Abiomed, Inc.
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FSN Ref: 2025-FSN-000103 FSCA Ref: 2025-FA-000103

Date: 2025-06-24

URGENT Field Safety Notice
Risk of Automated Impella Controller (AIC) not detecting an Impella pump when it is connected.

For Attention of*: All Automated Impella Controller (AIC)

Contact details of local representative (name, e-mail, telephone, address etc.)*
This could be a distributor or local branch of the manufacturer. To be added at the appropriate stage in the different local languages.

Please,

- review this Field Safety Notice.
- complete the mandatory information in the Customer Reply Form, page 9.
- confirm/correct information of Healthcare Organisation. If you respond for more than one Institution, include the name in the field “This Customer reply form also applies to these additional organizations:” on the last page 10.
- Send the Customer Reply Form by email to DL-EUFSCA@its.jnj.com within 7 working days.

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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*
	Abiomed has identified an AIC issue that may prevent the detection of an Impella pump when connected to an AIC. Product is not being removed, and hospital inventory may continue to be used. As indicated in IFUs, Abiomed recommends having a back-up AIC available in the event of a device failure. The pump detection issue may occur with any of the Abiomed Impella pumps and may occur during console-to-console transfer or at initiation of therapy at case start. There is no visual alarm displayed on the AIC screen to indicate the detection issue in these situations.

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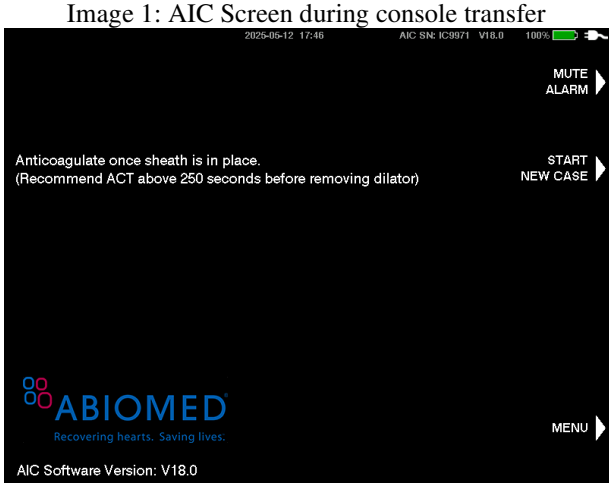
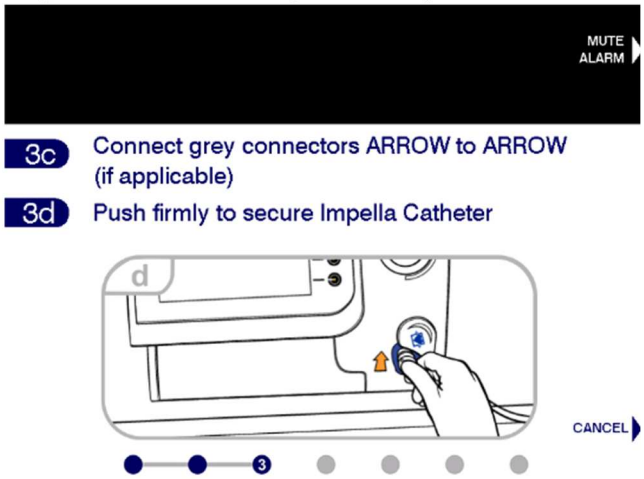
During console-to-console transfer, if the pump is not detected once connected to the AIC the AIC screen in Image 1 remains and does not advance.

Image 1: AIC Screen during console transfer



During case start, if the pump is not detected once connected to the AIC, the AIC screen in Image 2 remains and does not advance.

Image 2: AIC Screen during case start up



An occurrence rate of 0.02% was identified from complaints related to this issue from January 01, 2021 to May 21, 2025. One (1) complaint over this date range reported a patient death that is associated to this detection issue. As such, the probability of patients experiencing harm based on this issue is extremely rare. However, if the AIC fails to recognize the pump, there is the potential for the patient to experience inadequate hemodynamic support. Such exposure particularly poses risks to patients in cardiogenic shock, where episodes of inadequate support may not be well tolerated and may lead to life-threatening conditions (hypoperfusion and cardiogenic shock) with the potential for permanent impairment.

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RECOMMENDATIONS:

Product is not being removed, and hospital inventory may continue to be used.

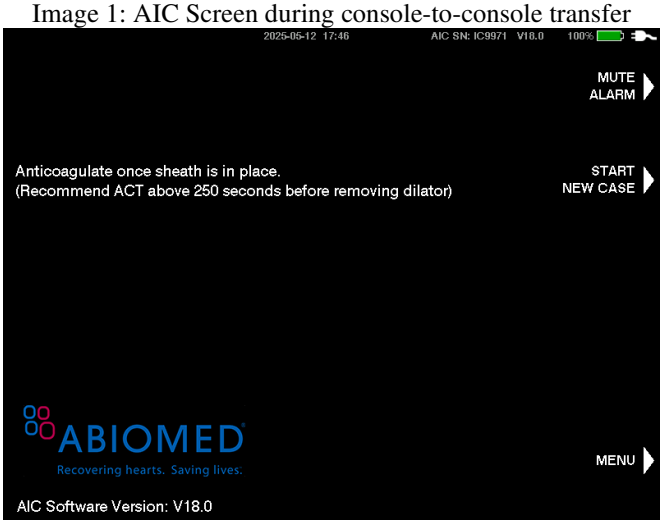
As indicated in IFUs, have a back-up Automated Impella Controller (AIC) available in the unlikely event of a device failure.

Console-to-Console Transfer:

If the AIC screen in Image 1 remains for more than 20 seconds and does not advance after connecting the pump to the transferred console:

- Immediately switch the pump to the previous console to restore support to the patient.
- If the previous console displays an alarm message, switch to a different console if available.
- Restart the console that does not advance from Image 1 before attempting to re-connect a pump.

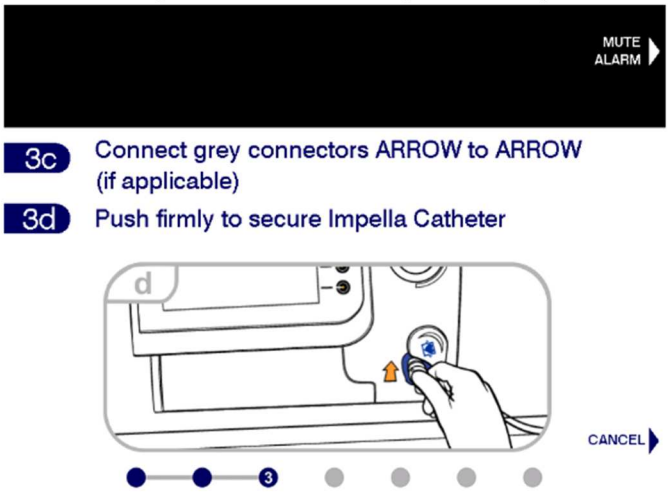
Image 1: AIC Screen during console-to-console transfer



Case Start:

If the AIC screen in Image 2 remains for more than 20 seconds after connecting the pump and does not progress to indicate "Detecting Impella", either re-start the case on the console or switch the pump to a different console.

Image 2: AIC Screen during case start up



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	ACTIONS TO BE TAKEN BY CUSTOMER/USER: Please follow the recommendations provided to minimize the risk associated with this issue while Abiomed implements appropriate corrective actions. Such corrective actions will likely be implemented through console servicing. • 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. • 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.
2.	2. Hazard giving rise to the FSCA*
	Health Hazard Evaluation conclusion: Physicians rely on clinical expertise and data to make decisions. In standard clinical use, it is understood that the AIC controller may need to be replaced, which may result in an anticipated temporary period of inadequate hemodynamic support during the period of controller exchange. During a planned transition, physicians may anticipate and respond to the potential risk. The probability of harm may be increased during unanticipated controller exchanges. If the AIC fails to recognize the pump, this has the potential to result in inadequate hemodynamic support, which can reasonably be expected to lead to reversible hemodynamic instability. Such exposure poses risks to patients, particularly for patients in cardiogenic shock, where prolonged episodes of inadequate support may not be well tolerated and may lead to life threatening injuries (hypoperfusion and cardiogenic shock) with the potential for permanent impairment. This situation could occur without user awareness, resulting in a reliance on clinical judgment amidst potentially inadequate guidance on the AIC and the IFU during critical moments. Although the probability of patients experiencing harm based on this issue is extremely rare, the identified product issue may alter the risk-benefit ratio. The absence of visual alarms and clear instructions during equipment failure may limit timely corrective interventions. The product issue would increase the risk to the patient but the overall benefit of Impella therapy is maintained.
2.	3. Probability of problem arising
	An occurrence rate of 0.02% was identified from complaints related to this issue from January 01, 2021 to May 21, 2025. One (1) complaint over this date range reported a patient death that is associated to this detection issue. As such, the probability of patients experiencing harm based on this issue is extremely rare. However, if the AIC fails to recognize the pump, there is the potential for the patient to experience inadequate hemodynamic support. Such exposure particularly poses risks to patients in cardiogenic shock, where episodes of inadequate support may not be well tolerated and may lead to life-threatening conditions (hypoperfusion and cardiogenic shock) with the potential for permanent impairment.
2.	4. Predicted risk to patient/users

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	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
	Recent reoccurrence, (detected through complaint vigilance), of a known AIC failure mode with AIC not recognizing a pump when connecting.
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 issue while Abiomed implements appropriate corrective actions. Such corrective actions will likely be implemented through console servicing. • 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. • 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. **To increase awareness of these recommendations:** *** Keep the copy of this FSN together with your IFU.**

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3.	2. By when should the action be completed?	Reinforcement of proper handling should be distributed to All Impella pumps users as soon as possible.
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.

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	Insert Name and Title here and signature below.

	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*	2025-FA-000103
FSN Date*	2025-06-25
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 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.