Abiomed, Inc.
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Phone: +1 978-646-1400
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www.abiomed.com

FSN Ref: 2026-FSN-0000136 FSCA Ref: 2026-FA-0000136

Date: 2026-06-05

URGENT Field Safety Notice
Missing Implementation of Field Change Notifications

For Attention of*:

Contact details of local representative (name, e-mail, telephone, address etc.) *
Abiomed Europe GmbH **Neuenhofer Weg 3** **D-52074 Aachen** **E-Mail: DL-EUFSCA@its.jnj.com** **Malte Flory Tel. +49 172 455 68 57** **Customer Service Tel.: +800 0 22 466 33**

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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-EU
1.	5. Software version
	All AIC Software versions
1.	6. Affected serial or lot number range
	Serial Number: IC1577
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 Removal: Abiomed has decided to initiate a voluntary medical device recall (removal) related to a retrospective review of servicing records. This review identified that there is one AIC unit (Serial Number IC1577) requiring specific hardware updates to address potential safety concerns. These hardware updates have been implemented through Abiomed's servicing process. The identified AICs that have not received service in the interim are still pending these updates. Below the issues and hardware updates that need to be implemented by Abiomed service to correct the issue on the identified device are summarized. **Field Change Notification (FCN) 23:** **Issue:** The proximity of the internal Video Graphics Array cable to the Digital Signal Processor chipset on the Impellatronic printed circuit assembly could potentially result in Electrostatic Discharge coupling into the Digital Signal Processor which may interrupt motor controls.

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	Hardware Update: Installation of a Twist Lok cable retention device to hold the Video Graphics Array cable away from the Digital Signal Processor chipset. **Implementation Date**: September 23, 2014 **Field Change Notification (FCN) 38:** **Issue:** Potential capacitor related issues on the Power Battery Manager, including the potential for the capacitors to cause pump stop, purge stop, and/or single fan fuse failures. **Hardware Update:** Add a new Power Battery Manager printed circuit board assembly with improved on-board components (capacitors and fuses). **Implementation Date:** July 28, 2017
2.	2. Hazard giving rise to the FSCA*
	Hazard associated with FCN 23: Electrostatic discharge (ESD) coupling into the DSP due to improper VGA cable routing, potentially interrupting motor control and causing pump stop. **Hazard associated with FCN 38:** Short circuit or failure of critical tantalum capacitors causing loss of electrical power to the pump or cooling system, leading to pump stop or system overheating.
2.	3. Probability of problem arising
	Abiomed has not received complaints related to the issues for the units pending these updates therefor a probability cannot be determined.
2.	4. Predicted risk to patient/users
	Predicted risk to patient/users for FCN 23: ESD-induced interruption of motor control may cause pump stop, leading to transient inadequate hemodynamic support or, in higher-risk patients, potential loss of support. **Predicted risk to patient/users for FCN 38:** Capacitor failure or short circuit may cause pump stop or system shutdown, require controller exchange and resulting in periods of inadequate or, in rare cases, complete loss of hemodynamic support.
2.	5. Further information to help characterise the problem
	N/A
2.	6. Background on Issue
	A retrospective review of Abiomed Field Change Notifications (FCNs) has been conducted as part of an investigation that was initiated based on an internal audit finding.

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	During the review four (4) FCNs (FCN 23, FCN 31, FCN 32, and FCN 38) were identified that were not fully conducted and required action on product in the field. Two (2) of the FCNs (FCN 23 and FCN 38) affected product in the European Union.
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 **Details on the Action to be Taken by the User:** • The Abiomed servicing team will contact you to coordinate the return of the device(s) to implement necessary changes. To ensure continuity of care, hospital inventory can continue to be used. • Upon contact from Abiomed's field servicing team, please work with them to return the identified device(s) for the change to be implemented. • Review, complete all fields, sign, and return the attached field safety notification (FSN) to DL-EUFSCA@its.jnj.com • 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.	
3.	2. By when the action should be completed?	30/Jun/2026
3.	3. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes

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3.	**4. Action Being Taken by the Manufacturer*** ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☒ Other ☐ None • Impacted products will be removed from the customer site, updates will be implemented, and product will be sent back to the customer.		
3.	5. By when the action should be completed?	30/Sep/2026	
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	Malte Flory Commercial Quality Sr Manager 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-FSN-0000136
FSN Date*	05/Jun/2026
Product/ Device name*	Automated Impella Controller (AIC)
Product Code(s)	0042-0000, 0042-0000-EU
Serial Number:	IC1577

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*	

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 Europe 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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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.