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

See Attachment 2 for Serial Numbers in Scope

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). During a retrospective review of servicing records, Abiomed identified that there are AIC units requiring specific hardware updates to address potential safety concerns. These hardware updates are intended to mitigate risks that could potentially lead to a delay or loss of hemodynamic support, which in turn may result in serious injury or death.

Our records indicate that your facility has one or more units requiring such hardware updates. **The Abiomed servicing team will contact you to coordinate the return of the device(s) to implement necessary changes. To ensure continuity of care, hospital inventory can continue to be used.**

REASON FOR NOTIFICATION:

Abiomed has identified that there are AIC units that require certain hardware updates to address potential safety issues. These hardware updates have been implemented through Abiomed's servicing process; therefore, AICs that have not received service still require these updates. Our records indicate that your AIC unit(s) may require one or more of the updates in the table below. The table below summarizes the different issues and hardware updates that correct the corresponding issue.

Issues	Hardware Update
The proximity of the internal Video Graphics Array cable to the Digital Signal Processor chipset on the Impellatronic printed circuit assembly could potentially result in Electrostatic Discharge coupling into the Digital Signal Processor which may interrupt motor controls.	Installation of a Twist-Lok cable retention device to hold the Video Graphics Array cable away from the Digital Signal Processor chipset.
There is a potential for the Compact Flash Memory Card dislodgement due to external applied forces, which could result in AIC startup failures and data-logging issues.	Add a Compact Flash Memory Card Retainer to ensure proper seating of the flash card and prevent dislodgement.
Improper routing of the fan wire within the AIC could lead to fan wire damage, which may result in console boot-up failure.	Add a wire clip that ensures proper fan wire routing. and prevent cable pinch/shorting.
Potential capacitor related issues on the Power Battery Manager, including the potential for the capacitors to cause pump stop, purge stop, and/or single-fan fuse failures.	Add a new Power Battery Manager printed circuit board assembly with improved on-board components (capacitors and fuses).

These hardware updates were implemented to address complaints received related to the issues listed in the table above. Abiomed has not received complaints related to the issues for the units pending these updates.

All four of the above-mentioned issues could lead to a failure to boot the controller or a sudden interruption in hemodynamic support. In all cases, the console would have to be exchanged for a replacement device, additionally delaying patient treatment. Delay or loss of hemodynamic support can have different consequences depending on the vulnerability and hemodynamic dependency of the supported patient and may lead to serious injury or death.

ACTIONS TO BE TAKEN BY CUSTOMER/USER:

- Our records show that your facility has one or more units of the devices subject to this recall. For the devices identified in Attachment 2, the Abiomed servicing team will contact you to coordinate the return of the device(s) to implement necessary changes. To ensure continuity of care, hospital inventory can continue to be used.
- Upon contact from Abiomed's field servicing team, please work with them to return the identified device(s) for the change to be implemented. Refer to Attachment 2 for list of impacted AIC serial numbers.
- Review, complete all fields, sign, and return the attached business reply form (BRF) provided to impacted customers and send it to Abiomed5664@sedgwick.com.
- 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.
- 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
Attachment 2 – US Serial Numbers in Scope

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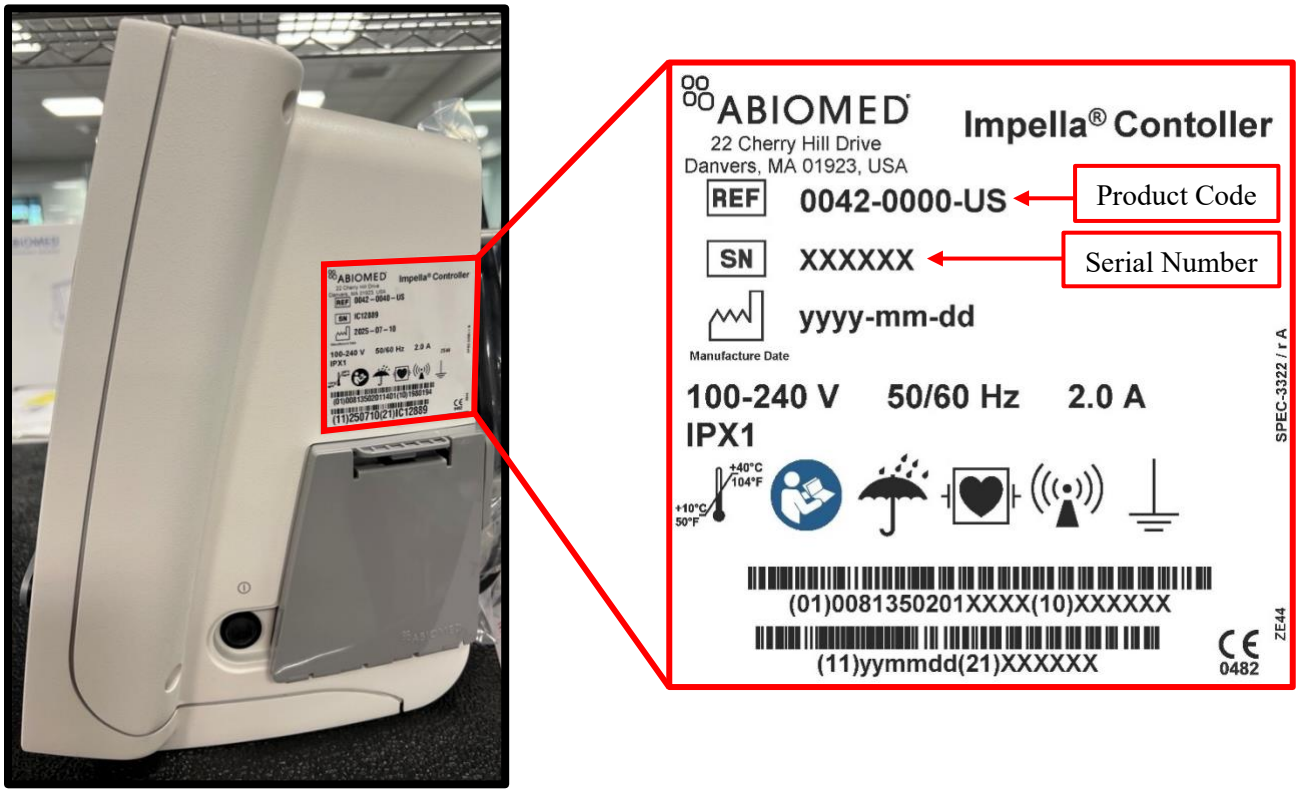
Attachment 1 – Product Identification Tool

Our records show that your facility has one or more units of the devices subject to this recall. Refer to Attachment 2 for list of impacted AIC serial numbers and use the below tool to identify the serial number on the Automated Impella Controller (AIC).

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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Attachment 2 – US Serial Numbers in Scope

IC1096	IC1142	IC1202	IC1203	IC1224	IC1231	IC1238	IC1390	IC1708	IC1741
IC1852	IC1853	IC2029	IC2071	IC2154	IC2314	IC2315	IC2575	IC3342	IC3398
IC4045	IC4060	IC2848	IC3269	IC3272	IC3277	IC3278	IC3281	IC3282	IC3284