

URGENT MEDICAL DEVICE CORRECTION (NOTIFICATION)
(Letter Issued on June 25, 2025 was Updated; see below)

Product Code(s)	Product Description(s)	UDI-DI(s)
0042-0000-US	Impella Controller, Packaged, US	00813502010022
0042-0010-US	Impella Optical Controller, Packaged, US	00813502010985
0042-0040-US	Optical, AIC, Impella Connect, Pkgd, US	00813502011401
1000432	AIC w/Impella Connect for ECP	00813502013030
1000201	Dbl optical, AIC Impella Connect, Phg US	00813502010442

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

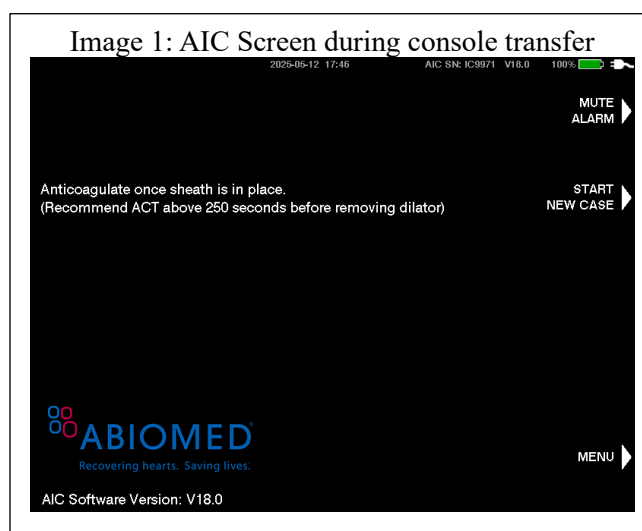
Dear Valued Customer,

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.

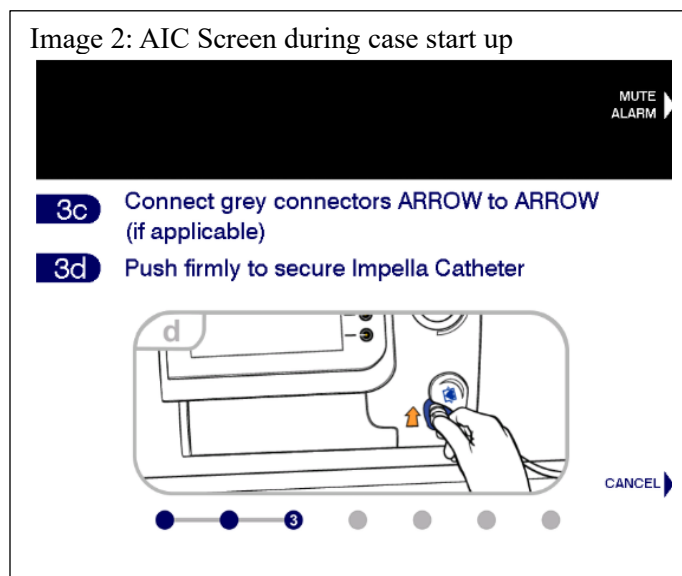
REASON FOR NOTIFICATION:

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. This is the only screen that will be shown in this transfer scenario.



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 associated with this detection issue. Additionally, one (1) complaint over this date range reported a patient death; however, it is determined not to be associated with 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:

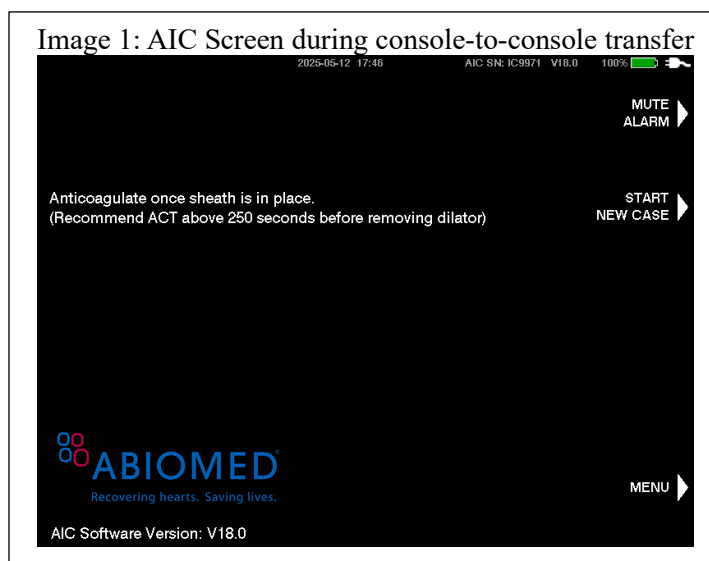
Product is not being removed, and hospital inventory may continue to be used.

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:

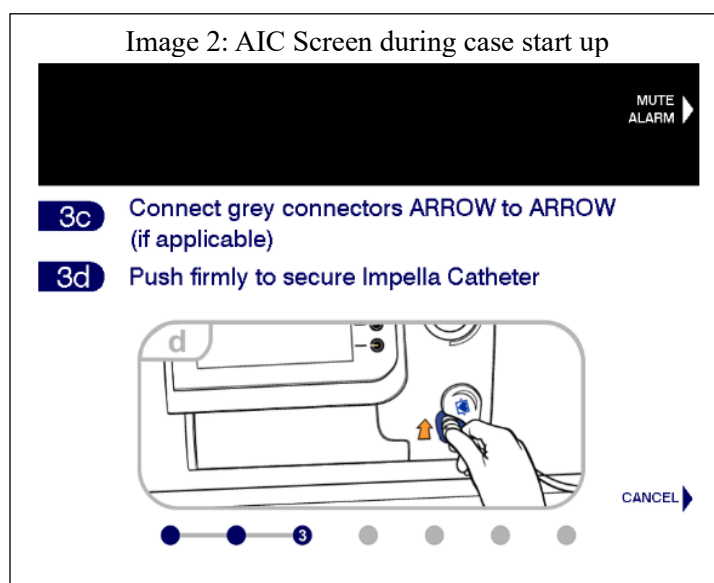
If the AIC screen in Image 1 remains for more than 20 seconds and does not advance after connecting the pump to the transferred console:

- 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 business response form (BRF) provided to impacted customers to abiomed6541@sedgwick.com.
- As with any medical device, adverse reactions or quality problems experienced with the use of this product should be reported to the FDA's MedWatch Adverse Event Reporting Program as per below instructions:
 - Complete and submit the report online: www.fda.gov/medwatch/report.htm or
 - Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.

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 onemd-field-actions@its.jnj.com or your local clinical field staff. Thank you for your cooperation.

Attachments:

Attachment 1 – Impella Pump Detection Issue Scenarios & Resolutions

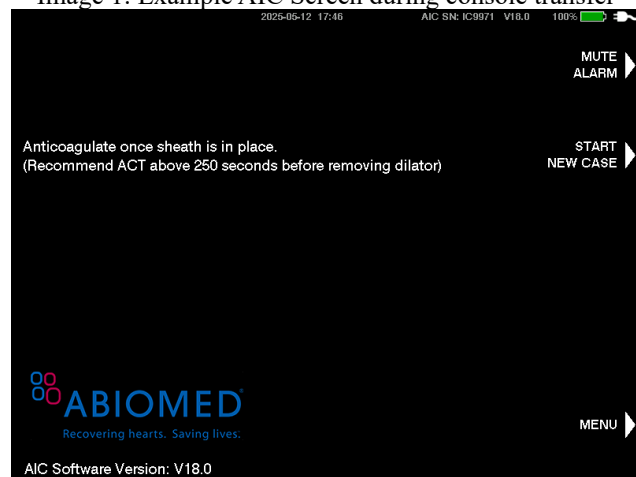
Attachment 1 – Impella Pump Detection Issue Scenarios & Resolutions

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

