Abiomed, Inc.
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www.abiomed.com

FSN Ref: 2025-FSN-000110 FSCA Ref: 2025-FA-000110

Date: 2025-10-10

URGENT Field Safety Notice
AIC Cybersecurity Notification

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 Kundenservice 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)*
	0042-0010; 0042-0040; 0042-0000. (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 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*
	As a result of an internal cyber security assessment, Abiomed initiated a Field Safety Corrective Action to notify customers of identified cybersecurity vulnerabilities related to the operating system in the Automated Impella Controller (AIC). These vulnerabilities have residual risk related to network and physical access that could be compromised and that result in uncontrolled risks affecting the AIC Operating System. Product is not being removed, and hospital inventory can continue to be used. If the identified cybersecurity vulnerabilities are exploited, it may affect the essential performance of the compromised AIC. This may potentially result in loss of device control or unexpected pump stop, which may result in a life-threatening injury, permanent impairment or death. To date, no cybersecurity incidents or harm to patients have been reported, and no life-threatening injury, permanent impairment or death have been reported in relation to the identified vulnerabilities. Abiomed is working on security updates and measures to address these cybersecurity vulnerabilities. To mitigate the vulnerability risk, Abiomed field representatives will contact customers to implement a USB driver isolation software patch and physical controls to

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	eliminate vulnerability or, if requested by the customer, to arrange disabling the AIC's network capabilities. The AIC may continue to be used as intended. Timing for the availability of the patch is currently estimated as January 2026. **RECOMMENDATIONS:** All Abiomed customers who are in possession of an AIC console that requires the correction will receive the Field Safety Notice. To date, no cybersecurity incidents or harm to patients have been reported, and no life-threatening injury, permanent impairment or death have been reported in relation to the identified vulnerabilities. Healthcare providers can continue to use the AIC as intended. **ACTIONS**: Product is not being removed, and hospital inventory can continue to be used. To mitigate the vulnerability risk, Abiomed field representatives will contact customers to implement a USB driver isolation software patch and physical controls to eliminate vulnerability or, if requested by the customer, to arrange disabling the AIC's network capabilities. The AIC may continue to be used as intended. Timing for the availability of the patch is currently estimated as January 2026. All vulnerabilities assessed are from the Operating System within the AIC and do not extend beyond the console itself. Our risk assessment has not identified any risks of these AIC vulnerabilities to hospital networks. If the customer has questions regarding this notice as they perform any hospital network risk assessments, they will be instructed to contact https://www.productsecurity.jnj.com/. Customers will also be instructed to keep the AIC in a secure environment with restricted access whether in clinical use or not. Please note that the following physical controls are part of our standard AIC controls and they remain in place: 1. The AIC ethernet port and data download via USB is disabled during clinical use. 2. Backup AIC is available per Instructions for Use (IFU). 3. USB port is inactive during patient therapy. **ACTIONS TO BE TAKEN BY CUSTOMER/USER:** * Follow actions described in Recommendations: * Review, complete all fields, sign, and return the attached Customer Reply Form to DL-EUFSCA@its.jnj.com. * If there is suspicion of a cybersecurity event, report to https://www.productsecurity.jnj.com/.
2.	2. Hazard giving rise to the FSCA*
	Health Hazard Evaluation conclusion: It is important to note that the probability of these cybersecurity threats materializing and potentially impacting patient care is exceedingly rare. The likelihood of significant device failure or interruption due to the identified hazards

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	is exceedingly rare and will not likely occur during clinical use, but the severity of potential patient harm remains high. Exposure to cybersecurity vulnerabilities or system disruptions in the Impella system may potentially be expected to result in loss of device control or support, which can lead to abrupt hemodynamic deterioration due to loss of hemodynamic support (S5). In patients with cardiogenic shock, such support interruption could cause tissue hypoperfusion and organ ischemia, potentially resulting in reversible tissue damage. Exposure to cybersecurity threats that result in failure to maintain adequate support or any event resulting in the need for an AIC exchange, may potentially result in a period of inadequate hemodynamic support (S3).If the issue leads to a AIC failure prior to initiation of therapy, this is typically considered a user inconvenience (S1), as a backup console can still be connected before therapy begins. The current product issues, if unmitigated, could shift the risk-benefit ratio unfavourably by allowing the potential for critical support failure; conversely, implementing appropriate safeguards and monitoring strategies can maintain the benefits of the Impella system, which are substantial in managing high-risk and critically ill patients. Inaction (not addressing the hazards) could lead to increased potential for device failure, increasing the risk in the risk-benefit profile of the device. Conversely, proactive mitigation and remediation measures can preserve the current favourable risk-benefit profile, supporting the use of Impella in life-threatening situations where it offers critical, often life-saving support.
2.	3. Probability of problem arising
	To date, no cybersecurity incidents or harm to patients have been reported, and no life-threatening injury, permanent impairment or death have been reported in relation to the identified vulnerabilities.
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
	This potential issue was detected during Abiomed internal cyber security assessment.
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

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ACTIONS TO BE TAKEN BY CUSTOMER/USER:

Please follow the recommendations described in **Section 2.1**. Such corrective actions will 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.
- Keep the AIC in a secure environment with restricted access whether in clinical use or not.
- 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.
- If there is suspicion of a cybersecurity event, report to https://www.productsecurity.jnj.com/

To increase awareness of these recommendations:
*** Keep the copy of this FSN together with your IFU.**

3.	2. By when should the action 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 we are 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.

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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

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	[redacted] 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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URGENT Field Safety Notice (FSN)

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Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	2025-FA-000110
FSN Date*	2025-10-10
Product/ Device name*	Automated Impella Controller (AIC)
Product Code(s)	0042-0000, 0042-0010; 0042-0040.

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 [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.