Johnson&Johnson MedTech

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URGENT MEDICAL DEVICE RECALL (REMOVAL)

Product Code(s)	Product Description(s)	UDI-DI(s)
0042-0000-US	Impella Controller, Packaged, US	00813502010022

Impacted US Serial Number(s)							
IC1026	IC1089	IC1250	IC1354	IC1452	IC1517	IC1535	IC1553
IC1029	IC1093	IC1258	IC1355	IC1461	IC1518	IC1538	IC1646
IC1043	IC1110	IC1272	IC1375	IC1496	IC1530	IC1539	IC1756
IC1046	IC1167	IC1293	IC1377	IC1501	IC1531	IC1540	IC2255
IC1040	IC1221	IC1317	IC1403	IC1508	IC1532	IC1550	IC2422
IC1047	IC1222	IC1320	IC1446	IC1515	IC1533	IC1551	IC2489
IC1088	IC1225	IC1353	IC1450	IC1516	IC1534	IC1552	IC3013

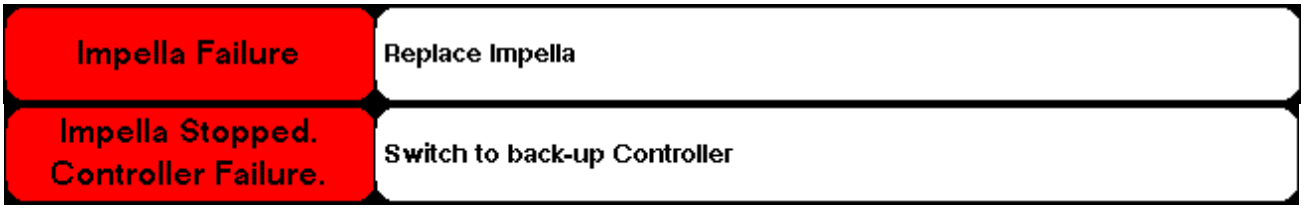
PLEASE DISTRIBUTE THIS INFORMATION TO APPROPRIATE PERSONNEL AT YOUR FACILITY WHO MAY USE THE PRODUCT THAT IS THE SUBJECT OF THIS NOTICE

Dear Valued Customer,

Please be advised that Abiomed, Inc. (“Abiomed”) has initiated a voluntary medical device recall (removal) of specific Automated Impella Controllers (AIC) (Product Code: 0042-0000-US). Our records show that your facility has one or more units of the devices subject to this recall. Abiomed asks that you quarantine and do not use the subject products. Please carefully review this notice for the steps that you should take in response to this medical device recall (removal).

REASON FOR NOTIFICATION:

Abiomed has identified specific AICs that have a Pump Driver Circuit Assembly that does not meet current specifications. These Pump Driver Circuit Assemblies contain 25v-rated tantalum capacitors instead of 35v-rated tantalum capacitors which may lead to decreased pump performance or pump stop and trigger an “Impella Failure” or “Impella Stopped. Controller Failure.” alarm.



An occurrence rate of 0.006% (27 complaints / 393,776 uses) was identified from global complaints related to alarms caused by this issue from January 01, 2011 to June 30, 2025. One (1) complaint over this date range reported a patient death related to this Pump Driver Circuit Assembly issue. This impacts 0.68% of total AIC units distributed to customers as of July 29, 2025.

The probability of patients experiencing harm based on this issue is rare. In the case of capacitor failure in the AIC, an abrupt pump stoppage or decreased performance of the AIC may occur, potentially resulting

in transient hemodynamic instability, loss of circulatory support, and/or death.

ACTIONS TO BE TAKEN BY CUSTOMER/USER:

- **Refer to serial numbers listed in this letter. ABIOMED ASKS THAT YOU QUARANTINE AND DO NOT USE THE SUBJECT PRODUCTS.**
- If you have one of the serial numbers listed, contact our Abiomed Field Service team, 1-800-422-8666, option 3 (email ra-abm-fieldaction@its.jnj.com) to initiate the remediation process.
- Your Abiomed Representative will work with you to review, complete all fields and sign the business reply form (BRF) provided to impacted customers and send it to OneMD-Field-Actions@its.jnj.com.
- 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.
- 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 ra-abm-fieldaction@its.jnj.com or your local clinical field staff. Thank you for your cooperation.

Attachments:

Attachment 1 – Product Identification Tool

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Attachment 1 – Product Identification Tool

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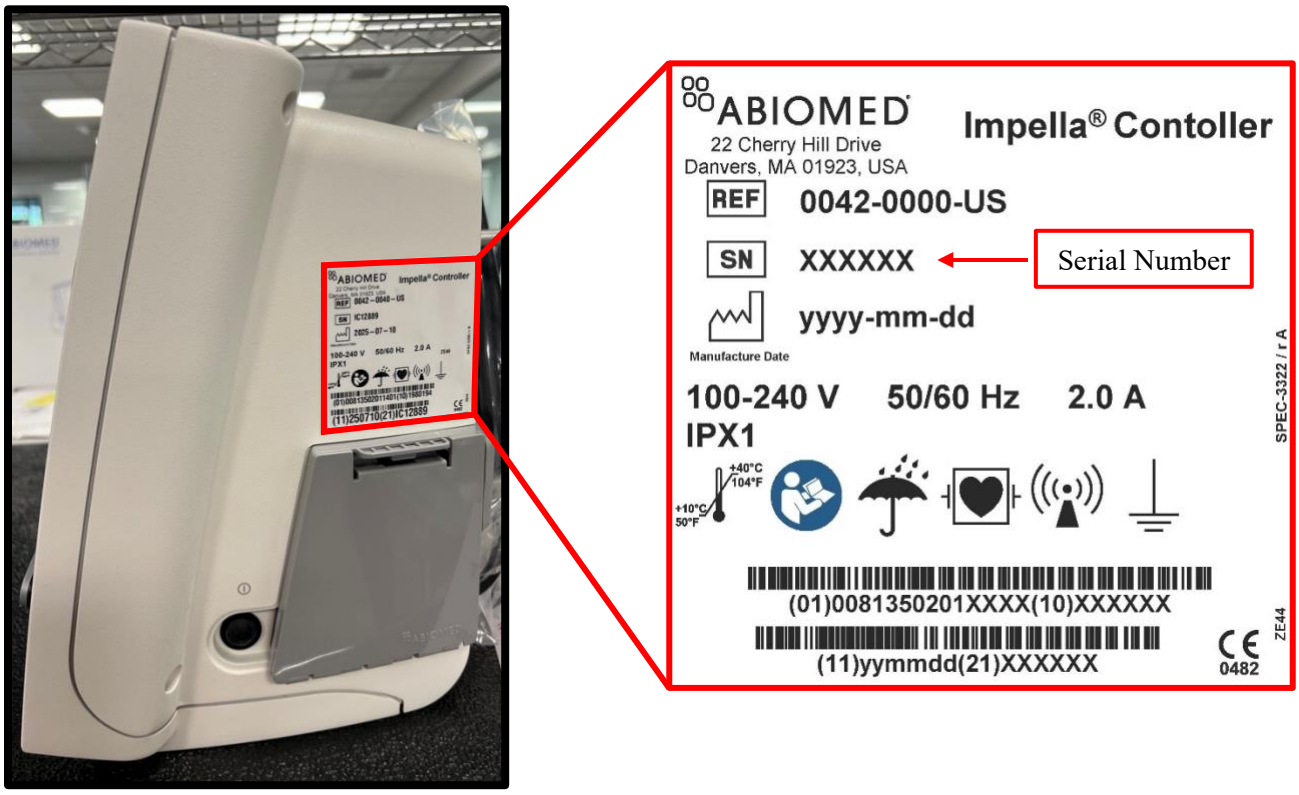
The Serial Number of the Automated Impella Controller (AIC) is located on the label on the right side of the device as shown below. If the Serial Number is missing or illegible, contact our Abiomed Field Service team, 1-800-422-8666, option 3 (email ra-abm-fieldaction@its.jnj.com) for assistance.



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