

URGENT MEDICAL DEVICE RECALL (REMOVAL)

US Letter – AIC Updates from Retrospective Records Review

US Product Code(s)	Product Description(s)	GTIN	Impacted US Serial Numbers
0042-0000-US	Impella Controller, Packaged, US	00813502010022	Limited to Specific Consoles - Refer to Attachment 1
0042-0010-US	Impella Optical Controller, Packaged, US	00813502010985	
0042-0040-US	Optical, AIC, Impella Controller, Pkgd, US	00813502011401	

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) to implement various hardware, firmware, and / or software update(s). Updates are available but have not been implemented consistently across all potentially impacted units either due to devices not being sent back for preventive maintenance or because Abiomed failed to apply the updates during preventive maintenance. Abiomed is initiating this recall to address this issue. Our records indicate that your facility has one or more units requiring such updates.

Hospital inventory can continue to be used to ensure continuity of care. Not all units are affected. Abiomed will contact you to coordinate scheduling of the removal, updates, and return of impacted units.

REASON FOR NOTIFICATION:

During a retrospective review of servicing records, Abiomed identified that there are AIC units requiring various hardware, firmware, and / or software update(s) to address quality issues with the potential for safety implications. Our records indicate that your AIC unit(s) may require one or more of the updates described in Table 1 below that are being implemented to address the issues. Updates include both hardware and software remediations. This field action will install the latest released software version onto your device which incorporates all currently available software updates.

No serious injury or deaths related to the issues were reported for units pending the updates described.

Table 1: Identified issues with potential impact, and the corresponding updates to be performed.

Issue(s) and Patient Impact(s)	Update(s)
A RFID firmware issue may result in failure of the AIC to recognize the purge cassette during case setup or cassette change. This issue may result in delay in procedure or therapy. In patients dependent on Impella support, delayed or interrupted purge flow may contribute to inadequate (low blood pressure or reduced cardiac output) or loss of	Update to the RFID firmware to address the communication failure between the AIC and purge cassette.

Issue(s) and Patient Impact(s)	Update(s)
hemodynamic support (cardiogenic shock or end-organ hypoperfusion) from the pump, hemolysis, and potential need for console replacement. Historical complaints identified communication failure between the AIC and Purge cassette. The estimated complaint rate at the time of updates was 0.04% (2 complaints as referenced in historical investigations and 4,957 usages over 2 years prior to the update(s) implementation).	
Historical complaints identified Rotary push button (RPB) sticking and unreliable actuation impacting operator ability to select and confirm menu entries. This can result in loss of control of the console. Loss of control of the console may trigger an unplanned console replacement or delay in treatment during case set-up. In patients dependent on Impella support, this may result in inadequate or loss of hemodynamic support by the pump. The estimated complaint rate at the time of updates was 0.01% (1 complaint identified through the update change order and 13,182 Impella usages over 2 years prior to the update(s) implementation).	Install a counterbore encoder hole into the front housing of the AIC, ensure the Rotary Push Button (RPB) nut sits deeper into the encoder shaft and is affixed to it.
Historical complaints identified AIC instability that could result in AIC start-up failure, inability to drive the pump, and the need for console exchange. This issue may trigger an unplanned console replacement during start-up, potentially leading to a delay of therapy. The estimated complaint rate at the time of updates was 0.04% (11 complaints identified through the update change order and 29,546 Impella usages over 2 years prior to the update(s) implementation).	Replace the capacitor on Power and Battery Management (PBM) & Impellatronic Printed Circuit Card Assembly (PCA) to address AIC start-up instability and failure.

Issue(s) and Patient Impact(s)	Update(s)
Internal testing identified that Negative Central Venous Pressure (CVP) values are present in Pulmonary Artery Pressure (PAP) calculations. There is a software defect related to calculator process crash which could result in a software reset and brief interruption in right-sided pump support. In patients with adequate native right ventricular function (right heart dysfunction), interruption of support is expected to be generally tolerated. In patients who are hemodynamically dependent on RP system support, interruption of pump support may lead to inadequate (low blood pressure or reduced cardiac output), or loss (cardiogenic shock or end-organ hypoperfusion) of hemodynamic support, or additional (surgical/medical) intervention. No complaints were identified that prompted the need for the update. A global complaints search was performed and identified a 0.002% complaint rate (2 complaints out of 89,273 usages from 28Jul2021 to 28Jul2023).	Deploy AIC software version 12.2 to add a display update to the Central Venous Pressure (CVP) signal on the placement screen and fix the software defect. Version 12.2 is the latest released US software version and incorporates all currently available updates.

ACTIONS TO BE TAKEN BY CUSTOMER/USER:

- **Hospital inventory can continue to be used while awaiting service from Abiomed to ensure continuity of care.**
- Our records show that your facility has one or more units of the devices subject to the issues associated with this recall. Refer to Attachment 1 for list of impacted US serial numbers.
- The Abiomed service team will contact you to coordinate the removal, update, and return of the device(s).
- Review, complete all fields, sign, and return the attached business reply form (BRF) provided to impacted customers and send to Abiomed5510@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 – List of Impacted US Serial Numbers

Attachment 2 – Product Identification Tool

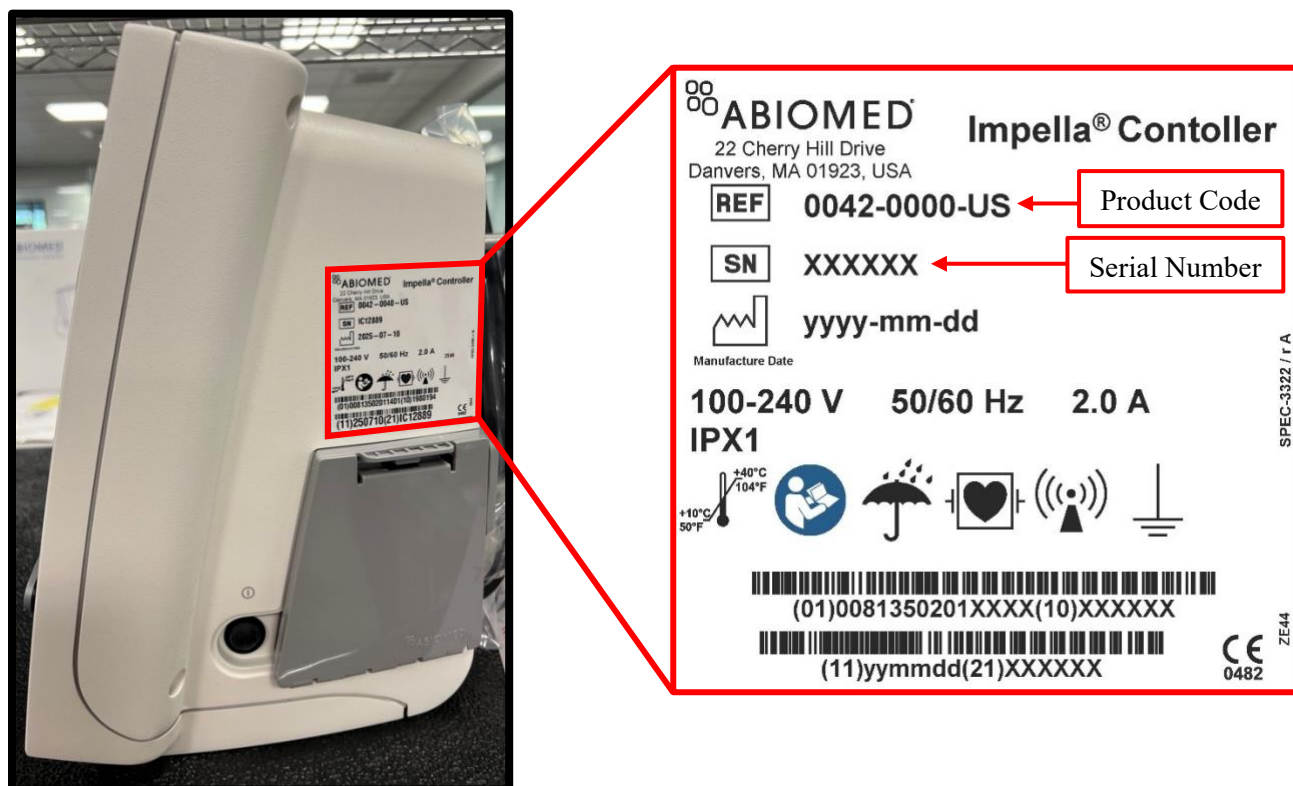
Attachment 1 – List of Impacted US Serial Numbers

IC1014	IC1612	IC2561	IC3154	IC3975	IC5120	IC6321	IC6835	IC8415	IC10531
IC1029	IC1741	IC2562	IC3155	IC3976	IC5151	IC6322	IC6962	IC8418	IC10383
IC1038	IC1771	IC2575	IC3244	IC4041	IC5201	IC6328	IC7004	IC8529	IC10578
IC1043	IC1852	IC2664	IC3246	IC4042	IC5056	IC6329	IC7036	IC8617	IC10549
IC1042	IC1853	IC2665	IC3342	IC4045	IC5549	IC6359	IC7170	IC8808	IC10557
IC1061	IC1708	IC2691	IC3398	IC4060	IC5605	IC6360	IC7213	IC8852	IC10717
IC1075	IC1964	IC2692	IC3347	IC4250	IC5661	IC6403	IC7214	IC8906	IC10722
IC1096	IC2071	IC2739	IC3351	IC4259	IC5662	IC6596	IC7239	IC9081	IC10769
IC1122	IC2069	IC2782	IC3609	IC4295	IC5598	IC6597	IC7241	IC9082	IC10879
IC1190	IC2154	IC2840	IC3714	IC4339	IC5720	IC6622	IC7677	IC9198	IC10877
IC1202	IC2227	IC2841	IC3715	IC4616	IC5721	IC6623	IC7787	IC9227	IC10900
IC1203	IC2314	IC2848	IC3772	IC4640	IC5745	IC6632	IC7880	IC9657	IC10926
IC1224	IC2315	IC2891	IC3773	IC4641	IC5749	IC6637	IC8024	IC9987	IC11012
IC1231	IC2029	IC2976	IC3806	IC4708	IC5750	IC6673	IC7912	IC10097	IC11068
IC1238	IC2321	IC2977	IC3822	IC4831	IC5828	IC6825	IC8179	IC10098	IC11158
IC1269	IC2428	IC3009	IC3823	IC4832	IC5984	IC6846	IC8216	IC10294	IC11147
IC1289	IC2429	IC3010	IC3919	IC4884	IC6042	IC6834	IC8349	IC10530	IC11353
IC1446									

Attachment 2 – Product Identification Tool

Our records show that your facility has one or more units of the devices subject to this recall. Refer to Attachment 1 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.



The Abiomed service team will contact you to coordinate the return of the device(s) to implement necessary updates. To ensure continuity of care, hospital inventory can continue to be used.