to dl-eufsca@its.jnj.com. • Contact our Abiomed Field Service team eufieldservice@its.jnj.com to coordinate next steps. • 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 the FSN in a visible area for awareness of the field safety notice and keep the copy of the FSN together with the IFU.	
3.	2. By when should the action be completed?	Quarantine of the impacted product should be completed immediately without delay.
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 A Corrective and Preventive Action (CAPA) has been initiated, and we are working diligently to confirm the root causes and to define an appropriate action plan to address the reported condition in the impacted AIC units.	
3.	5. By when should the action 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

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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	Colin McArthur Senior Director, Commercial Quality

	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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FSN Ref: 2025-FSN-000105 FSCA Ref: 2025/008/022/601/038 (MHRA)

URGENT Field Safety Notice (FSN)

Title.

Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	2025-FA-0000105
FSN Date*	2025-08-21
Product/ Device name*	Automated Impella Controller (AIC)
Product Code(s)	0042-0000
Serial number(s)	IC1519; IC1542

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 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**

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.