Abiomed, Inc.
22 Cherry Hill Dr.
Danvers, MA 01923 USA
Phone: +1 978-646-1400
Fax: +1 978-777-8411
www.abiomed.com

FSN Ref: 2026-FSN-0000160 FSCA Ref: 2026-FA-0000160

Date: 2026-10-20

URGENT Field Safety Notice

AIC Updates from Retrospective Records Review

For Attention of*: All Automated Impella Controller (AIC)

Contact details of local representative (name, e-mail, telephone, address etc.)*
E-Mail: DL-EUFSCA@its.jnj.com **Malte Flory** **Abiomed Europe GmbH** **Neuenhofer Weg 3** **D-52074 Aachen** **Customer Service Tel.: +800 0 22 466 33**

Abiomed, Inc.
22 Cherry Hill Dr.
Danvers, MA 01923 USA
Phone: +1 978-646-1400
Fax: +1 978-777-8411
www.abiomed.com

FSN Ref: 2026-FSN-0000160 FSCA Ref: 2026-FA-0000160

URGENT Field Safety Notice (FSN)
AIC Updates from Retrospective Records Review

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	All Automated Impella Controller (AIC)
1.	2. Commercial name(s)*
	Automated Impella Controller (AIC)
1.	3. Primary clinical purpose of device(s)*
	The Automated Impella Controller provides three functions to the operation of the Impella Catheter: • The controller provides an interface for monitoring and controlling the function of the Impella Catheter. • The controller provides a purge fluid to the Impella Catheter. • The controller provides backup power when the Impella Ventricular Support Systems are operated away from AC power.
1.	4. Device Model/Catalogue/part number(s)*
	0042-0000-EU; 0042-0000-UK; 0042-0010-EU; 0042-0010-UK; 0042-0040-EU; 0042-0040-UK (not all models apply to all countries)
1.	5. Software version
	All AIC Software versions
1.	6. Affected serial or lot number range
	See attached list of consoles in scope of the Field Action
1.	7. Associated devices
	All Impella heart pump models are run by the Automated Impella Controller (AIC). The user monitors the pump through the AIC user interface. The AIC also drives the Purge Cassette to provide purge fluid to the Impella pumps.

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	Abiomed has decided to initiate a Field Safety Corrective Action for design changes that were previously implemented through the Abiomed field service process. Abiomed identified these through a retrospective review of field change notices (FCNs). This retrospective review, completed on June 25, 2026, identified there were specific hardware, firmware, and software updates implemented to Automated Impella Controllers (AICs) in the field through servicing to address quality issues with the potential for safety implications. At the time of hardware, firmware, and software update execution, no field notification was communicated to customers with AICs pending these updates. 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. Therefore,

Abiomed, Inc.
22 Cherry Hill Dr.
Danvers, MA 01923 USA
Phone: +1 978-646-1400
Fax: +1 978-777-8411
www.abiomed.com

on July 28, 2026, and August 6, 2026, Abiomed subsequently decided to initiate the Field Safety Corrective Action for the AICs that are pending some or all these updates.

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

The table below summarizes the different issues and the corresponding updates that were implemented to correct them. No serious injury or deaths related to the issues were reported for units pending the updates described in this table under FCN 24 and FCN 44.

Issue(s)	Update(s)	Start Date(s) for Update(s) Execution
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 hemodynamic support (cardiogenic shock or end-organ hypoperfusion) from the pump, haemolysis, 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%.	Update to the RFID firmware to address the communication failure between the AIC and purge cassette. (FCN 24)	November 3, 2014
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	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. (FCN 44)	January 17, 2017

Abiomed, Inc.
22 Cherry Hill Dr.
Danvers, MA 01923 USA
Phone: +1 978-646-1400
Fax: +1 978-777-8411
www.abiomed.com

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%.		
Two software defects resulting in the screen freezing during purge cassette change wizard and false controller error alarm. These defects may result in delayed initiation of support during set-up which in highest-risk populations, can lead to temporary inadequate hemodynamic support and temporary loss of hemodynamic support, but is unlikely to occur in the general population. A global complaints search was performed and identified a 0.07% complaint rate related to the False Controller Error alarm and / or Screen Freezing during Purge Cassette Change Wizard The complaints review determined that there have been 16 cases which were reported as serious injury due to console exchange. There were five (5) reported deaths that were determined to be unrelated to the software defects.	The update was implemented to deploy AIC SW V12.3 / 12.3.1 and address two software defects. (FCN 113) Version 12.3 / 12.3.1 is the latest released software version for applicable local markets and incorporates all currently available updates.	July 16, 2025

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 (RA-ABM-EUFieldServic@ITS.JNJ.com) for assistance.

Abiomed, Inc.
22 Cherry Hill Dr.
Danvers, MA 01923 USA
Phone: +1 978-646-1400
Fax: +1 978-777-8411
www.abiomed.com



Recommendations for the customers:

- Hospital inventory can continue to be used while awaiting service from Abiomed to ensure continuity of care.
- 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 Field Safety Notification (FSN) to **DL-EUFSCA@its.jnj.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.

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 DL-EUFSCA@its.jnj.com or your local clinical field staff.

2. 2. Hazard giving rise to the FSCA*

The Hazard giving rise to the FSCA of the three issues related to AIC

FCN 24
Exposure to the RFID firmware issue may result in failure of the AIC to recognize the purge cassette during case setup or cassette change. The most likely consequences are

Abiomed, Inc.
22 Cherry Hill Dr.
Danvers, MA 01923 USA
Phone: +1 978-646-1400
Fax: +1 978-777-8411
www.abiomed.com

	user inconvenience or delay in procedure or therapy. In patients who are hemodynamically dependent on Impella support, delayed or interrupted purge flow may contribute to inadequate hemodynamic support, loss of hemodynamic support, haemolysis, and potential need for device replacement. Changing the purge cassette is part of the standard operating procedure during ongoing therapy. As such, the severity and probability of the identified harms are aligned with current risk management documentation. The probability of clinically significant harm is assessed higher for patients at greatest risk because clinical dependence on pump support may reduce tolerance for interruption or delay in therapy. For the general population, probability is assessed lower where patient stability and native cardiac output are present. Clinical monitoring, alternate support, and timely intervention may mitigate the duration or impact of an adverse event. Based on the available information, this product issue is not expected to change the overall benefit-risk profile of the Impella System. Inaction could allow continued exposure to the identified failure mode, whereas implementation of the firmware update is expected to reduce the likelihood of recurrence without introducing a newly identified patient harm. Even with the issue present, the available information supports that the benefit of Impella therapy continued to outweigh the identified risks. Implementing FCN 24 reduces risk to health by reducing the likelihood of identified potential harms. FCN 44 Exposure to the Rotary Push Button sticking may result in the need for AIC exchange. During standard clinical use scenarios, it is accepted that the user may have to replace the AIC controller under planned conditions. Usually, this will result in a tolerated temporary loss of support. There is an anticipated associated risk of a loss of hemodynamic support during the transition, which is done out of clinical necessity. Physicians are expected to take reasonable measures and use clinical acumen to determine if transfer between devices is necessitated by the patient. This is achieved through careful preparation, planning, and occurs in a controlled environment. The current issue of sudden loss of control over the console by failure of the push button would almost always result in a user inconvenience and may trigger an unplanned console replacement. If encountered during case set-up, this could cause a delay in treatment. Only under unusual circumstances, exposure may result in inadequate or loss of hemodynamic support which is considered a life-threatening injury with the potential for permanent impairment. The change implemented reduced the risk to health as the mitigated product issue increased the risk to the patient, but the life-sustaining benefit of Impella support was maintained regardless of action or inaction. FCN 113 AIC SW V12.3 addresses known AIC software anomalies associated with the Purge Cassette Change Wizard and False Controller Error – Optical Communication Stopped. The identified potential harms include user inconvenience, and delayed initiation of support during initial setup. In the general population: temporary inadequate hemodynamic support, and temporary loss of hemodynamic support. In the population at

Abiomed, Inc.
22 Cherry Hill Dr.
Danvers, MA 01923 USA
Phone: +1 978-646-1400
Fax: +1 978-777-8411
www.abiomed.com

	greatest risk, temporary inadequate hemodynamic support, and temporary loss of hemodynamic support. Physicians rely on clinical expertise and diagnostic data to make decisions. In standard clinical use, it is understood that the AIC controller may be replaced or purge cassettes exchanged, which may result in a temporary period of loss of or inadequate hemodynamic support during the period of controller or purge cassette exchange. During a planned transition, physicians are expected to anticipate and respond to potential risks. The probability of harm may be increased during unanticipated controller exchanges. Patients with cardiogenic shock or those hemodynamically dependent on Impella support represent the population at greatest risk, as a temporary interruption in support may be less tolerated in this population than in the general supported population. The assessed harms, severity, and probability of harm are aligned with current risk management documentation, and no new potential harms were identified. Existing clinical mitigations include the use of the device in highly monitored care settings, availability of a backup of AIC, and established AIC replacement workflows. Removal of the AIC from the field may negatively impact public health because the AIC is required to control Impella pumps, and no similar alternative controller is available for this function. The changes implemented in FCN 113 reduced risk to health by reducing potential harm. Even with the issue present, the benefit of Impella therapy continued to outweigh the risks, and the positive benefit-risk ratio remained regardless of action or inaction to be taken.
2.	3. Probability of problem arising
	Refer to the table in the section 2.1 of the FSN
2.	4. Predicted risk to patient/users
	For the issues related to FCNs 24, and 44 no serious injury or deaths related to the issues were reported for units pending the updates described. Regarding the False Controller Error alarm and / or Screen Freezing during Purge Cassette Change Wizard issues (addressed through FCN 113), a global complaints search was performed and identified a 0.07% complaint rate (88 complaints out of 123,310 usages of all AIC consoles from May 4, 2024 – May 4, 2026). Of the 88 adverse events, 83 involved non-serious patient events (67 were reported for malfunction and 16 reported serious injuries were reported due to console exchange). The remaining five (5) adverse events were reported as deaths. In these five (5) cases, Medical Safety verified that the death was not related to the AIC error alarms resulting from the software defects.
2.	5. Further information to help characterise the problem
	Please follow instructions in section 2.1
2.	6. Background on Issue
	The retrospective review, completed on June 25, 2026, identified there were specific hardware, firmware, and software updates implemented to Automated Impella Controllers (AICs) in the field through servicing to address quality issues with the potential for safety

Abiomed, Inc.
22 Cherry Hill Dr.
Danvers, MA 01923 USA
Phone: +1 978-646-1400
Fax: +1 978-777-8411
www.abiomed.com

	implications. At the time of hardware, firmware, and software update execution, no field notification was communicated to customers with AICs pending these updates.
2.	7. Other information relevant to FSCA
	N/A

3. Type of Action to mitigate the risk*		
3.	1. Action To Be Taken by the User* ☒ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device ☐ On-site device modification / inspection ☐ Follow patient management recommendations. ☐ Take note of amendment / reinforcement of Instructions For Use (IFU) ☒ Other ☐ None **Follow the recommendations as specified in Section 2.1** To increase awareness of these recommendations: - Keep the copy of this FSN together with your IFU.	
3.	2. By when the action should be completed?	As soon as practical.
3.	3. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	**4. Action Being Taken by the Manufacturer*** ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☒ Other ☐ None Communication to the customers will be initiated to receive the affected consoles to implement FCNs (24,44,113). A CAPA investigation is open to identify the root causes for not updating a subset of AICs.	
3.	5. By when the action should be completed?	Abiomed has prioritised the consoles in scope for updates. Communication to the customers will be initiated at the earliest to implement the FCNs (24,44,113).
3.	6. Is the FSN required to be communicated to the patient /lay user?	No
4. General Information*		
4.	1. FSN Type*	New

Abiomed, Inc.
22 Cherry Hill Dr.
Danvers, MA 01923 USA
Phone: +1 978-646-1400
Fax: +1 978-777-8411
www.abiomed.com

4.	2. For updated FSN, reference number and date of previous FSN	N/A
4.	3. For Updated FSN, key new information as follows:	
	N/A	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4.	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	N/A	
4.	6. Anticipated timescale for follow-up FSN	N/A
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Abiomed Inc.
	b. Address	22 Cherry Hill Drive, Danvers, MA, US
	c. Website address	www.heartrecovery.com
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
4.	9. List of attachments/appendices:	None
4.	10. Name/Signature	Malte Flory Senior Manager, Commercial Quality EMEA

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where Impella pumps have been transferred. Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action and keep this FSN together with the existing version of the product IFU. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback. *

Abiomed, Inc.
22 Cherry Hill Dr.
Danvers, MA 01923 USA
Phone: +1 978-646-1400
Fax: +1 978-777-8411
www.abiomed.com

FSN Ref: 2026-FSN-0000160 FSCA Ref: 2026-FA-0000160

URGENT Field Safety Notice (FSN)
AIC Updates from Retrospective Records Review
Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	2026-FA-0000160
FSN Date*	2026-10-20
Product/ Device name*	Automated Impella Controller (AIC)
Product Code(s)	0042-0000-EU, 0042-0010-EU, 0042-0040-EU, 0042-0000-UK, 0042-0010-UK; 0042-0040-UK.

2. Customer Details	
Account Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

If additional organizations are covered by your response, please ensure their details are recorded in the table on the next page.

3. Customer action undertaken on behalf of Healthcare Organisation		
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content*	Complete
☐	The information and required actions have been brought to the attention of all relevant users*	Complete
☐	I have a query please contact me	Enter contact details if different from above and brief description of query
Print Name*		
Signature*		
Date*		

4. Return acknowledgement to sender	
Email	DL-EUFSCA@its.jnj.com
Customer Helpline	+800 0 22 466 33
Postal Address	Abiomed GmbH Att. of Malte Flory Neuenhofer Weg 3 52074 Aachen -Germany
Web Portal	www.abiomed.eu; www.heartrecovery.eu
Deadline for returning the customer reply form*	**Please return within 7 working days**

Mandatory fields are marked with *

Abiomed, Inc.
22 Cherry Hill Dr.
Danvers, MA 01923 USA
Phone: +1 978-646-1400
Fax: +1 978-777-8411
www.abiomed.com

FSN Ref: 2026-FSN-0000160 FSCA Ref: 2026-FA-0000160

This Customer reply form also applies to these additional organizations:

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.