

**URGENT MEDICAL DEVICE RECALL (CORRECTION)**  
**AIC EPC Software Error**

<b>Product Code(s)</b>	<b>Product Description(s)</b>	<b>Affected Serial No.</b>
0042-0000-AU	Impella Controller, Packaged, AU	AIC with software version 6.0.1–6.0.3 and ≥7.1
0042-0000-CA	Impella Controller, Packaged, CA	
0042-0000-EU	Impella Controller, Packaged, EU	
0042-0000-IN	Impella Controller, Packaged, IN	
0042-0000-JP	Impella Controller, Packaged, JP	
0042-0000-UK	Impella Controller, Packaged, UK	
0042-0000-US	Impella Controller, Packaged, US	
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-AU	Optical, AIC, Impella Connect, Packaged, AU	
0042-0040-CA	Optical AIC w/Impella Connect, Packaged, CA	
0042-0040-EU	Optical, AIC, w/Impella Connect, Packaged, EU	
0042-0040-JP	Optical, AIC, w/Impella Connect, Packaged, Japan	
0042-0040-UK	Optical, AIC, Impella Connect, Packaged, UK	
0042-0040-US	Optical, AIC, Impella Connect, Packaged, US	

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

May 18, 2026

Dear Valued Customer,

Abiomed, Inc. has issued a voluntary device recall (correction) to notify customers of a potential software error in the Automated Impella Controller (“AIC”) when used in conjunction with left ventricular Impella devices. This potential software error, in a specific clinical circumstance, could contribute to serious injury or death in certain patient populations. The information in this notification is being provided to support appropriate clinical awareness, monitoring, and patient support as needed. **Product is not being removed, and hospital inventory can continue to be used.**

**REASON FOR NOTIFICATION:**

Abiomed has identified that when a patient is treated with a left ventricular Impella device and experiences an extended period (>80 minutes) with no residual pulsatility (<12 mmHg on the aortic placement signal), the Automated Impella Controller (AIC) may be forced to restart because of an internal software error. This can occur if there is a sudden change in left ventricular (LV) pressure while

the left ventricular pressure (LVP) calculation is active (level of support above P-3). Disabling the aortic placement signal and the LVP display does not prevent the AIC from restarting.

During the restart, the AIC screen will turn black without further alert and the pump will stop, during which the patient is unsupported by the Impella system and regurgitation via the cannula may occur. After the AIC restarts, the pump will automatically ramp up speed to the previous P-level. The total time from pump stop to reach previous P-level may take up to 75 seconds based on preliminary data. Replacement of the AIC with another AIC would not resolve the potential for an AIC restart.

Abiomed is actively working on a software update to the AIC to address this issue.

### **POTENTIAL PATIENT IMPACT:**

Patients without alternate mechanical support in place could be at increased risk for serious injury or death due to the resulting lack of hemodynamic support in the event of system reboot.

A review of global complaints from January 1, 2024 to February 28, 2026 identified the software issue in 0.006% of cases (8 reported complaints out of 125,714 cases performed). The complaints review determined that there has been one (1) patient death where the association of the above-described restart to the patient outcome could not be excluded. There have been two (2) cases where the failure resulted in a pump stop. In these two cases, the user chose to exchange the AIC console, which is considered a medical intervention and reportable as a serious injury. As a reminder, replacement of the AIC with another AIC would not resolve the potential for an AIC restart.

### **ACTIONS TO BE TAKEN BY CUSTOMER/USER:**

- Product is NOT being removed, and hospital inventory can continue to be used.
- In the scenario of extended (>80 min) lack of pulsatility (< 12 mmHg), followed by a sudden change in LV pressure an AIC console restart will occur during support levels greater than P-3. Additional hemodynamic support may be required in this hemodynamically compromised population.
- If such an episode is encountered, a console exchange is unnecessary as the phenomenon will recur on the exchange device.
- In patients additionally supported with veno-arterial ECMO, unloading of the ventricle at a level of support of P-3 or lower will avoid the restart from happening as the LVP calculator causing the issue is off.
- Abiomed is actively working on a software update to the AIC to address this issue.
- Review, complete all fields, sign, and return the attached business response form (BRF) (refer to Attachment 1) to your local Abiomed representative.
- Forward this notice 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 this notice in a visible area for awareness.
- 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 1 – Business Reply Form (BRF)**  
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0042-0040-US	Optical, AIC, Impella Connect, Packaged, US	

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 information provided in this letter and actions were taken appropriately.

<b>Acknowledgement Signature</b>		<b>Date</b>	
<b>Print Name</b>		<b>Telephone</b>	
<b>Account Name &amp; Address</b>			
<b>Email</b>			
<b>Comments:</b>			