

URGENT MEDICAL DEVICE CORRECTION
AIC Cybersecurity Notification

Product Code(s)	Product Description(s)	Affected Lots / Serial No.
0042-0000-AU	Impella Controller, Packaged, AU	All lots and serial numbers are affected
0042-0000-CA	Impella Controller, Packaged, CA	
0042-0000-EU	Impella Controller, Packaged, EU	
0042-0000-EU-L	Impella Controller, Packaged, EU, Loaner	
0042-0000-IN	Impella Controller, Packaged, IN	
0042-0000-JP	Impella Controller, Packaged, JP	
0042-0000-JP-L	Impella Controller, Japan, Loaner	
0042-0000-UK	Impella Controller, Packaged, UK	
0042-0000-UK-L	Impella Controller, Packaged, UK, Loaner	
0042-0000-US	Impella Controller, Packaged, US	
0042-0000-US-L	Impella Controller, Packaged, US, Loaner	
0042-0010-AU	Impella Optical Controller, Packaged, AU	
0042-0010-EU	Impella Optical Controller, Packaged, EU	
0042-0010-EU-L	Impella Optical Controller, EU, Loaner	
0042-0010-IN	Impella Optical Controller, Packaged, IN	
0042-0010-UK	Impella Optical Controller, Packaged, UK	
0042-0010-UK-L	Impella Optical Controller, UK, Loaner	
0042-0010-US	Impella Optical Controller, Packaged, US	
0042-0010-US-L	Impella Optical Controller, US, Loaner	
0042-0040-AU	Optical, AIC, Impella Connect, Packaged, AU	
0042-0040-CA	Optical AIC w/Impella Connect, Packaged, CA	
0042-0040-CT	AIC w/Remote Link, Packaged, CIn Trl, US	
0042-0040-CT-L	AIC w/Remote Link, Packaged, CIn Trl, US, Loaner	
0042-0040-EU	Optical, AIC, w/Impella Connect, Packaged, EU	
0042-0040-EU-L	Optical, AIC, w/Impella Connect, EU, Loaner	
0042-0040-JP	Optical, AIC, w/Impella Connect, Packaged, Japan	
0042-0040-JP-L	Optical AIC w/Impella Connect, Packaged, JP	
0042-0040-UK	Optical, AIC, Impella Connect, Packaged, UK	
0042-0040-US	Optical, AIC, Impella Connect, Packaged, US	
0042-0040-US-L	Optical, AIC, Impella Connect, Packaged, US, Loaner	
1000201	Double optical, AIC, Impella Connect, Packaged, US	
1000432	AIC, w/Impella Connect for ECP	

PLEASE DISTRIBUTE THIS INFORMATION TO BIOMEDICAL ENGINEERING, IT DEPARTMENT, AND OTHER APPROPRIATE PERSONNEL AT YOUR FACILITY WHO MAY USE THE PRODUCT THAT IS THE SUBJECT OF THIS NOTICE

October 13, 2025

Dear Valued Customer,

Please be advised that Abiomed, Inc (“Abiomed”) has initiated a voluntary medical device recall (correction) to notify customers of cybersecurity vulnerabilities related to the operating system in the Automated Impella Controller (“AIC”) that were discovered through internal cybersecurity risk

assessments. **Product is not being removed, and hospital inventory can continue to be used.**

REASON FOR NOTIFICATION:

Abiomed has identified cybersecurity vulnerabilities that have residual risk related to network and physical access that could be compromised and that result in uncontrolled risks affecting the Automated Impella Controller (AIC) Operating System. 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. Healthcare providers can continue to use the AIC as intended.

Abiomed is working on security updates and measures to address these cybersecurity vulnerabilities. To mitigate the vulnerabilities risk, your Abiomed field representative will contact you to implement changes to control the vulnerabilities risk or, if you prefer, to arrange disabling AIC's network capabilities. The AIC may continue to be used as intended. Timing for the availability of the changes is estimated as December 2025.

NEXT STEPS:

- Product is NOT being removed, and hospital inventory can continue to be used.
Note to Hospital Departments: 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 you have questions regarding this notice as you perform your hospital network risk assessments, please contact <https://www.productsecurity.jnj.com/>.
- Keep the AIC in a secure environment with restricted access whether in clinical use or not.
- To mitigate the vulnerability risk, your Abiomed field representative will contact you to arrange implementation of changes to control vulnerabilities risk. The AIC may continue to be used as intended.

If you elect to initiate disabling of the AIC's network capabilities prior to an Abiomed field representative contacting you, you must reach out via ra-abm-fieldaction@its.jnj.com or to your local clinical field staff for instructions. Please note a clinical field staff will need to ensure all steps have been taken if you decide to self-initiate disabling.

DISABLING THE AIC'S NETWORK CAPABILITIES WILL NOT AFFECT THE FUNCTION OF THE AIC OR THE IMPELLA HEART PUMP. THE REMOTE VIEWING CAPABILITIES THROUGH IMPELLA CONNECT WILL BE UNAVAILABLE FOR A PERIOD OF TIME. WE WILL CONTINUE TO INFORM YOU OF ANY PERTINENT INFORMATION.

- Review this notice carefully, and forward to anyone in your facility that needs to be informed including Biomedical Engineering, IT Department, and those who manage, transport, store, stock, or use the AIC.

- If the AIC has been forwarded to another facility, contact that facility and provide them with this notice.

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:

- Review, complete all fields, sign, and return the attached business response form (BRF) (refer to Attachment 1) to your local Abiomed representative.
- If there is suspicion of a cybersecurity event, report to <https://www.productsecurity.jnj.com/>
- 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)

Product Code(s)	Product Description(s)	Affected Lots / Serial No.
0042-0000-AU	Impella Controller, Packaged, AU	All lots and serial numbers are affected
0042-0000-CA	Impella Controller, Packaged, CA	
0042-0000-EU	Impella Controller, Packaged, EU	
0042-0000-EU-L	Impella Controller, Packaged, EU, Loaner	
0042-0000-IN	Impella Controller, Packaged, IN	
0042-0000-JP	Impella Controller, Packaged, JP	
0042-0000-JP-L	Impella Controller, Japan, Loaner	
0042-0000-UK	Impella Controller, Packaged, UK	
0042-0000-UK-L	Impella Controller, Packaged, UK, Loaner	
0042-0000-US	Impella Controller, Packaged, US	
0042-0000-US-L	Impella Controller, Packaged, US, Loaner	
0042-0010-AU	Impella Optical Controller, Packaged, AU	
0042-0010-EU	Impella Optical Controller, Packaged, EU	
0042-0010-EU-L	Impella Optical Controller, EU, Loaner	
0042-0010-IN	Impella Optical Controller, Packaged, IN	
0042-0010-UK	Impella Optical Controller, Packaged, UK	
0042-0010-UK-L	Impella Optical Controller, UK, Loaner	
0042-0010-US	Impella Optical Controller, Packaged, US	
0042-0010-US-L	Impella Optical Controller, US, Loaner	
0042-0040-AU	Optical, AIC, Impella Connect, Packaged, AU	
0042-0040-CA	Optical AIC w/Impella Connect, Packaged, CA	
0042-0040-CT	AIC w/Remote Link, Packaged, Cln Trl, US	
0042-0040-CT-L	AIC w/Remote Link, Packaged, Cln Trl, US, Loaner	
0042-0040-EU	Optical, AIC, w/Impella Connect, Packaged, EU	
0042-0040-EU-L	Optical, AIC, w/Impella Connect, EU, Loaner	
0042-0040-JP	Optical, AIC, w/Impella Connect, Packaged, Japan	
0042-0040-JP-L	Optical AIC w/Impella Connect, Packaged, JP	
0042-0040-UK	Optical, AIC, Impella Connect, Packaged, UK	
0042-0040-US	Optical, AIC, Impella Connect, Packaged, US	
0042-0040-US-L	Optical, AIC, Impella Connect, Packaged, US, Loaner	
1000201	Double optical, AIC, Impella Connect, Packaged, US	
1000432	AIC, w/Impella Connect for ECP	

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 taken appropriately.

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