

URGENT MEDICAL DEVICE CORRECTION (NOTIFICATION)

PLEASE DISTRIBUTE THIS INFORMATION TO APPROPRIATE PERSONNEL AT YOUR FACILITY WHO MAY USE THE PRODUCT THAT IS THE SUBJECT OF THIS NOTICE

June 25th, 2025

Dear Valued Customer,

Please be advised that Abiomed, Inc (“Abiomed”) has initiated a device correction (notification) to inform you of a potential issue with the Automated Impella Controller (AIC) not detecting an Impella pump when it is connected. 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.

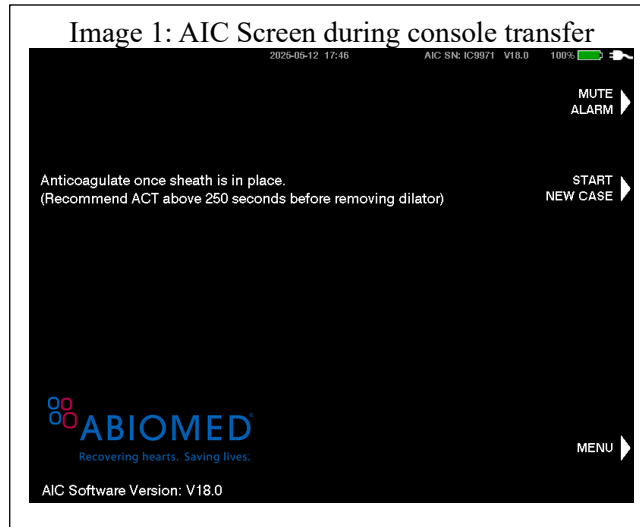
Product Code(s)	Product Description(s)	Affected Lots / Serial No.
0042-0000	Impella Controller, Packaged	All lots and serial numbers are affected
0042-0000-AU	Impella Controller, Packaged, AU	
0042-0000-IN	Impella Controller, Packaged, IN	
0042-0000-UK	Impella Controller, Packaged, UK	
0042-0000-US	Impella Controller, Packaged, US	
0042-0010	Impella Optical Controller	
0042-0010-AU	Impella Optical Controller, Packaged, AU	
0042-0010-EU	Impella Optical Controller, Packaged, EU	
0042-0010-IN	Impella Optical Controller, Packaged, IN	
0042-0010-UK	Impella Optical Controller, Packaged, UK	
0042-0010-US	Impella Optical Controller, Packaged, US	
0042-0040	AIC, Optical, Impella Connect, Packaged	
0042-0040-AU	AIC, Optical, Impella Connect, Packaged, AU	
0042-0040-UK	AIC, Optical, Impella Connect, Packaged, UK	
0042-0040-US	AIC, Optical, Impella Connect, Packaged, US	
0042-0040-KR	AIC, Optical, Impella Connect, Packaged, KR	

REASON FOR NOTIFICATION:

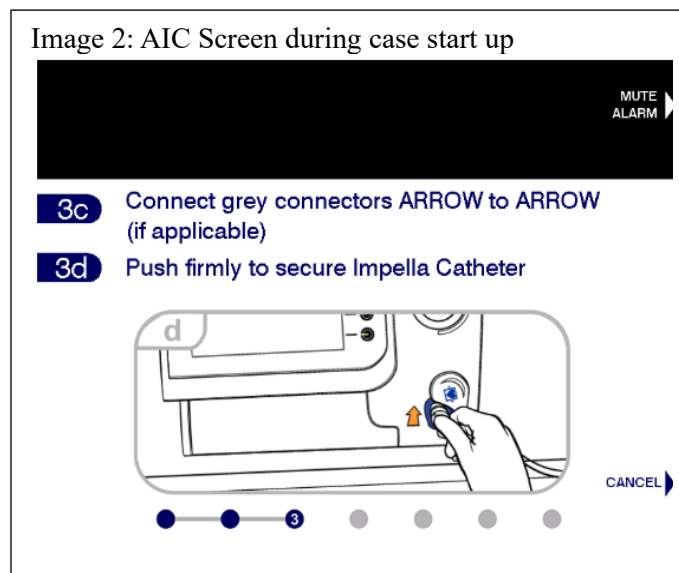
Abiomed has identified an AIC issue that may prevent the detection of an Impella pump when connected to an AIC. The pump detection issue may occur with any of the Abiomed Impella pumps and may occur during console-to-console transfer or at initiation of therapy at case start. There is no visual alarm

displayed on the AIC screen to indicate the detection issue in these situations.

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.



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.



An occurrence rate of 0.02% was identified from complaints related to this issue from January 01, 2021, to May 21, 2025. Two (2) complaints 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.

RECOMMENDATIONS:

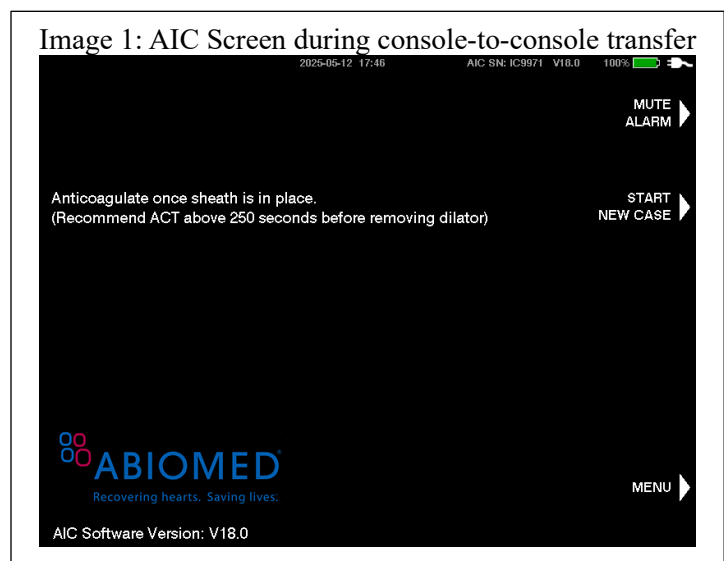
Product is not being removed, and hospital inventory may continue to be used.

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:

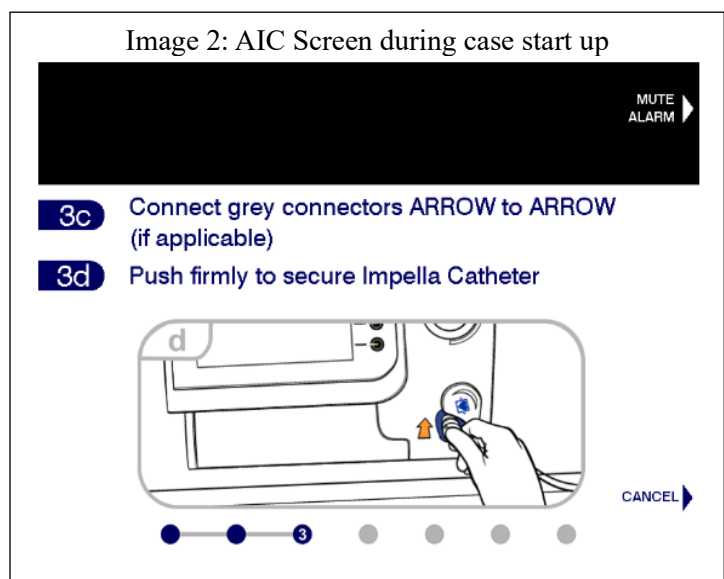
If the AIC screen in Image 1 remains for more than 20 seconds and does not advance after connecting the pump to the transferred console:

- 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.



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.



Note: Attachment 2 provides this guidance for additional visual representation and reference.

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 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.
- Review, complete all fields, sign, and return the attached business response form (BRF) (refer to Attachment 1) to your local Abiomed representative.
- As with any medical device, adverse reactions or quality problems experienced with the use of this product should be reported according to your procedures and applicable regulatory requirements.

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 your local clinical field staff. Thank you for your cooperation.

Attachments:

Attachment 1 – Business Reply Form

Attachment 2 – Impella Pump Detection Issue Scenarios & Resolutions

Attachment 1 – Business Reply Form (BRF)

Product Code(s)	Product Description(s)
0042-0000	Impella Controller, Packaged
0042-0000-AU	Impella Controller, Packaged, AU
0042-0000-IN	Impella Controller, Packaged, IN
0042-0000-UK	Impella Controller, Packaged, UK
0042-0000-US	Impella Controller, Packaged, US
0042-0010	Impella Optical Controller
0042-0010-AU	Impella Optical Controller, Packaged, AU
0042-0010-EU	Impella Optical Controller, Packaged, EU
0042-0010-IN	Impella Optical Controller, Packaged, IN
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0042-0040-AU	AIC, Optical, Impella Connect, Packaged, AU
0042-0040-UK	AIC, Optical, Impella Connect, Packaged, UK
0042-0040-US	AIC, Optical, Impella Connect, Packaged, US
0042-0040-KR	AIC, Optical, Impella Connect, Packaged, KR

Please complete this Business Reply Form **within 3 business days upon receipt of the notification** and return this form to your local Abiomed representative.

By signing this form, I am confirming that I have read and understand the correction (notification) information provided in this letter and actions were appropriately taken.

Acknowledgement Signature		Date	
Print Name		Telephone	
Account Name & Address			
Email			
Comments:			

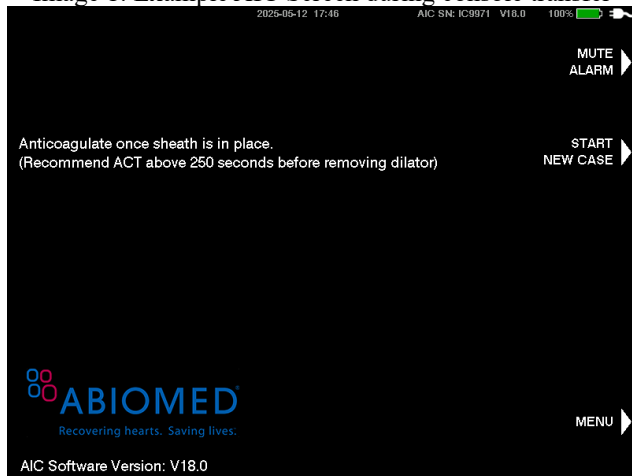
Attachment 2: Impella Pump Detection Issue Scenarios & Resolutions

Console-to-Console Transfer Scenario:

During 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: Example AIC Screen during console transfer



Case Start Scenario:

During 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: Example AIC Screen during case start up

