Johnson&Johnson MedTech

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URGENT MEDICAL DEVICE CORRECTION (NOTIFICATION)

Update to Instructions for Use
US Customer Letter

Impella Product Code	Impella Product Description	UDI-DI
0046-0035	Impella RP® with SmartAssist®	00813502011869
1000323	Impella RP Flex™ with SmartAssist®	00813502012811

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,

Abiomed, Inc. has issued a voluntary device correction to notify users that the differential pressure (dP) sensor in Impella RP® devices may malfunction, causing sensor values to drift. The Automated Impella Controller (AIC) may display inaccurate pump flow rates, Pulmonary Artery (PA) Placement Signal, Pulmonary Artery Pulsatility Index (PAPi), and Central Venous (CV) Placement Signal if sensor drift occurs. Inaccurate displayed information on the AIC has resulted in the user making clinical interventions including inaccurate P-level adjustments or unnecessary pump exchanges. **However, the dP sensor does not affect the pump's ability to provide hemodynamic support.** The dP sensor is only present on Impella RP devices and not on Impella 5.5 and Impella CP devices.

Clinicians should:

- continue to monitor patient hemodynamics with approved diagnostic devices and continue to verify Impella positioning with imaging before clinical interventions.
- refer to the P-level flow rates listed in the Instructions for Use (IFUs), as shown in Figure 1, and rely on these values rather than the AIC display. The values in the IFU reflect the flow rate range of the pump on defined pressure gradients under controlled conditions. Clinicians should be aware that actual pump flow depends on preload, afterload, and can vary due to suction, incorrect positioning, or presence of thrombus in the inlet.
- trend pump metrics to monitor pump performance and to identify sudden change, noting that abrupt changes in the displayed flow rate need to be assessed both against the flow rate listed in the IFU and across temporal trends. An abrupt change in flow or abrupt discrepancy from the expected flow rate listed in the IFU may indicate a need to reassess pump positioning and performance, patient conditions, and clinical hemodynamics.

The IFUs will be appropriately updated to emphasize the guidance on flow management. Refer to Attachment 1 for intended IFU modifications. US FDA is aware of this correction, and the intended IFU modifications included in Attachment 1 of this letter.

A review of global complaints from September 29, 2023, to January 15, 2026, found dP sensor drift reported in 2.5% of Impella RP cases, with 0.5% reporting pump or console exchanges. The complaints review determined that there have been no patient deaths attributed to this issue; however, in 22 cases, the failure resulted in the user choosing to exchange the pump or console which is considered medical intervention.

Product removal is not required, and hospitals may continue to use existing inventory.

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Figure 1: P-Level Flow Rates provided in (left) RP Flex IFU 10003286 revision H and (right) RP with SmartAssist IFU 0052-9013 revision H

Table 5.4 P-Level Flow Rates

P-Level	*Flow Rate (L/min)
P-0	0.0
P-1	0.0–0.9
P-2	0.0–1.3
P-3	0.0–1.8
P-4	0.7–2.3
P-5	1.3–2.6
P-6	2.0–3.0
P-7	2.7–3.4
P-8	3.2–3.7
P-9	3.7–4.2

**Flow rate depends on preload and afterload and can vary due to suction or incorrect positioning.*

Table 5.4 P-Level Flow Rates

P-Level	*Flow Rate (L/min)
P-0	0.0
P-1	0.0–1.2
P-2	0.0–1.6
P-3	0.0–2.0
P-4	1.3–2.9
P-5	1.6–3.1
P-6	2.4–3.5
P-7	3.0–4.0
P-8	3.4–4.2
P-9	3.9–4.4

**Flow rate depends on preload and afterload and can vary due to suction or incorrect positioning.*

REASON FOR NOTIFICATION:

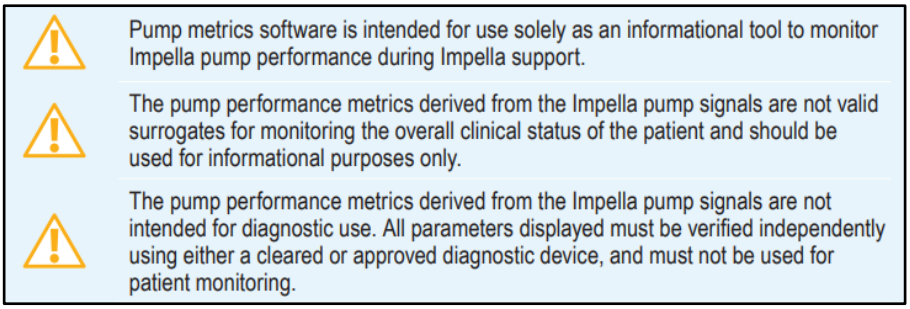
Abiomed has identified a risk of dP sensor drift in Impella RP® pumps, which may cause inaccurate flow readings, Pulmonary Artery (PA) Placement Signal, Pulmonary Artery Pulsatility Index (PAPi) and Central Venous (CV) Placement Signal. There is no way to confirm error in the flow calculation directly from the pump signals in these situations. When the dP sensor signal exceeds the operating range for the sensor, the flow calculation will disable and a "Placement Signal Not Reliable" (PSNR) alarm will be displayed on the AIC, as shown in Figure 2. Please note that the PSNR alarm may not be triggered in all instances of dP sensor drift.

Figure 2: Example AIC screen during PSNR due to the dP sensor

As per the IFU Cautions in Figure 3 (below), clinicians should continue to: monitor patient hemodynamics with approved diagnostic devices, verify Impella positioning with imaging, and refer to the P-level flow rates listed in the Instructions for Use (IFUs), as shown in Figure 1 in this letter. These

values reflect the flow rate range of the pump on defined pressure gradients under controlled conditions; actual pump flow depends on preload, afterload, and can vary due to suction, incorrect positioning, or presence of thrombus in the inlet.

Figure 3: Cautions in RP Flex IFU 10003286 revision H and RP with SmartAssist IFU 0052-9013 revision H



Pump metrics and displayed Impella flow should still be trended for monitoring pump performance and identifying sudden changes. An abrupt change in flow or abrupt discrepancy from the expected flow rate listed in the IFU may indicate a need to reassess pump positioning and performance, patient conditions, and clinical hemodynamics.

RISK TO HEALTH

Inaccurate displayed information on the AIC has resulted in the user making clinical interventions including inaccurate P-level adjustments or unnecessary pump exchanges.

IFUs will be updated to clarify that the Impella RP flow rates in the tables should be relied on over the AIC displayed flow rate. Refer to Attachment 1 for intended IFU modifications.

Note: “Placement Signal” is a naming convention; it is not used for monitoring placement on Impella RP pumps.

ACTIONS TO BE TAKEN BY CUSTOMER/USER:

- Product is NOT being removed from the field and does not need to be returned.
- Patients should be assessed with approved diagnostic devices before clinical interventions.
- Review, complete all fields, sign, and return the business reply form (BRF) provided to impacted customers and send it to Abiomed4437@sedgwick.
- 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.
- Post a copy of this notice in a visible area for awareness.
- 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 onemd-field-actions@its.jnj.com or your local clinical field staff. Thank you for your cooperation.

Attachments:
Attachment 1 – IFU Modification Details

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Attachment 1 – IFU Modification Details

New Caution (Impella RP with SmartAssist and Impella RP Flex with SmartAssist):

Displayed flow and metrics may be inaccurate due to differential pressure sensor drift. Sensor accuracy can also be affected by physical contact including handling during insertion, presence of thrombus in the inlet, contact with concomitant lines or devices, or contact with patient anatomy. Table 5.4 P-Level Flow Rates should be relied on over the AIC displayed flow. Clinicians should continue to use pump metrics to monitor Impella pump performance, monitor patient hemodynamics using cleared or approved diagnostic devices, and monitor Impella positioning with imaging. An abrupt change in flow or abrupt discrepancy from the IFU may indicate a need to reassess pump positioning and performance, patient conditions, and clinical hemodynamics.

Addition to Section 5: Using the Automated Impella Controller with Impella RP System Catheter (Impella RP with SmartAssist and Impella RP Flex with SmartAssist):

Differential Pressure Sensor and Effects on Flow Calculation

The differential pressure sensor is used to calculate Impella flow. Sensor signal may drift and become inaccurate due to sensor malfunction. Sensor accuracy can also be impacted by physical contact with the sensor and therefore should be avoided; this includes handling during insertion, presence of thrombus in the inlet, contact with concomitant lines or devices, or contact with patient anatomy.

Table 5.4 P-Level Flow Rates should be relied on over the AIC displayed flow, however displayed Impella flow and pump metrics should still be monitored and trended for monitoring pump performance and identifying sudden changes. An abrupt change in flow or abrupt discrepancy from the IFU may indicate a need to reassess pump positioning and performance, patient conditions, and clinical hemodynamics. Monitor patient hemodynamics using cleared or approved diagnostic devices, and monitor Impella positioning with imaging. Monitor the motor current waveform and the circular catheter operation icon to monitor pump function. The circular catheter operation icon rotates when the Impella RP (Flex) with SmartAssist System Catheter is running.

When the differential pressure sensor signal exceeds the operating range for the sensor, a Placement Signal Not Reliable alarm will occur, the controller will no longer calculate the PA Placement Signal, the Central Venous Placement Signal, nor the Impella flow rate, and the controller will display a yellow triangular caution icon with the message "Flow Calculation Disabled." When this occurs, refer to Table 5.4 P-Level Flow Rates, and monitor the motor current waveform and the circular catheter operation icon to monitor pump function. Continue to monitor patient hemodynamics using cleared or approved diagnostic devices and continue to monitor Impella positioning with imaging.
Note: Placement Signal Not Reliable alarm may not occur in all instances of sensor drift